2. Term:

Phase I Base Period: The term of this Agreement commences on the effective date of award and continues through twenty four (24) months thereafter.

Phase II Option Period: If exercised, commences on the effective date of option exercise and continues through twenty four (24) months thereafter. This option may be exercised any time prior to the expiration date of the Cooperative Agreement (Phase I Base Period).

3. Terms and Conditions: This Agreement is subject to the terms and conditions set forth in the attached Exhibit A, entitled "DARPA Agency Specific Terms And Conditions," dated July 2016 and to any special terms and conditions in this Agreement Schedule. An Intellectual Property Rights Identification and Assertion List dated April 14, 2017 is provided in the attached Exhibit D.

4. Agreement Officer's Representative: The Agreement Officer's Representative (AOR) representing the Government under this Agreement is:

SPAWARSYSCEN PACIFIC
ATTN.: Ernest Arias
53560 Hull Street
San Diego, CA 92152
E-mail: ernie.arias@navy.mil, Phone: 619-553-3579

The AOR Appointment Memo is provided as Exhibit C to this Cooperative Agreement.

5. Miscellaneous Point of Contacts (POC): The following POCs are provided in reference to Exhibit A, Article 5:

a) Dr. Renee Wegrzyn (DARPA Program Manager)
Biological Technologies Office (BTO)
675 N. Randolph Street Arlington, VA 22203-2114
Email: renee.wegrzyn@darpa.mil

b) Susan K. Shean (Agreements Officer)
675 North Randolph Street Arlington, VA 22203-2114
Email: susan.shean@darpa.mil

c) DARPA/Research Services
675 N. Randolph Street Arlington, VA 22203-2114
Email: ResearchServices@darpa.mil

6. Administrative Agreements Office: The Administrative Agreement Office (AAO) for this Cooperative Agreement is:

Office of Naval Research (ONRR) Atlanta
100 Alabama Street, SW
Suite 4R15
Atlanta, GA 30303-3104
ONR_Atlanta@navy.mil; T: 404-562-1600
Code: N66020

7. Principal Investigator: The Principal Investigator shall be responsible for this effort.

Dr. John Godwin
North Carolina State University
David Clark Labs 156, Box 7558

Raleigh, NC 27695
T: 919-513-2936
Email: john_godwin@ncsu.edu

The Recipient agrees to notify the AAO before changing the Principal Investigator.

8. Agreement Funding: This Agreement is incrementally funded in the amount of $437,903.00. The Government's obligation to make payments to the Recipient is limited to only those funds obligated by this Agreement or by modification to this Agreement. Subject to availability of funds and continued satisfactory progress on the Agreement as determined by the Government, the Government agrees to provide funding according to the following schedule:

FY17: $1,033,409.00
FY18: $1,022,769.00
FY19: $395,514.00

9. Payments: Payments will be made to the Recipient on a reimbursement basis and shall be made by electronic funds transfer in accordance with the account information provided to the System for Award Management (SAM).

10. Substantial Involvement: Substantial involvement is expected between the U. S. Government and the Recipient when carrying out the activity contemplated in this Agreement. It will include the U. S. Government's (a) sharing responsibility for the management, control, direction, or performance of the project, and (b) retaining the right to intervene in the conduct or performance of the project. The substantial involvement will include the U.S. Government's direction of activities to develop the research protocols necessary to complete the work and the approval of analysis mechanisms.

11. Option: The Government may require the performance of the following option. The Agreements Officer may exercise the option by providing written notice to the Performer at least thirty days prior to the end of the Agreement:

Phase 2 Option Period - $2,146,694.00 (24 Months)

11. List of Exhibits:

Exhibit A - DARPA Agency Specific Terms and Conditions (July 2016) - 5 pages

Exhibit B - Research Description Document (April 10, 2017) - 24pages

Exhibit C - Agreements Officer's Representative Appointment Memorandum (April 17, 2017) - 3 pages

Exhibit D - Intellectual Property Rights Identification and Assertion List (April 14, 2017) – 3 pages

FOR NORTH CAROLINA STATE UNIVERSITY

(Signature)

Barbara M. Asbell, CRA
Sr. Contract Negotiator
NCSU Sponsored Programs

(Name, Title)

7/5/2017
(Date)

FOR THE UNITED STATES OF AMERICA
DEFENSE ADVANCED RESEARCH PROJECTS AGENCY

(Signature)

1-6-17
(Date)

Susan K. Shean
Agreements Officer

EXHIBIT A
JULY, 2016
DARPA AGENCY SPECIFIC TERMS AND CONDITIONS

This award is subject to the DoD Research and Development (R&D) general terms and conditions, which can be found at http://www.onr.navy.mil/Contracts-Grants/submit-proposal/grants-proposal/grants-terms-conditions.aspx under the header "DoD Research and Development General Terms and Conditions," dated July, 2016 and are incorporated herein. The DARPA Agency Specific Terms and Conditions supplement the DoD Research and Development general terms and conditions. This document addresses agency-specific concerns in addition to the above referenced regulations. Award recipients (hereafter, recipient) are accountable for all applicable statutory and regulatory requirements that govern these awards, even if not specifically listed in this document or documents referenced herein.

ORDER OF PRECEDENCE

Any inconsistencies in the requirements of this award shall be resolved in the following order:

- Federal statutes
- Federal regulations
- 2 CFR part 200, as modified and supplemented by DoD's interim implementation found in 2 CFR part 1103
- Award-specific terms and conditions (DARPA Agency Specific terms and conditions)
- DoD Research and Development general terms and conditions

In case of disagreement with any requirements of this award, the recipient shall contact the Agreements Officer listed in the award document in order to resolve the issue. The recipient shall not assess any costs to the award or accept any payments until the issue is resolved.

1. Research Responsibility
2. Amendment of Award
3. Payments
4. Prior Approvals
5. Reports and Reports Distribution
6. Public Release or Dissemination of Information
7. Acknowledgment of Sponsorship
8. Intellectual Property Matters
9. Activities Abroad
10. Security
11. Research Involving Recombinant DNA Molecules
12. Restrictions on Printing
13. Prohibition on Awarding to Entities that Require Certain Internal Confidentiality Agreements

1) **Research Responsibility**:

a) The recipient has full responsibility for the conduct of the research activity supported by this award, in accordance with the recipient's proposal, and the terms and conditions specified in this award. Recipients are encouraged to suggest or propose to discontinue or modify unpromising lines of investigation or to explore interesting leads which may appear during the development of the research. However, they must consult the Agreement Officer's Representative (AOR) through the Administrative Agreements Officer (AAO) before significantly deviating from the objectives or overall program of the research originally proposed.

b) The recipient shall immediately notify the Agreements Officer of developments that have a significant impact on the award-supported activities. Also, notification shall be given in the case of problems, delays, or adverse conditions which materially impair the ability to meet the objectives of the award. This notification shall include a statement of the action taken or contemplated, and any assistance needed to resolve the situation.

2) **Amendment of Award:** The only method by which this award can be amended is by a formal, written amendment signed byeither the Agreements Officer or the AAO. No other communications, whether oral or in writing, shall modify this award.

3) **Payments:**

a) Submitting Payments Through Wide Area Work Flow (WAWF): All payments shall be made by funds transfers to the bank account registered in the System for Award Management (SAM), http://www.sam.gov. The recipient agrees to maintain its registration in SAM, including information necessary to facilitate payment via Electronic Funds Transfer (EFT). Should a change in registry or other incident necessitate the payment to an account other than that maintained in SAM, it is the recipient's responsibility to notify the AGO/AAO and obtain a modification to this award reflecting the change. The Government shall not be held responsible for any misdirection or loss of payment which occurs as the result of a recipient's failure to maintain correct/current EFT information within its SAM registration.

1) Any request for advance payments must be approved by the AGO/AAO at the Administrative Office designated in the award document.

2) Wide Area Work Flow (WAWF) has been designated as the Department of Defense standard for electronic invoicing and payment. Electronic submission of payment requests requires the recipient to register in WAWF and have the appropriate CAGE code activated. The recipient's SAM Electronic Business Point of Contact (EBPOC) is responsible for activating the CAGE code in WAWF by calling 1-866-618-5988. Once the recipient's CAGE Code is activated, the SAM EBPOC will self-register in WAWF (https://wawf.eb.mil) and follow the instructions for a group administrator. The ONR Regional Offices will assist in this process. The ONR Regional Office is listed as the Administrative Office in the award document. Please call the ONR Regional Office with any questions regarding access to or use of WAWF.

4) **Prior Approvals:**

In addition to the prior approvals required by the DoD R&D general terms and conditions, prior written approval is required for the following actions:

- The subaward, transfer, or contracting out of any work under this award, unless described in the recipient's proposal and specifically approved and funded in the Award Schedule. The recipient's request for approval shall include the following supporting data:
  (i) Basis for contractor selection;
  (ii) Justification for lack of competition when competitive bids or offers are not obtained;
  (iii) Basis for award cost or price, to include price or cost analysis performed by the recipient; and
  (iv) Approval of the GOR/AOR.

5) **Reports and Reports Distribution**: Reports shall be furnished as specified below:

a) Report Types.

1) *Monthly Financial Report* - The recipient shall provide monthly financial progress reports. The purpose of these reports is to provide a brief on project progress and inform DARPA of any potential issues. The Monthly Financial report shall be delivered no later than the 15th day of the month, covering costs through the end of the previous month, using the Enclosure (1) template of Exhibit B Research Description Document.

2) *Monthly Technical Report* - This report, due 30 days after the reporting period, shall keep the Government informed of recipient activity and progress toward accomplishment of award objectives and any potential technical issues. A recommended format will be provided by the DARPA Program Manager.

3) *Quarterly Technical Report* - This report, due 30 days after the reporting period, shall keep the Government informed of recipient activity and progress toward accomplishment of award objectives and advancement in state-of-the-art on the research and development involved. The report shall be submitted using the Enclosure (2) template of Exhibit B Research Description Document.

4) *Special Technical Report* - This report, due as required, shall document the results of a significant task, test, event or symposium.

5) *Final Technical Report* - This report, due 90 days after expiration or termination of the award, shall document the results of the complete effort. It shall contain brief information on each of the following:

a) A comparison of actual accomplishments with the goals and objectives established for the award, the findings of the investigator, or both.

b) Reasons why established goals were not met, if appropriate.

c) Other pertinent information.

6) *Final Financial Status Report* - This report, due 90 days after completion of the award, shall be submitted on a Standard Form 425 "Federal Financial Report (FFR)". The report shall be on a cash or accrual basis, depending on how the recipient's accounting records are normally kept.

7) *Report of Federal Cash Transactions [applicable only to advance payment awards]* – This report, due 15 days following the end of each quarter, shall be submitted on a Standard Form 425. The recipient shall provide forecasts of Federal cash requirements in the "Remarks" section of the report.

b) Report Distribution:

Addresses	Report Types [5.(a)]	Number of Copies
Agreements Officer's Representative Email: ernie.arias@navy.mil	1, 2, 3, 4, 5, 6, 7	1
DARPA Program Manager Email: renee.wegrzyn@darpa.mil	1, 2, 3, 4, 5, 6, 7	1
Administrative Agreements Officer	1, 3, 4, 6, 7	1

Email: ONR_Atlanta@navy.mil		
DARPA/Research Services Email: ResearchServices@darpa.mil	6	1
Defense Technical Information Center ATTN: DTIC-O 8725 John J. Kingman Road Ft. Belvoir, VA 22060-6218	6	2
DARPA Agreements Officer Email: susan.shean@darpa.mil	1, 2, 3, 4, 6, 7	1
DARPA CMO Closeout Email : CMO_Closeout@darpa.mil	6	1

6) **Public Release or Dissemination of Information**

a) At this time, DARPA expects the work performed under this award to be fundamental research, and it is, therefore, not subject to publication restrictions. Papers resulting from unclassified contracted fundamental research are exempt from prepublication controls and requirements, pursuant to DoD Instruction 5230.27 dated October 6, 1987.

b) All papers resulting from this award will include the following distribution statement:

"Approved for public release; distribution is unlimited."

c) Should the character of the research change during award performance so that the research is no longer considered fundamental, the award will be modified to impose the restrictions on public release and dissemination of information that apply to those research efforts that are not considered fundamental research.

7) **Acknowledgment of Sponsorship:**

a) The recipient agrees that in the release of information relating to this award, such release shall include a statement to the effect that (1) the project or effort depicted was or is sponsored by the Defense Advanced Research Projects Agency, (2) the content of the information does not necessarily reflect the position or the policy of the Government, and (3) no official endorsement should be inferred.

b) For the purpose of this article, information includes news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association proceedings, symposia, etc.

c) Nothing in the foregoing shall affect compliance with the requirements of the clause entitled "Security."

8) **Intellectual Property Matters**: Questions regarding intellectual property matters should be referred to Agreements Officer.

All patent reports (interim and final) shall be submitted using the i-Edison.gov reporting website (http://s-edison.info.nih.gov/iEdison). In the event the recipient is unable to submit reports through i-Edison, the recipient may utilize DD Form 882, Report of Inventions and Subcontracts, for submission of interim and final invention reports. The DD Form 882 and all invention disclosures shall be submitted to the AGO/AAO for proper disposition and forwarding to the Agreements Officer.

9) **Activities Abroad:** The recipient shall assure that project activities carried on outside the United States are coordinated as necessary with appropriate Government authorities and that appropriate licenses, permits, or approvals are obtained prior to undertaking proposed activities. The awarding agency does not assume

responsibility for recipient compliance with the laws and regulations of the country in which the activities are to be conducted.

10) **Security:** The recipient may not be granted access to classified information under this award. If security restrictions should happen to apply to certain aspects of the proposed research, the recipient will be so informed. In the event that the scientific work under this award may need classification, or involve access to or storage of any classified data, the Government shall make its decision on the need to classify, or require such access or storage, within 30 days after receipt of written notice from the recipient. If the decision is affirmative, the Government shall invoke the clause in reference to the "Termination" proceedings in the DoD R&D general terms and conditions.

11) **Research Involving Recombinant DNA Molecules**: Any recipient performing research involving recombinant DNA molecules and/or organisms and viruses containing recombinant DNA molecules agrees, by acceptance of this award, to comply with the National Institutes of Health "Guidelines for Research Involving Recombinant DNA Molecules," July 5, 1994 (59 FR 34496) as amended, or such later revision of those guidelines as may be published in the Federal Register.

12) **Restrictions on Printing**:

Unless otherwise authorized in writing by the AGO/AAO, reports, data, or other written material produced using funds provided by this award and submitted hereunder shall be reproduced only by duplicating processes and shall not exceed 5,000 single page reports or a total of 25,000 pages of a multiple page report. These restrictions do not preclude the writing, editing, and preparation of manuscript or reproducible copy of related illustrative materials if required as a part of this award, or incidental printing such as forms or materials necessary to be used by the recipient to respond to the terms of the award. To satisfy the requirements of the Defense Technical Information Center, at least one copy of each technical report submitted to the Defense Technical Information Center must be black typing or reproduction of black on white paper or suitable for reproduction by photographic techniques. Reprints of published technical articles are not within the scope of this paragraph.

In accordance with Executive Order 12873, dated October 20, 1993, as amended by Executive Order 12995, dated March 25, 1996, the recipient is encouraged to submit paper documents, such as letters or reports, that are printed/copied double-sided on recycled paper that has at least 30 percent postconsumer material.

13) **Prohibition on Awarding to Entities that Require Certain Internal Confidentiality Agreements**

a) The recipient shall not require employees, contractors, or subrecipients seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or contractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

b) The recipient must notify its employees, contractors, or subrecipients that the prohibitions and restrictions of any internal confidentiality agreements inconsistent with paragraph (a) of this award provision are no longer in effect.

c) The prohibition in paragraph (a) of this award provision does not contravene requirements applicable to any form issued by a Federal department or agency governing the nondisclosure of classified information.

d) If the Government determines that the recipient is not in compliance with this award provision, it:

1) Will prohibit the recipient's use of any FY 2016 or FY 2015 funds under this award, in accordance with Federal appropriations law; and

2) May pursue other remedies available for the recipient's material failure to comply with award terms and conditions.

EXHIBIT B
RESEARCH DESCRIPTION DOCUMENT

Title: Restoring Ecosystems and Biodiversity through Development of Safe and Effective Gene Drive Technologies

Date: April 10, 2017

1.0 SCOPE

This project will address the DARPA-relevant application of maintaining and protecting ecosystem biodiversity identified in BAA 16-59. Invasive rodents are a primary agent of biodiversity loss worldwide by directly and indirectly causing extinction and endangerment of species on islands. The overall goal of this effort is to develop safe, controllable, and effective gene drive technologies in mice that can potentially be applied in the future to eradicate invasive mouse populations on islands. Because mice are a well-established genetic model organism, this research will also advance evaluation of a gene-drive approach to rodent control more generally.

1.1 BACKGROUND

The proposed research under the Safe Genes program will address Technical Areas 1 and 3 using the powerful genetic model system of the house mouse (Mus musculus) with research and engagement efforts in five areas. Invasive mice represent a significant threat to biodiversity on many islands around the world including in the U.S. and house mice are a powerful and tractable model system generally for testing gene drive function in a mammal. The major component of this work will involve developing and testing technologies for biasing offspring sex ratios in mice using both a naturally-occurring meiotic drive system (the t-allele modified to drive the male sex gene sry) and a synthetic drive system based on CRISPR-Cas genome editing and a novel 'trans-effector' drive system that instead targets the Y chromosome with the goal of producing strongly female-biased offspring sex ratios.

The potential for spatially limiting drive function through genome-level targeting of population-specific private alleles will complement the development of synthetic drives. Following small scale testing of drive function and effective biasing of offspring sex ratios, trials evaluating drive function in more naturalistic contexts will be conducted in highly biosecure simulated natural environments at the National Wildlife Research Center, a USDA facility. Evaluations of drive function will be complemented and informed by mathematical modeling of drive function with modeling efforts incorporating parameters from genetic characterizations and guiding trials in simulated natural environments. Risk assessments will include structured hazard analysis and probabilistic risk assessment for the synthetic trans-effector drive to be developed. Complementing these technical activities will be engagement with regulatory, stakeholder, and community engagement.

Travel is authorized for attendance at the Kick-Off meeting, annual Program Manager meetings, annual PI/site visit meetings, collaborator meetings, ELSI activities, and conferences, as applicable.

2.0 APPLICABLE DOCUMENTS

2.1 DARPA-BAA-16-59.

3.0 PROJECT WORK DESCRIPTION AND REQUIREMENTS

Animal use is anticipated in this effort. Research that involves the use of animals shall be administratively reviewed by a DoD veterinarian prior to the Recipient initiating any animal research. The Recipient shall obtain all necessary Institutional Animal Care and Use Committee (IACUC)

approval and secondary DoD approval from the Animal Care and Use Review Office (ACURO) prior to using any DARPA money for animal related expenses. The Recipient is not to begin any research or purchase any materials, equipment, etc. that would involve animal use until the protocol(s) have been approved. Once the Recipient receives its copy of the Protocol Approval Letter from the DoD Regulatory Office, the Recipient is approved to proceed with the effort involving animal use in accordance with guidance in the Protocol Approval Letter(s). DARPA Contracts Management Office will incorporate the Protocol Approval Letter(s) as an attachment to the Agreement. Any changes to the protocol must receive IACUC and ACURO approval prior to implementation.

Data sharing is anticipated in this effort. The Recipient shall support data sharing with other performers including sharing of raw and processed experimental data, processing methods used, algorithms used to process the data, artifact information, research reports, and software including source code and executables. The Recipient shall deliver to DARPA in the form identified by the DARPA Program Manager, all the experimental data collected in this effort within four months of completion of data collection (or at a date agreed upon in the statement of work). Experimental data should be accompanied with sufficient meta-data to capture laboratory conditions, equipment, supplies/reagents, procedures and methodology and will be conducted in a manner that provides enough description for a third party to look at and conduct appropriate analysis and interpretation of data. DARPA, for the purposes of scientific research, may choose to share this data with other performers in the program, with a third party, and possibly with a larger research community in the future. Data sharing will be included in the project milestones and reported regularly to DARPA.

Activities to address Ethical, Legal, and Social Issues (ELSI) are anticipated in this effort. The Recipient shall support ELSI activities with DARPA including semi-annual teleconference calls with the Legal, Ethical, Environmental, Dual-Use, and Responsible Innovation (LEEDR) Panel and regular feedback from the Panel regarding the performer's activities. ELSI activities will be reported regularly to DARPA.

The Recipient shall engage with relevant regulatory bodies to identify and mitigate challenges to transition of the resulting technology and in anticipation of future deployment.

3.1 BASE PERIOD (PHASE 1)

Technical Area 1 - Control of genome editing activity.

3.1.1. Identify, test, and achieve basic demonstration of candidate genome editing controllers. (TA1 Task 1)

The Recipient shall:

3.1.1.1 Engineer t-Sry mice to express Sry under doxycycline control. Using biased inheritance of the t-allele, skew offspring sex ratios towards males. This shall be accomplished by putting the Sry transgene into the tw2 variant of the t-allele under the control of doxycycline using a Tet-Off system. Insert i) tetracycline transactivator protein (tTA) into the t-allele (an inversion on chromosome 17) and ii) inclusion of *TetO* operator sequences in the promoter region of the t-Sry transgene by CRISPR-Cas mutagenesis. Doxycycline shall be administered to mice in drinking water (2 mg/ml) for two weeks following mating.

3.1.1.1.1 *Performance Metrics and Assessment*: Key metrics for success shall be significant biasing of offspring sex ratios in matings with wild-derived females: >90% males depending on presence of doxycycline. With doxycycline treatment, normal male and female ratios should occur, i.e., not statistically different from 1:1. Without doxycycline treatment, sex ratios will be biased towards males, of which half are predicted to be sterile, masculinized genotypic females (XX-tSry). The other half of offspring produced should be fertile males (XY-tSry). Testicular morphology shall be examined to

assess any histologically-detectable aberrations in male sexual development or function. Stability of progeny sex-ratio biasing (>90% males predicted) shall be confirmed across at least three generations in the absence of doxycycline and nine litters overall (litter sizes 7-8 pups; 31 sexed offspring should be necessary to detect difference from 1:1 with 90% predicted males and at 95% power). Litter sizes and weanling success shall be assessed for differences relative to controls (no doxycycline in drinking water).

3.1.1.1.2 *Deliverables:* Inducible control of Sry expression and sex reversal in t-Sry mice. A mouse line with Sry inserted in the autosomal t-complex with expression under doxycycline control. This strain should exhibit greater than 90% meiotic drive (>90% of offspring inherit the tw2 allele from heterozygote sires). Offspring inheriting the tw2 allele with Sry inserted are predicted to differentiate as males in at least 90% of offspring, This line shall be delivered and characterized for sex ratio characteristics in the presence and absence of doxycycline (to be completed by 18 months).

3.1.1.2 Engineering sex-specific progeny endonuclease gene drives in mice "Generation I Drives"

Linked Phase II Option Period tasks: 3.2.1.3, 3.2.1.4

Generate the first functional synthetic gene drives in mice and establish the optimal homing strategy (zygotic versus germline) and endonuclease (CAS9 versus CPF1) for maximum efficiency. A split-drive strategy shall be employed for maximum safety and to allow direct comparison of germline and zygotic homing using Vasa- and CMV-driven CAS9/Cpf1, respectively. This subtask shall deliver initial components for pursuing the Trans-Effector Drive (TED) strategy and provide critical quantitative data to facilitate optimal design.

All of the mouse strains for this subtask shall be generated by the SA Genome Editing Facility using an optimised CRISPR-assisted homology directed repair protocol in C57BL/6 strain zygotes. Zygotes shall be injected with CAS9/Cpf1 mRNA, a gRNA against the insertion site and a repair template (oligonucleotide (Target mice) or plasmid (gRNA, CMV-Cpf1 and Vasa-CAS9/CPF1 mice)) that contains the insertion sequence flanked by homology arms. Injected zygotes shall be transferred to pseudo-pregnant females for further development, and the resulting founder pups screened for the insertion event by PCR of genomic DNA. Plasmid and oligonucleotide templates shall be sourced commercially or generated in house. High scoring gRNA sequences for the insertion events have been identified bioinformatically via Benchling.

3.1.1.2.1. Generation of transgenic mice (Generation I Drive)

3.1.1.2.1.1 Performance Metrics and Assessment. Six transgenic lines shall be generated as follows:

a) gRNA mice (2 lines (Cas9 and Cpf1 versions)). These strains shall contain the following elements inserted into the first intron of the *Tyrosinase* (*Tyr*) gene:
   - U6:gRNA expression cassette to drive ubiquitous expression of a single gRNA that binds to the "target sequence" (see target mice below).
   - CMV: fluorescent marker expression cassette. This ubiquitously-expressed fluorescent reporter will facilitate rapid analysis of homing events in the gametes and progeny of gene drive mice generated in Sub tasks 3.1.1.2.2 and 3.1.1.2.3. Expression of the fluorescence reporter shall be validated by epifluorescence microscopy of ear notch biopsy tissue.
   - To generate gRNA mice, a single donor plasmid containing the gRNA and fluorescence marker expression cassettes will be inserted into the first intron of the *Tyr* gene using CRISPR. This insertion is expected to generate a null allele that, in the homozygous state, would generate mice with a white coat colour (*Tyr* +/+ and *Tyr* +/- mice are black). The white coat phenotype will be confirmed in gRNA/gRNA mice. This design feature facilitates rapid scoring of zygotic homing events.

b) Target mice (1 line). This line shall contain the 20bp target sequence for the gRNA produced by gRNA transgenic mice and is compatible with both Cpf1 and Cas9. Critically, this gRNA target sequence does not occur in wild type mice. The gRNA target is derived from the bacterial neomycin phosphotransferase gene and has been validated as a Cas9 target in mouse ES cells containing this sequence. As the inserted target sequence is small and located within the intron, expect that this mutation will not result in detectable loss of Tyrosinase activity. To confirm this, Target/Target and Target/gRNA mice shall be generated and assessed for coat colour (should be black).

c) Vasa-CAS9 and Vasa-Cpf1 mice (2 lines) shall be used for germline homing experiments. CAS9/Cpf1 expression in the germline shall be driven by the previously-validated *Vasa* promoter. An expression cassette containing the 5.6 kb *Vasa* promoter linked to CAS9 shall be inserted into the "safe harbour" ROSA26 locus using CRISPR-assisted recombination.

d) CMV-Cpf1 mice. (1 line) This line shall be identical to the published CMV-CAS9 line in which CAS9 (and GFP) are ubiquitously expressed from the CMV promoter (to enable zygotic homing).

Transgenic founder animals shall be validated via direct sequencing. Germline transmission shall be established via genotyping of founder progeny. Fluorescence marker activity shall be confirmed by epifluorescence microscopy of tissue biopsies. Sequenced-validated transmitting founders (minimum 1/line) shall be considered validated for the purpose of proceeding to Subtasks 1.3.2 and 1.3.3.

3.1.1.2.1.2. *Deliverables:* Generation of transgenic mouse lines to enable completion of 3.1.1.2.2 and 3.1.1.2.3. Timeline for completion is within initial 12 months.

3.1.1.2.2 Assess stability, efficiency of CAS9-mediated germline and zygotic homing. The homing target (for both germline and zygotic strategies) is the Tyrosinase gene (required for black coat color). Zygotic homing events will result in Tyr loss-of-function (due to homozygosity of the gene drive) generating mice with a white coat. Germline homing shall be scored via transmission of the fluorescent reporter cassette (e.g., nTomato incorporated into the gene drive as "cargo" with successful homing of construct). Timeline for completion is within initial 18 months.

Zygotic homing: To measure the rate of zygotic homing, cross CMV-CAS9/+ ; Target/Target mice with +/+ ; gRNA/gRNA mice. Two genotypes will be generated in G1 (Generation 1) progeny: CMV-CAS9/+; Target/gRNA (experimental) and +/+; Target/gRNA (negative control). If homing occurs in the experimental zygotes, the "Target" allele shall be replaced with the "gRNA" allele. The resulting animal will therefore become homozygous for the gRNA allele and will develop a white coat colour due to the absence of Tyrosinase activity. Conversely, if there is no cleavage of the Target allele, or cleavage occurs but is repaired by Non-homologous end joining (NHEJ) (resulting in a small deletion), the resulting animal will retain one functional *Tyr* allele and therefore develop a black coat colour. PCR and sequencing of genomic DNA from black mice shall be performed to determine the frequency of NHEJ-induced deletions. The rate of zygotic homing (maximum = 1.0) shall be calculated as follows: number of white mice/total mice. If the coat colour screening strategy does not work as intended (for example, if some Tyrosinase activity remains in the gRNA allele), coat colour scoring shall not be used and all progeny shall be genotyped by PCR. Up to 300 mice will be required in total (i.e. across all generations) to detect a homing rate of 70% with 95% confidence.

Transmission and stability of the zygotic-homing gene drive. The Recipient shall first investigate whether homing in G1 zygotes generates a functional gRNA allele that can be transmitted to G2 progeny. CMV-CAS9/+; gRNA/gRNA males from G1 shall be crossed with +/+; Target/Target females to generate G2 progeny. If homing has occurred correctly in G1 zygotes, all G2 progeny should inherit a gRNA allele and will therefore exhibit marker fluorescence as neonatal pups. Experimental (CAS9-positive) mice shall be scored for (white) coat colour and the G2 zygotic homing rate calculated as described above. If the gRNA alleles generated in G1 males are fully functional, there will be no significant difference in the G1 and G2 homing rates. To determine whether the homing rate

is stable across several generations, G3 mice shall be generated using the same mating and scoring protocol. PCR/sequencing of black mice shall also be performed to determine the frequency of deletion alleles generated by NHEJ. Five (white) CMV-CAS9/+; gRNA/gRNA males shall be used as studs for each generation.

Germline homing: To measure the rate of germline homing, begin by crossing Vasa-CAS9/+ ; Target/Target mice with +/+ ; gRNA/gRNA mice. Two genotypes shall be generated in the somatic cells of the G1 adult progeny: Vasa-CAS9/+ ; Target/gRNA (experimental) and +/+ ; Target/gRNA (negative control). If homing occurs in the germline of the experimental mice, the "Target" allele shall be replaced with the "gRNA" allele, thereby generating gRNA/gRNA homozygous cells. All gametes derived from these cells will contain the gRNA allele and therefore express the fluorescence marker. In contrast, if homing does not occur, the germ cell will contain only one copy of the gRNA allele. As a result, only 50% of their gametic progeny will express nTomato (i.e. those gametes that inherit the gRNA allele). To rapidly obtain a robust estimate of G1 homing events in males, isolate sperm from adult G1 mice and score these cells for fluorescence marker expression by epifluorescence microscopy. Approximately 200 sperm shall be scored from 10 G1 animals. The rate of germline homing (maximum rate = 1.0) shall be calculated as follows: ((no. of red fluorescent sperm/total sperm) – 0.5) * 2). Five negative control G1 males shall also be analysed (expected frequency of nTomato-positive sperm is 50%).

Transmission and stability of the germline-homing gene drive. Investigate whether homing in the germline of G1 males generates a functional gRNA allele that can be transmitted to G2 progeny. Experimental (CMV-CAS9/+; gRNA/Target (somatic genotype)) males from G1 shall be crossed with +/+ ; Target/Target females to generate G2 progeny. The rate of gRNA allele transmission from G1 to G2 mice will reflect the homing frequency in the G1 germline, i.e. if G1 germline homing is 100% efficient, all of the G2 progeny will be nTomato-positive. Assessing the fluorescence marker expression status of G2 pups will therefore allow to calculate the germline homing rate as follows: ((no. of fluorescent pups/total pups) – 0.5) * 2). These data should corroborate the germline homing rates calculated from G1 sperm analysis. To calculate the homing rate in G2 mice, fluorescence analysis of G3 pups generated from G2 (CMV-CAS9/+; gRNA/Target (somatic)) males mated to +/+; Target/Target females. Determine the frequency of NHEJ-induced deletion events in the germline of each generation by performing PCR/sequencing analysis of the target locus in fluorescence-negative pups.

3.1.1.2.2.1 *Performance Metrics and Assessment*:

Efficiency - Homing efficiency of >70% and NHEJ frequency of <30% in either zygotic or germline context as determined by i) direct sequencing, ii) white coat color due to tyrosinase gene disruption with effective Cas9 homing and homology-directed repair (HDR), and iii) reporter fluorescence in progeny of gene drive bearing parents indicating effective Cas9 homing.

Stability – Homing efficiency remains >70% and NHEJ frequency remains <30% in either zygotic or germline context over 3 generations.

Specificity - Mutation rate of < 5% at off-target sites (defined as sequences with 3 or fewer mismatches to the on-target site) to be assessed in 5 independent samples (animals/embryos).

Safety - Average litter size of "homing crosses" is comparable (within 20%) with CAS9-only transmission (minimum 10 litters). Absence of overt malformation in >90% mice with successful homing event.

3.1.1.2.2.2 *Deliverables:* The key deliverable shall be direct quantitative comparison of germline versus zygotic CAS9-mediated homing strategies. The second key deliverable shall be experimental data (homing/NHEJ rates and reproductive fitness) that will inform modeling of gene drive activity

(Timeline for completion is within initial 18 months). First generation data to be generated by 14 months. Third generation data to be generated by 18 months.

3.1.1.2.3 Assess stability, efficiency of Cpf1-mediated germline and zygotic homing. (TA1 Subtask 1.3.3). Use an identical approach to 3.1.1.2.2 except using Cpf1 as the homing endonuclease.

3.1.1.2.3.1 *Performance Metrics and Assessment.*

Efficiency - Homing efficiency of >70% and NHEJ frequency of <30% in either zygotic or germline context as determined by i) direct sequencing, ii) white coat color due to tyrosinase gene disruption with effective Cas9 homing and homology-directed repair (HDR), and iii) nTomato fluorescence in progeny of gene drive bearing parents indicating effective Cas9 homing.

Stability – Homing efficiency remains >70% and NHEJ frequency remains <30% in either zygotic or germline context over 3 generations.

Specificity - Mutation rate of < 5% at off-target sites (defined as sequences with 3 or fewer mismatches to the on-target site) to be assessed in 5 independent samples (animals/embryos).

Safety - Average litter size of "homing crosses" is comparable (within 20%) with CPF1-only transmission. Absence of overt malformation in >90% mice with successful homing event.

3.1.1.2.3.1 *Deliverables:* Direct quantitative comparison of germline versus zygotic CPF1-mediated homing strategies. In silico analysis using bespoke individual based modelling of experimental data (homing/NHEJ rates and reproductive fitness) to determine potential for gene drive spread on island populations. First generation data to be generated by 14 months. Third generation data to be generated by 18 months.

3.1.1.3. Develop an efficient feminizing endonuclease gene drive (Y-shredder). (TA1 Subtask 1.3.4) Downselect and develop the best performing gene drive platform (i.e. highest efficiency and stability) from 3.1.1.2.2 and 3.1.1.2.3 into a Y-shredding gene drive that generates an excess of female progeny. Using direct sequence analysis, identify several gRNAs that target repetitive sequences present in up to 300 copies on the Y-chromosome with potential Y-shredding activity. The subtask shall be performed in two steps:

a) Assess efficacy of Y-shredding in mouse embryonic stem cells (ESC) via transient transfection/selection of gRNA expression constructs followed by Y-chromosome dosage analysis using qPCR of Y linked loci and FISH with Y paint. Assess off-target cleavage via BLESS analysis.

b) Generate modified "gRNA" transgenic mouse (see 3.1.1.2.2 and 3.1.1.2.3) containing Y-shredder gRNA (as well as the homing gRNA)

c) Assess Y shredding and homing simultaneously by performing matings as described in 3.1.1.2.2 and 3.1.1.2.3.

Overall timeline for completion is 21 months.

Linked Phase II Option Period tasks: 3.2.1.4

3.1.1.3.1 *Performance Metrics and Assessment:*

Y-shredder efficiency - There should be a >50% reduction in Y chromosome content in ES cells pools expressing Y-shredder gRNA as indicated by PCR and fluorescence *in situ* hybridization labelling the Y-chromosome (Milestone 1).

Transmission of Y-shredder- Sequence validation of transmission of Y-shredding gene drive mouse line (Milestone 2).

Biasing of progeny sex ratios by Y-shredder - Mice that express the Y-shredder gRNA should be >75% females (50% XX females and shredding of Y chromosomes in at least 50% of XY zygotes) as assessed by gonadal phenotyping and sex chromosome PCR (Milestone 3). Safety and specificity criteria as for 3.1.1.2.2 and 3.1.1.2.3.

3.1.1.3.2 *Deliverables:*

Milestone 1. Complete screening of candidate Y shredding gRNAs (Cas9 or Cpf1) by transient expression in mouse ES cells (9 months)

Milestone 2. Generation of transgenic mouse line incorporating Y-shredding gRNA into gene drive construct (15 months)

Milestone 3. Generation of Y-shredder drive through assessment of progeny from Milestone 2 for sex and Y chromosome content. (21 months)

3.1.1.4: Spatial limitation of gene drives by targeting of 'Private Alleles'. (TA1 Subtask 1.4)

Linked Optional Phase II tasks: 3.2.1.3, 3.2.1.4

3.1.1.4.1. Selection of Islands. Island selection shall determine populations for investigation of the possibility of Private Alleles to serve as potential targets of PAM-sensitive, spatially-limited gene drives. Regulatory and community engagement shall be integrated with genetic investigations, so island selection will also provide direction to project activities in these areas (3.1.4, 3.1.5, 3.2.4, 3.2.5*)*. Key criteria for island selection are provided below. Social engagement and regulatory considerations will provide additional filters. Fulfilment of both obligate and desirable criteria would likely be necessary for any potential future field trial and, seek to sample from islands that fulfil all six criteria with one exception. Southeast Farallon Island is the source of progenitors for an already existing breeding colony in the Recipient's lab where there are preliminary data available and that will support simulated natural environment trials in the optional phase. The U.S. Fish and Wildlife Service has also performed some ecological characterizations of the invasive mouse population on Southeast Farallon Island, which fulfils criteria 1-5 but would present some challenges for a traditional rodenticide based method of eradication (criterion 6).

Obligate criteria for Selection of Islands for private allele characterizations:

1) Island is within a country with a mature regulatory environment for genetically modified organisms. Our primary focus will be on the U.S. and Australia due to having research team members in both countries, but island possibilities in New Zealand will also be considered.

2) Island is within a country or overseas territory where *Mus musculus* populations are present and non-native.

3) Island is biosecure based on two key criteria: i) Either closed to the public or has only infrequent and controlled visitation, ii) Remote enough to avoid unassisted immigration or emigration of mice (i.e., >1km from other land masses).

4) *M. musculus* are the only rodent species present.

Desirable criteria for selection of islands for private allele characterizations:

5) Reasonably economical and feasible to visit the island year-round. Island should also have a maximum of two probable sources of introduction from a mainland or other island source to facilitate potential source population genetic characterizations.

6) No challenges exist to treatment using traditional, rodenticide-based methods to eradicate mice. Key characteristics include: i) uninhabited (besides research station or similar), ii) no livestock present, iii) no native rodents, iv) no species endemic to that island that may be negatively impacted by a rodenticide application, v) no non-target species of concern, vi) regulatory environment allows the use of brodifacoum bait products, vii) small - island size <300 ha, viii) single land managing entity.

3.1.1.4.1.1 *Performance Metrics and Assessment:* Identify five islands with invasive mouse populations and satisfying all six criteria (initial engagements with relevant regulatory authorities and stakeholders will be undertaken as part of 3.1.4 and 3.1.5 in Phase I). The sixth island to be included here is

Southeast Farallon Island because invasive mice to present a biodiversity threat and particularly because the Recipient has a breeding colony of wild-derived mice that would support Optional Phase simulated natural environment trials.

3.1.1.4.1.2 *Deliverables:* Define a list of six islands and associated potential source populations that shall be the focus for genetic studies of Private Alleles in 3.1.1.4.2. Documentation of the process of selection, a list of islands considered but not selected, and other key aspects of deliberations to be provided to DARPA Safe Genes program personnel. (by 3 months)

3.1.1.4.2. Identify population-specific Private Alleles in six mouse island populations and adjacent mainland populations. These locations shall be determined in task 3.1.1.3.1. (TA1 Sub-Subtask 1.4.1)

3.1.1.4.2.1 *Performance Metrics and Assessment:* Use targeted capture and next-generation sequencing technologies (Illumina Mi-Seq) to test for the presence of island-specific polymorphisms (private alleles) that can act as gRNA targets for a synthetic gene drive that will not function outside the island population. Genomic sequencing shall be conducted on six invasive mouse populations and the most likely source/potential escape populations for the invasive mouse populations. The goal shall be to obtain sequence information for a minimum of 100 individual mice (total) trapped from at least three locations on each island and from one or two likely source populations (islands with more probable current source populations shall be avoided). Average length of a minimum of 800 sequenced genomic locations shall be 590 base pairs. Genomic comparisons shall utilize the PHYLUCE package (https://www.github.com/faircloth-lab/phyluce). A sequence shall be considered a private allele if present and homozygous in all individuals of an island population and absent from the likely nearby source population (important for preventing transmission in the event of a gene drive carrier mouse moving to the source population). The most useful private alleles would form PAM sequences in the island populations that are not present in likely source populations. In the event private PAM sequences are not identified, define a private allele as differing by at least two nucleotides in the 25 nucleotides adjacent to the PAM sequence that could be targeted with a gRNA since this should prevent nuclease activity.

3.1.1.4.2.2 *Deliverables:* Provide detailed sequence information for the selected islands allowing assessment of whether island-specific private alleles are present. This is critical for determining the feasibility of achieving spatial limitation of gene drive function through targeting of gRNAs to these island-specific sequences. Through this process gain population level information about the island mice including detection of population differentiation, genetic diversity and effective population size. If private alleles are not identified for the chosen islands (considered an unlikely outcome), learn important demographic and population genetic information about potential target islands for any possible future release of constructs that are successful (to be completed by 21 months)

3.1.1.5 Develop efficient PAM-sensitive gene drive. Experimentally test limitation of private-allele focused synthetic gene drives in mice. *(previously TA1 Task 1.4.3)* This subtask will utilize the most the most effective homing strategy (Cpf1 or Cas9; zygotic or germline) established in 3.1.1.2 (Phase I). The PAM-sensitive gene drive will consist of a Neo-PAM "homing target" strain (containing a Private allele identified in 3.1.1.4 [Phase I] or a synthetic neo-PAM allele in the tyrosinase gene) and a Neo-PAM gene drive strain containing an endonuclease and gRNA expression cassette integrated at the same genomic location as the neo-PAM. Efficiency, specificity and safety of the PAM-sensitive gene drive will be assessed by comparing the progeny of Neo-PAM (homing target) x Neo-PAM (gene drive) (experimental cross) versus wild-type x Neo-PAM (gene drive) (negative control). Transgenic lines will be generated and validated as described in 3.1.1.2.

Linked Phase II Option Period tasks: 3.2.1, 3.2.2, 3.2.3, 3.2.4

3.1.1.5.1 *Performance Metrics and Assessment:*

Efficiency - Homing efficiency of >70% and NHEJ frequency of <30% in either zygotic or germline context as determined by genotyping of progeny from Neo-PAM (homing target) x Neo-PAM (gene drive) transgenic matings.

Specificity - Mutation rate of < 5% at off-target sites (defined as sequences with 3 or fewer mismatches to the on-target site) to be assessed in 5 independent samples (animals/embryos). Homing rate is <1% in mice that lack the neo-PAM ("private allele").

Safety - Average litter size is comparable (within 20%) between "homing crosses" (Neo-PAM (homing target) x Neo-PAM (gene drive) and controls (wild type x Neo-PAM (gene drive). Absence of overt malformation in >90% mice with successful homing event.

3.1.1.5.2 *Deliverables:*

Milestone 1: Generation and validation (allele sequence and transmission) of the Neo-PAM (homing target) and Neo-PAM (gene drive) transgenic lines (by 18 months)

Milestone 2: Development of a PAM-sensitive gene drive with the performance metrics described in 3.1.1.3.2.1 (by 24 months)

3.1.2 Systematic and structured hazard analysis for PAM sensitive, Y-shredding, Tandem Gene Drive

Linked Phase II Option Period tasks: 3.2.2

3.1.2.1 Risk Assessment

Complete a systematic hazard analysis, within a framework that is designed to identify Adverse Outcome Pathways (see risk assessment innovation). Identify failure modes from the genomic and proteomic scale, to the population and community scale, and use the concept of Adverse Outcome Pathways to describe the circumstances that lead to adverse effects on the target organism (transgenic mice; examples include off-target endonuclease activity that may lead to developmental malformations, and reproductive impairment as indicated by fertility and gonadal structure), and non-target organisms in the communities that the target organism may be released into (examples could include changes in the densities of domesticated or wild species that are deemed valuable by local communities and/or protected under national legislation). Adverse effects are identified during the hazard analysis, and are defined as detrimental changes to project, DARPA or community values. For example, outcomes that compromise the genetic isolation offered by private alleles, reduce the target organism's susceptibility to conventional control methods or reduce the birth rate of a non-target organism would likely be considered as adverse effects in this context.

The hazards analysis shall use structured, systematic hazard analysis methods, specifically Failure Modes and Effects Analysis (FMEA) and HAZOP (GenHAZ), to identify environmental hazards, and their Adverse Outcomes Pathways, associated with the uncontained release of transgenic mice containing the PAM sensitive, Y shredding TED. The analysis shall be guided by, and reflect, any environmental values and concerns identified by the stakeholder engagement activities funded in Phase I.

3.1.2.1.1 *Performance Metrics and Assessment:*

Completion of a 2-3 day Failure Modes and Effects workshop with at least 3 internal (to the project) subject matter experts and at least 2 external experts (subject to availability).

Completion of a 2-3 day HAZOP workshop with at least 3 internal (to the project) subject matter experts and at least 2 external experts (subject to availability).

Description of (possibly multiple) pathways that lead to adverse outcomes for at least 3 ecological values (examples could include predation on or competition with non-target native species, changes in disease transmission, shifts in native predator behavior associated with altering invasive mouse densities). The three ecological values that would be the focus of adverse outcome pathway

descriptions would be informed by input and coordination with the stakeholder engagement team).

3.1.2.1.2 *Deliverables:* (Analysis complete by 18 months)

Structured, systematic hazard analysis for uncontained release of transgenic mice carrying PAM sensitive, Y shredding TED.

3.1.3 Mathematical modeling of performance of Genome editing controller mechanisms. (Subtask 4.3)

Linked Optional phase tasks: 3.2.1, 3.2.3

3.1.3.1 *Performance Metrics and Assessment:* Developed spatially-explicit, stochastic, individual-based models (IBM) describing the population dynamics of an invasive mouse population occupying continuous space coupled with models developed for evolutionary invasion analysis. The spatial IBM shall describe the behaviour, dynamics, genetic composition, selection and evolution of individuals located in 2-dimensional continuous, heterogeneous environment. Critical to the development of initial models shall be data gathered in completing subtasks 3.1.1.2.2 and 3.1.1.2.3 on efficiency and stability of homing and NHEJ levels for Cas9 and Cpf1 zygotic and germline homing approaches as these variables are predicted to represent key failure modes for gene drive function. Together with metrics for subtasks 3.1.1.2.1 and 3.1.1.2.2, the modeling in this subtask shall inform the choice of drive construct down-selected for trials in simulated natural environments in the Optional phase.

3.1.3.2 *Deliverables:*

Construction of spatial, stochastic individual-based model for mouse population, parameterized using location-specific data.

Analysis of gene drive strategies, including uncertainty analysis to quantify confidence in model predictions and identify key uncertainties (ecological, behavioral and genetic) that impact predictive ability.

Milestones:

Construction of initial model. (to be completed by month 12)

Parameterization and analysis of initial model, model refinement to include increasing biological complexity, and analysis of refined model. (to be completed by month 21)

3.1.4 Regulatory Engagement

Linked Phase II Option Period tasks: 3.2.4

3.1.4.1 Meet with regulators to describe and discuss the plans and progress of studies undertaken in this project including construct design and development. The goal shall be to allow for integrated planning of detailed studies that will be required to be in compliance with US, Australian, and New Zealand law relevant to gene drives as regulations are developed for this technology. Coordinate with i) engagement efforts that are underway with federal regulators in Australia, in association with the Synthetic Biology Future Science Platform, and with state regulators in Western Australia and Queensland, and ii) partners at Landcare Research in New Zealand.

3.1.4.1.1 *Performance Metrics and Assessment:*

Meet with Regulators in the United States (FDA/EPA/USDA) twice annually, the timing of which will be based on technical progress. The meetings will focus on sharing programmatic and technical progress of the project under the Safe Genes program. The regulators will be updated on progress and facilitate changes to studies as necessary.

Meet with the Office of the Gene Technology Regulator (OGTR) in Australia once annually or as applicable based on technical progress. The meetings will focus on sharing programmatic and technical progress of the project under the Safe Genes program. The regulators will be updated on progress and facilitate changes to studies as necessary.

Regulatory engagement efforts in this task will be coordinated with regulatory engagement activities in New Zealand.

3.1.4.1.2 *Deliverables:*

Records of meetings and particularly key issues, concerns, and updates. (three meetings with U.S. regulators by month 21 and two meetings with Australian regulators). On an annual basis, a formal report shall be submitted that includes analysis and outcomes of the meetings and recommendations for a path forward for gene drives informed by input from regulatory agencies in the U.S., Australia, and New Zealand.

3.1.5 Engagement

The engagement efforts shall focus on US locations for budgetary and logistical reasons. However, efforts in this task shall be coordinated with and complemented by ongoing community efforts in Australia and New Zealand, through members of GBIR partnership (Genetic Biocontrol of Invasive Rodents) and led by the Recipient. In New Zealand, coordinate with a just-initiated project being conducted by the 'New Zealand's Biological Heritage National Science Challenge' on 'Exploring New Zealand's social license towards novel pest control technologies. Community engagement is planned by in Australia as part of wider effort to gain social license for environmental applications of synthetic biology technologies.

Linked Phase II Option Period tasks: 3.2.5

3.1.5.1 Stakeholder landscape analysis. (SubTask 8.1)

3.1.5.1.1 *Performance Metrics and Assessment:*

Review of stakeholder maps and notes from prior workshops on gene drives at NC State University.

Identification of national NGOs, interest groups, and U.S. federal agencies that would have a voice in the political and social debates of future releases.

Identify 1-2 local, state, or regional stakeholders for each of the identified candidate islands (See Task 3.1.1.3).

Conduct 15-20 interviews with leaders identified from stakeholder list, collecting information about interests, issue positions, and expertise.

Analyze interviews in Dedoose (online qualitative data analysis interface).

3.1.5.1.2 *Deliverables:* (to be completed by 9 months)

Stakeholder map, reflecting interests, positions, and influences of various stakeholder groups for each of six islands identified as potential release sites (Task 3.1.1.3).

Narrative to describe key insights of stakeholder map, including justification of invitations to Stakeholder Workshop #1 (Task 3.1.5.2).

3.1.5.2 Stakeholder Workshop #1. (SubTask 8.2)

3.1.5.2.1 *Performance Metrics and Assessment:*

In consultation with project technical leads, regulatory leads, and DARPA LEEDR panel, develop draft technology scenarios appropriate to the identified U.S. island candidate sites.

Drawing on the landscape analysis (3.1.5.1), create a list of 10-20 key stakeholders that represent diverse interests and perspectives.

Identify 1-2 key stakeholders relevant to each identified U.S. island candidate site.

In line with budgetary constraints, confirm participation of 10-20 diverse stakeholders for workshop.

Organize and facilitate stakeholder workshop #1.

3.1.5.2.2 *Deliverables:* (to be completed by 21 months)

Draft technology scenarios for consideration at stakeholder workshop.

Workshop report, including recommendations of stakeholder group on each scenario that inform directions for technical innovation and the design of community focus groups (Task 3.1.2.6).

Updated stakeholder map with revised narrative.

3.2 PHASE II OPTION PERIOD

Technical Area 1 - Control of genome editing activity.

3.2.1 Demonstrate genome editing controllers that enable spatial control of genome editing activity.

The Recipient shall:

3.2.1.1 Build tandem-drive (TED) system in mice. Generate and test a Y-shredding PAM-sensitive TED in mice.

Build on the Y-shredder (3.1.1.2.4.) and PAM-specific drives (3.1.1.3.2.) generated in Phase I. The TED system shall consist of two PAM-sensitive Drives (Drive A and Drive B) each of which carries a component of the Y-shredder which becomes active only when Drives A and B are present in the same animal. The efficiency and stability of the TED system shall be assessed over 3 generations. Transgenic lines shall be generated as described in 3.1.1.2.

3.2.1.1.1 *Performance Metrics and Assessment:*

Efficiency - Homing efficiency of >70% and NHEJ frequency of <30% in either zygotic or germline context as determined by genotyping of progeny from Drive A x Drive B matings. >75% generation female progeny from progeny of Drive A x Drive B matings as assessed by gonadal phenotyping and sex chromosome PCR.

Specificity - Mutation rate of < 5% at off-target sites (defined as sequences with 3 or fewer mismatches to the on-target site) to be assessed in 5 independent samples (animals/embryos). Homing rate is <1% in mice that lack the Drive A or Drive B neo-PAM ("private allele").

Stability – Homing efficiency remains >70% and NHEJ frequency remains <30% over 3 generations. >75% generation of female progeny after 3 generations.

Safety - Absence of overt malformation in >90% mice with successful homing event.

3.2.1.1.2 *Deliverables:*

Milestone 1. Generation and validation (allele sequence and transmission) of Drive A and Drive B transgenic lines. (by 30 months)

Milestone 2. Development of a TED gene drive with the performance metrics described in 3.2.2.1.1. across 3 generations. (by 39 months)

3.2.1.2 Test population suppression effects of t-Sry mice in Simulated Natural Environments at the United States Department of Agriculture National Wildlife Research Center (NWRC).

Using the t-Sry mice developed in 3.1.1.1, tests of population suppression through production of predominantly male offspring shall provide the first set of trials using Simulated Natural Environments (SNEs) at NWRC in Phase II Option Period. These trials shall employ mice from Godwin Laboratory Farallon Islands mouse colony as the 'base population' for the trial. SNE trials shall initially include 36 animals of which six shall be t-Sry males. These t-Sry carriers shall be F1 hybrids between the strain the drive is developed in (C57BL/6J) and wild-derived males from the Farallon Islands stock (experiments in the Godwin laboratory have shown that i) wild-derived mice will breed with both C57BL/6J and C57BL/6Jx129 mice and produce fully viable offspring and ii) that the resultant hybrid males are successful in aggressive competition with wild-derived males). The other mice used to begin

the trial shall be six wild-type males (i.e., non t-allele bearing) and 24 females from the outbred Godwin Laboratory Farallons Islands stock.

3.2.1.2.1 *Performance Metrics and Assessment:*

Two separate trials shall run for six months with the goal of assessing the success of the t-Sry construct spreading in a relatively complex environment across a minimum of three generations. Mice shall be randomly culled between generations if necessary to maintain an overall population of 40 animals.

Trials shall be closely monitored and the following metrics shall be assessed for females and litters: i) mating success of females (% with pups), ii) pup genotypes using PCR for presence of the t-Sry construct using ear punch samples obtained at 14-18 days of age (before weaning), iii) progeny sex ratios (visual sexing based on external morphology - sexually dimorphic after 9 days of age), iv) litter size, v) weaning success based on inspections of nests and visual monitoring of individually-marked pups (colored ear tags), vi) space use within the simulated natural environment based on visual observation and monitoring by RFID tags and regularly-spaced antennas.

As the reproductive fitness of t-Sry vs. wild-type males is likely to be critical in determining the spread (or lack of spread) of the t-Sry genotype and thus hypothesized offspring sex ratios, trials shall be closely monitored and the following metrics shall be assessed for males: i) territory establishment and space use as determined by visual monitoring of the tagged individuals and RFID tracking, ii) female residency within areas used by males, and iii) aggressive interactions with other tagged males during regular observations.

Progeny sex ratios are expected to be >90% males for matings between t-Sry carrying males and females, but not statistically significantly different from 50% female for matings between wild-type males and females.

3.2.1.2.2 Deliverables (by 36 months)

Tests of population suppression through generation of male-biased progeny sex ratios utilizing a naturally-occurring meiotic drive system (the t allele) modified to include a masculinizing gene in a relatively complex simulated natural environment and highly biosecure conditions. Additionally, these trials with the t-Sry construct in the first stage of Phase II Option Period will provide valuable general tests of protocols and procedures that will inform the subsequent mouse population trials with synthetic drive constructs using the SNEs at NWRC.

3.2.1.3 Test private allele limitation of drive function in Simulated Natural Environments at NWRC *(TA1 SubTask 1.3).*

Test of limitation of gene drive function in complex Simulated Natural Environments (SNE) at the NWRC using private allele targeting drives. These trials shall employ either naturally-occurring private alleles identified in Godwin laboratory Farallon Islands mouse colony or a laboratory strain synthetic sequence backcrossed into wild-derived mice from the Godwin Lab Farallon Islands mouse colony to be used as the 'base population' for the trial. SNE trials shall initially include 40 animals of which four shall be female gene drive carriers (carrying the Y-shredder construct to be developed in Phase I). These gene drive carriers shall be F1 hybrids between the strain the drive is developed in (C57BL/6J) and wild-derived males from the Godwin Lab Farallon Islands stock (or males with the PAM-sensitive site backcrossed in if necessary). The other mice shall include 18 private allele carriers, and 18 shall be non-private allele carriers (50% female, 50% male for each group). Modeling results from Phase I and Phase II Option Period could suggest important alterations of these proposed proportions of gene drive carriers and non-carriers.

3.2.1.3.1 *Performance Metrics and Assessment:*

Two separate trials shall run for six months with the goal of assessing drive function in a complex environment across a minimum of three generations. Mice shall be randomly culled between

generations if necessary to maintain an overall population of 40 animals.

Trials shall be closely monitored and the following metrics shall be assessed for females and litters: i) mating success of females (% with pups), ii) pup genotypes using PCR for presence of the private allele and gene drive construct using ear punch samples obtained at 14-18 days of age (before weaning), iii) progeny sex ratios (visual sexing based on external morphology - sexually dimorphic after 9 days of age), iv) litter size, v) weaning success based on inspections of nests and visual monitoring of individually-marked pups (colored ear tags), vi) space use within the simulated natural environment based on visual observation and monitoring by RFID tags and regularly-spaced antennas.

As male reproductive fitness is likely to be critical, trials shall be closely monitored and the following metrics shall be assessed for males: i) territory establishment and space use as determined by visual monitoring and RFID tracking, ii) female residency within areas used by males, and iii) aggressive interactions with other tagged males during regular observations.

Progeny sex ratios are expected to be >90% females (~50% XX and 50% XO) for matings between gene drive carriers and private allele carrier males, but 50% female for matings between gene drive carrier females and males who do not carry the private allele (pups heterozygous for drive construct).

Population sex ratio predictions shall be derived from modeling efforts, but the general prediction is that the population will become progressively more female-biased as long as males carrying the private allele are present and mating successfully. If the proportion of these private allele positive males declines to zero, spread of the gene drive should stop.

Integration with modeling (3.1.3 in Phase II Option Period: Parameter estimates shall be updated each generation; updated model runs will be generated and compared to behavior seen in the SNE.

3.2.1.3.2 *Deliverables:* (by 42 months)

A test of limitation of gene drive function by genetic polymorphism in a small population under highly biosecure conditions.

A test of spatial limitation of gene drive function through targeting of geographically-limited genetic polymorphisms in a relatively complex, but biosecure environment.

3.2.1.4 Test trans-effector drive (TED) function in simulated natural environments. (SubTask 1.4)

Using the two PAM-sensitive Drives (Drive A and Drive B) developed for subtask 3.1.1.1 in the Phase II Option Period, each of which carries a component of the Y-shredder which becomes active only when Drives A and B are present in the same animal, trials in the SNEs shall test the trans-effector drive (TED) approach. SNE trials shall initially include 40 animals: four shall be Drive A carriers, four shall be Drive B carriers, and 32 shall be wild-type non-carriers derived from the Godwin Laboratory Farallon Islands mouse colony (50% female, 50% male). All animals shall be homozygous for the genomic sequences targeted by both PAM-specific drives. Modeling results from Phase I and Phase II Option Period could guide alteration of the currently-planned proportions of gene drive carriers and non-carriers introduced to SNEs to begin trials.

3.2.1.4.1 *Performance Metrics and Assessment:*

Two separate trials run for up to seven months with the goal of assessing TED function in a complex environment across a minimum of four generations. Mice shall be randomly culled between generations if necessary to maintain an overall population of 40 animals.

Trials shall be closely monitored and the following metrics shall be assessed for females: i) litter sizes, time to producing litters across maternal genotypes (Drive A, Drive B, both, or neither - assessed by PCR), relative mating success of gene drive carriers and non-carriers at the population (% of pups carrying Drive A, Drive B, both, or neither - assessed by PCR from ear punch samples) and weaning success based on inspections of nests and visual monitoring of individually-marked pups (colored ear

tags applied at two weeks of age), ii) progeny sex ratios (visual sexing based on external morphology - sexually dimorphic after nine days), and iii) comparisons of gonadal histology for a minimum of 10 XX and 10 XO females in drive carriers.

Trials shall be closely monitored and the following metrics shall be assessed for males: i) territory establishment and space use as determined by visual monitoring and RFID tracking, ii) female residency within areas used by males, and iii) the outcome of aggressive interactions with other tagged males during regular observations.

Progeny sex ratios are expected to be >90% female (~50% XX and 50% XO) for individuals carrying both Drive A and Drive B, but not statistically significantly different from 50% female for individuals carrying only Drive A, only Drive B, or neither drive construct.

Specific population sex ratio predictions will be developed during modeling activities (3.1.3 in Phase I and 3.1.3 in Phase II Option Period, but the general prediction is that the population will exhibit a progressively more female-biased overall sex ratio as both Drive A and Drive B increase in frequency, creating a functional Y-shredder mechanism when present in the same animal and thus predicted reproductively-functional females (to be tested initially in 3.1.1.1 in Phase II Option Period. Overall population size should decline when males become limiting (preliminary modeling suggests population declines will occur at five or fewer mates per male).

3.2.1.4.2 *Deliverables:* (to be completed by 48 months)

The key deliverable will be experimental tests of population suppression through mixing of two drive strains in a relatively complex simulated natural environment, each carrying one part of the female-to-male transformation system - in this case causing Y-shredding and all-female progeny. Additionally, using statistical model fits to trial data, the second key deliverable will be refined estimates of critical trans-drive parameters, including fitness costs, homing efficacy and NHEJ rate. Thus, testing is iterative and model-informed.

3.2.2 Probabilistic ecological risk assessment for PAM sensitive, Y-shredding, Tandem Gene Drive. (Task 2)

3.2.2.1 Risk Assessment (CSIRO)

The scope and geographic boundaries of the probabilistic environmental risk assessment will be determined by outcomes of Phase 1, specifically: a) the values and concerns identified by stakeholders and community groups; b) the assessment and measurement endpoints that reflect these concerns; c) the results of the systematic hazard analysis; and, d) the preferred island location. The risk assessment will use formal elicitation to quantify the likelihood of adverse outcomes pathways, and their associated consequences (see risk assessment innovation). Adverse outcome pathways will be modelled using techniques such as fault and event tree analysis, (possibly hierarchical) statistical models and qualitative mathematical models. Direct and indirect elicitation will target the parameters, structure and/or response variables within these models. Environmental consequences will be expressed in terms measurable changes to at least three of the ecological endpoints identified in Phase 1.

The risk assessment will consider surveillance protocols, using the concepts and methods of area freedom surveillance and compliance (see risk assessment innovation), to test the feasibility and cost implications of implementing post-release surveillance strategies that monitor the efficacy of the genetic and geographic containment strategies that are built into the PAM-sensitive trans-homing gene drive, and also provide an early-warning capability for adverse target and non-target effects.

3.2.2.1.1 *Performance Metrics and Assessment:*

Completion of risk models for at least 3 ecological endpoints

Completion of all direct (and/or) indirect elicitation workshops necessary to parameterise the risk models, with at least 3 internal (to the project) subject matter experts and (subject to availability) at least 3 external subject matter experts

Provision of quantitative risk predictions for at least 3 ecological endpoints

A single recommended surveillance protocol to detect adverse target and non-target effects associated with the open release of TED mice in a specified island's location.

3.2.2.1.2 *Deliverables:* (completed by 48 months)

Comprehensive, probabilistic risk assessment for open release of PAM sensitive, Y-shredding, TED drive within a specified island location

Recommended post release surveillance and monitoring strategy

3.2.3 Mathematical modeling of performance of Genome editors.

3.2.3.1 Mathematical modeling of genome editor performance in increasingly complex environments.

Using experimental data and refining models developed in Phase I, efforts in the optional phase shall inform experimental trials in simulated natural environments and incorporate additional biological and ecological complexity to identify key factors influencing drive performance.

3.2.3.1.1 *Performance Metrics and Assessment:*

Completion of individual-based spatially-explicit population models for at least 3 island environments.

Completion of model-parameter specification and inference-based model sensitivity analysis.

Provision of a robust model framework for identifying key drive, ecological and behavioral parameters that impact performance of the drive.

3.2.3.1.2 *Deliverables:* completed by month 42)

Development of detailed biology-rich models, including mating behavior and population structure informed by complex environment data appropriate for SNE that has utility for predicting gene drive performance in SNE (and other ecological contexts).

Parameterization of model, initially drawing upon *a priori* data and with online updating as data is acquired from SNE experiments. Real-time comparison between model predictions and results from SNE experiments with the potential for adjusting SNE experiments (e.g. release numbers) if model indicates this would increase the informativeness of the experiment.

Sensitivity and uncertainty analysis to identify key drive, ecological and behavioral parameters that impact performance of the drive.

3.2.4 Regulatory Engagement.

Continue engagement with regulators to describe and discuss the plans and progress of studies undertaken in this project in Phase II Option Period. These discussions shall include construct design and development as well as other developments directly relevant to this project that may take place in this active area of research. The continued goal in Phase II Option Period is to integrate planning of detailed studies that will be required to be in compliance with US, Australian, and New Zealand law relevant to gene drives in the developing regulatory environment for this technology. As noted for 3.1.4 in Phase I, regulatory engagement activities shall be coordinated with engagement efforts that are underway with federal regulators in Australia, in association with the Synthetic Biology Future Science Platform, and with state regulators in Western Australia and Queensland.

3.2.4.1. Regulatory engagement.

3.2.4.1.1 *Performance Metrics and Assessment:*

Meet with Regulators in the United States (FDA/EPA/USDA) twice annually. The meetings shall focus

on sharing programmatic and technical progress of the project under the Safe Genes program. The regulators shall be updated on progress and facilitate changes to studies as necessary.

Meet with the Office of the Gene Technology Regulator (OGTR) in Australia once annually. The meetings shall focus on sharing programmatic and technical progress of the project under the Safe Genes program. The regulators shall will be updated on progress and facilitate changes to studies as necessary.

Regulatory engagement efforts in this task shall be coordinated with regulatory engagement activities conducted in New Zealand.

3.2.4.1.2 *Deliverables:* (completed by 45 months)

The key deliverable shall be records of these meetings and particularly key issues, concerns, and updates. On an annual basis, a formal report shall be submitted that includes analysis and outcomes of the meetings and recommendations for a path forward for gene drives informed by input from regulatory agencies in the U.S., Australia, and New Zealand.

3.2.5 Engagement with Communities. (Task 8)

3.2.5.1 Community engagement focus group workshops. (SubTask 8.3)

3.2.5.1.1 *Performance Metrics and Assessment:*

Identify three communities for focus group workshops, relevant to the remaining feasible candidate island release sites. Communities might include nearby islands or populations on the mainland.

Identification of local partners relevant to each identified community.

In consultation with local partners and with attention to demographic diversity, recruit 20-50 community members for each of three sites.

Drawing on Stakeholder Workshop Report, design focus group agenda for each community.

Conduct three focus group workshops.

3.2.5.1.2 *Deliverables:* (completed by 42 months)

Information materials relevant for scenarios for each of three community focus group workshops.

Workshop report that includes appendices that address specific issues for each of three community focus groups.

3.2.5.2 Engagement report for dissemination. (SubTask 8.5)

3.2.5.2.1 *Performance Metrics and Assessment:*

Drawing on stakeholder map (Task 3.1.5.1), the Stakeholder Workshop Report (Task 3.1.5.2), and the community engagement focus group workshops report (Task 3.1.2.6.1), compose a draft report on lessons learned regarding stakeholder and community engagement, the formulation and use of scenarios, and recommended next steps for stakeholder, community and public engagement for project-relevant technologies.

3.2.5.2.2. Deliverables. (to be completed by month 48)

Engagement report (to be cleared through DARPA Public Affairs Office prior to distribution to stakeholders, project personnel, local partners, and broader public and academic audiences).

Technical Area 3 - Genetic Remediation

3.2.6 Genetic Remediation

The Recipient shall:

3.2.6.1 Demonstrate genetic remediation strategies that can be utilized while remaining Effective, Specific, Safe, Stable.

3.2.6.1.1 Inhibition of Y-shredder PAM-sensitive TED gene drive (SubTask 1.1). Confirm that the TED system developed in 3.1.1.1 exhibits homing activity on the Neo-Pam ("private allele") population and not on a simulated "neighboring population" lacking the private allele (i.e. wild-type mice).

3.2.6.1.1.1 *Performance Metrics and Assessment*:

Specificity - Homing rate is <1% in mice that lack the neo-PAM ("private allele"). Mutation rate of < 5% at off-target sites (defined as sequences with 3 or fewer mismatches to the on-target site) to be assessed in 5 independent samples (animals/embryos).

Efficiency - Drive A and Drive B homing efficiency is >70% and NHEJ frequency is <30% in mice that carry the Neo-PAM.

Safety - Average litter size is comparable (within 20%) between "homing crosses" (Neo-PAM (homing target) x Neo-PAM (gene drive) and controls (wild type x Neo-PAM (gene drive). Absence of overt malformation in >90% mice with successful homing event.

3.2.6.1.1.2 *Deliverables:*

Milestone 1. Proof-of-concept for island-population specificity of the TED strategy with homing in mice that have the private allele, but not in mice lacking this allele. Subtask to be completed by 39 months.

3.2.6.1.2 Development of a TED reversal Drive.

Recognizing that it would be desirable to have the capability to delete the TED drive from the target population (island mice) if there is evidence of an unanticipated adverse outcome arising from TED drive deployment. Construct and test a TED reversal drive (TEDrev) which is designed to remove Drive A and Drive B from the genome. The reversal strategy "subverts" the programmable endonuclease that is used for TED homing (e.g. Cas9) to instead cause deletion of TED drive. Two versions of the TEDrev drive shall be generated (see 3.1.1.2), revA and revB, each of which contains an identical gRNA expression cassette integrated at the same genomic location as Drive A and Drive B, respectively. The gRNA expressed by the TEDrev drives shall target the homing endonuclease (e.g., Cas9) sequence. Thus, individuals that carry one copy of Drive A and one copy of revA (one inherited from each parent) shall cut the Drive A allele in the Cas9 sequence. Homology Directed Repair of the double stranded break using the revA allele as a template will simultaneously result in deletion of Drive A and duplication (homing) of revA. The equivalent repair mechanism/outcome would occur in a Drive B/revB individual (i.e., they become revB/revB). Because the revA and revB become homozygous after homing, they should rapidly spread through the TED-carrying population. Notably this strategy is generalizable as it targets the Cas9 sequence (or could be easily adapted for Cpf1). By removal of the drive machinery, this approach also imparts a near genetic ground-state on the carrying individual that consists only of a single gRNA expression cassette. Furthermore, because TEDrev homing could also occur in trans (i.e. gRNA generated from revA could cut Cas9 at Drive B), it should be possible to convert a Drive B/+ individual to +/+. The trans effect could also restore a Drive A/+ individual to +/+. This trans-homing potential of our TEDrev strategy is a significant innovation and is the only approach described to date that will fully restore the genetic ground-state of a gene drive allele by replacement of a gene drive with a WT sequence. RevA and revB mouse strains shall be generated as described in TA1 subtask 1.3.

To test the TEDrev (including trans-homing), matings shall as described below (Drive A=DA; Drive B =DB, '→' = expected progeny outcomes, assumes zygotic homing).

1. DA/DA x revA/PAM-A: i) DA /revA → revA/revA, ii) DA /PAM-A → DA / DA.

2. DB/DB x revB/PAM-B: i) DB/revB → revB/revB, ii) DB /PAM-B → DB/DB.

3. DA/DA; DB/DB x PAM-A/+; revB/revB: i) DA /PAM-A; DB/revB→DA / DA; revB/revB.

ii) DA /+; DB /revB → +/+; revB/revB.

iii) DA / DA; DB / DB x revA/revA; PAM-B/+.

a. DA /revA; Drive B/PAM-B → DA/DA; DB/DB, b. DA/revA; Drive B/+ → DA/DA; +/+.

Progeny shall be genotyped by PCR. X chromosome dosage PCR will show whether individuals that transiently harbor DA, DB and revA or revB undergo Y shredding before revA/revB homing.

3.2.6.1.2.1 *Performance Metrics and Assessment:*

Efficiency - >90% reversion/removal of Drive A and Drive B in progeny of RevA/RevB x TED matings.

3.2.6.1.2.2 *Deliverables:*

Milestone 1: Generation of the RevA and RevB transgenic lines. (by 39 months)

Milestone 2: Validation of RevA and RevB activity using performance metrics in 3.3.2.1.2.1. (by 48 months)

3.2.6.1.3 Demonstrate the utility of *in silico* models for the prediction of performance of genetic remediation tools.

3.2.6.1.3.1 *Performance Metrics and Assessment:*

Development of simple models (stochastic, individual-based but with little biological complexity, e.g. simple description of population structure) of drive reversal.

Extension of models to incorporate additional biological detail, including mating behavior and population structure informed by earlier tasks, to enable evaluation of reversal drives in realistic ecological contexts

Parameterization of model, initially drawing upon *a priori* data and with online updating as data is acquired from experiments. Use of insights gained from model to potentially adjust experiments and to indicate potential for improvement of reversal drive

Sensitivity and uncertainty analysis to identify key drive, ecological and behavioral parameters that impact performance of the reversal drive.

3.2.6.1.3.2 *Deliverables:*

Detailed models will incorporate findings on reproductive behavior, reproductive success, and sex ratios from studies under TA1 to predicting effectiveness of inhibiting trans-effector drives and TED reversal drive performance in small scale and simulated natural environment contexts. The deliverables should be identification of key drive, ecological and behavioral parameters that impact performance of remediation tools.

3.3.2._: Data Sharing

See data sharing section (4.1.x and 4.2.x)

4.0 MILESTONES

4.1 BASE PERIOD (PHASE I)

Technical Area 1 - Control of genome editing activity.

4.1.1 Month 21: 3.1.1.1 Engineer t-Sry mice to express Sry under doxycycline control.

4.1.2 Month 12: 3.1.1.2.1 Generation of transgenic mice (Generation I Drive)

4.1.3 Month 18: 3.1.1.2.2 Assess stability, efficiency of CAS9-mediated germline and zygotic homing

4.1.4 Month 18: 3.1.1.2.3 Assess stability, efficiency of Cpf1-mediated germline and zygotic homing

4.1.5 Month 21: 3.1.1.3. Develop an efficient feminizing endonuclease gene drive (Y-shredder)

4.1.6 Month 3: 3.1.1.4.1 Selection of Islands

4.1.7 Month 21: Identify population-specific Private Alleles in six mouse island population and adjacent mainland populations

4.1.8 Month 24: 3.1.1.5 Develop efficient PAM-sensitive gene drive

4.1.9 Month 21: 3.1.2 Systematic and structured hazard analysis for PAM sensitive, Y-shredding, Tandem Gene Drive

4.1.10 Month 12: 3.1.3 Mathematical modeling of performance of Genome editing controller mechanisms: Construction of initial model

4.1.11 Month 21: 3.1.3 Parameterization and analysis of initial model, model refinement to include increasing biological complexity, and analysis of refined model

Data Sharing – (Dates may be updated based on tasks and schedule agreed upon in the technical areas)

Deliver experimental data collected in this effort within four months of completion of data collection

4.1.12 Month 24: Sex ratio data from t-Sry task (3.1.1.1) uploaded into a data sharing platform to be identified by the DARPA Program Manager (PM)

4.1.13 Month 15: Sequence data confirming generation of transgenic founder mice (3.1.1.2) by month 12 uploaded into a data sharing platform to be identified by the PM

4.1.14 Month 21: Data on efficiency, stability, specificity, and safety for CAS9 germline and zygotic lines (see 3.1.1.2.2) generated by month 18 uploaded into a data sharing platform to be identified by the PM

4.1.15 Month 21: Data on efficiency, stability, specificity, and safety for CPF1 germline and zygotic lines (see 3.1.1.2.3) generated by month 18 uploaded into a data sharing platform to be identified by the PM

4.1.16 Month 12: Data on Y-shredder efficiency (see 3.1.1.3) generated by month 9 uploaded into a data sharing platform to be identified by the PM

4.1.17 Month 18: Data on transmission of Y-shredder (see 3.1.1.3) generated by month 15 uploaded into a data sharing platform to be identified by the PM

4.1.18 Month 24: Data on progeny sex ratios in Y-shredder construct line (see 3.1.1.3) generated by month 21 uploaded into a data sharing platform to be identified by the PM

4.1.19 Month 6: Islands selected for private allele characterization together with documentation of selection process and list of islands considered (see 3.1.1.4) generated by month 3 uploaded into a data sharing platform to be identified by the PM

4.1.20 Month 24: Sequence data from private allele identification (see 3.1.1.4.2) generated by month 21 uploaded into a data sharing platform to be identified by the PM

4.1.21 Month 21: Data from development of PAM-sensitive gene drive including efficiency, specificity, and safety metrics (see 3.1.1.5) generated by month 18 uploaded into a data sharing platform to be identified by the PM

4.1.22 Month 24: Data generated from structured, systematic hazard analysis for PAM-sensitive Y-shredder TED drive will be uploaded to a data sharing platform identified by the PM.

4.1.23 Month 24: Data generated from mathematical modeling (see 3.1.3) will be uploaded to a data sharing platform identified by the PM.

4.1.24 Month 12: Stakeholder map and associated narrative (see 3.1.5.1) will be uploaded to a data sharing platform identified by the PM.

4.1.25 Month 24: Workshop report and updated stakeholder map information following stakeholder workshop (see 3.1.5.2) will be uploaded to a data sharing platform identified by the PM.

ELSI

4.1.26 Month 24: 3.1.5 Engagement: stakeholder analysis and workshop.

Regulatory Engagement

4.1.27 Month 24: 3.1.4 - Records of meetings with U.S., New Zealand, and Australian regulators, including an annual report.

4.2 PHASE II OPTION PERIOD

Technical Area 1 - Control of genome editing activity.

4.2.1 Month 30: 3.1.1.1 Build tandem-drive (TED) system in mice - Generation and validation of Drive A and Drive B transgenic lines

4.2.2 Month 39: 3.1.1.1 Build tandem-drive (TED) system in mice - Development of a TED gene drive

4.2.3 Month 36: 3.1.1.2 Test population suppression effects of t-Sry mice in Simulated Natural Environments

4.2.4 Month 42: 3.1.1.3 Test 'private allele' approach in mice in Simulated Natural Environments

4.2.5 Month 48: 3.1.1.4 Test trans-effector drive (TED) approach in simulated natural environments

4.2.6 Month 48: 3.1.2 Probabilistic ecological risk assessment for PAM sensitive, Y-shredding, Tandem Gene Drive

4.2.7 Month 42: 3.2.3 Mathematical modeling of performance of Genome editors

4.2.8 Month 45: 3.1.4 Regulatory engagement

4.2.9 Month 42: 3.1.5.1 Community engagement focus group workshops

4.2.10 Month 48: 3.1.5.2 Engagement report for dissemination

Technical Area 3 - Genetic Remediation

4.2.11 Month 39: 3.3.1.1.1 Inhibition of Y-shredder PAM-sensitive TED gene drive

4.2.12 Month 48: 3.3.1.1.2 Development and testing of a TED reversal Drive

4.2.13 Month 48: 3.3.1.1.3 Demonstrate the utility of *in silico* models for the prediction of performance of genetic remediation tools

Data Sharing (Dates may be updated based on tasks and schedule agreed upon in the technical areas.)

Deliver experimental data collected in this effort within four months of completion of data collection.

4.2.14 Month 33: Data on efficiency, specificity, stability, and safety for generation and validation phase of construction of tandem-drive system (see Phase II Option Period task 3.1.1.1) collected up until month 30 into a data sharing platform to be identified by the PM.

4.2.15 Month 42: Data on efficiency, specificity, stability, and safety for generation and validation phase of construction of tandem-drive system (see Phase II Option Period task 3.1.1.1) collected up until month 39 into a data sharing platform to be identified by the PM.

4.2.16 Month 39: Data collected on population suppression effects of t-Sry mice in SNE trials (see Phase II Option Period task 3.1.1.2) up until month 36 into a data sharing platform to be identified by the PM.

4.2.17 Month 45: Data collected on private allele limitation of drive function in SNE trials (see Phase II Option Period task 3.1.1.3) up until month 42 into a data sharing platform to be identified by the PM.

4.2.18 Month 48: Data collected on trans-effector drive (TED) function in SNE trials (see Phase II Option Period task 3.1.1.4) up until month 42 into a data sharing platform to be identified by the PM.

4.2.19 Month 48: Data from probabilistic risk assessment of PAM-sensitive, Y-shredder TED drive (see Phase II Option Period task 3.1.2) up until month 45 into a data sharing platform to be identified by the PM.

4.2.20 Month 45: Data collected on mathematical modeling of TED drive function in island environments (see Phase II Option Period task 3.1.3) generated up until month 42 into a data sharing platform to be identified by the PM.

ELSI

4.2.21 Month 42: Report on community engagement workshops

4.2.22 Month 48: Engagement report for dissemination

Regulatory Engagement

4.2.23 Month 48: Records of meetings with U.S., New Zealand, and Australian regulators, including an annual report.

5.0 PROGRAM MANAGEMENT AND REVIEW

The Government will actively monitor, review and approve the Recipient's performance to ensure all the performers are in sync and matched with the Government's requirements. The Government will ensure that each of the performers share experimental data across the program. The Government will further ensure that the performers develop techniques and capabilities that are compatible and integrate with each other. The Recipient shall collaborate and cooperate with other performers in the program under the direction of the Government. At the Government PI meeting, all performers shall demonstrate their technical capabilities and engage or challenge each other in a cooperative and challenge environment. Along these lines, the Government will ensure that the performers each share DCA technical information with each other to enable the testing/challenging of each other's capabilities. The Government will further oversee the program and will review, approve, and participate in the demonstrations, as well as determine which performers will advance to the Phase II Option Period. The Government shall review and approve all releases to the press that reference DARPA or DOD or this Program (excluding peer reviewed publications of scientific findings).

5.1 KICK-OFF MEETING

The Recipient shall participate in a kick off meeting. In this meeting, the Recipient shall present a program management plan and financial tracking plan. The Recipient shall provide, ahead of time, presentation materials for the meeting.

5.2 MONTHLY FINANCIAL REPORTS

The Recipient shall provide monthly financial progress reports. The purpose of these reports is to provide a brief on project progress and inform DARPA of any potential issues. The Monthly Financial

report shall be delivered no later than the 15th day of the month, covering costs through the end of the previous month, using the Enclosure (1) template.

5.3 DELETED

5.4 MONTHLY TECHNICAL REPORTS

The Recipient shall provide monthly technical update reports to and hold teleconferences with DARPA. The purpose of these monthly technical updates is to present a summary of work completed and milestones met; discuss any problems encountered; update the program schedule; present the program financial status; and discuss remaining work regarding technical tasks, data sharing, and ELSI activities. Monthly updates shall also include all technical data items generated under this funding including but not limited to experimental data; processed data, along with methods of processing used; research reports and publications; and software (source code and executables). A recommended format will be provided by the Program Manager.

5.5 QUARTERLY TECHNICAL REPORTS

The Recipient shall provide detailed technical quarterly progress reports. The purpose of these reports is to present a summary of work completed and milestones met; discuss any problems encountered; update the program schedule; present the program financial status; and discuss remaining work regarding technical tasks, data sharing, and ELSI activities. Quarterly reports shall also include all technical data items generated under this funding including but not limited to experimental data; processed data, along with methods of processing used; research reports and publications; and software (source code and executables). The report shall be submitted using the Enclosure (2) template.

5.6 ANNUAL PI MEETING

The Recipient shall participate in annual meetings with all Principal Investigators of the Safe Genes Program. In this meeting, the Recipient shall present a summary report of all work completed and milestones accomplished, present a program management plan and financial tracking plan. The Recipient shall provide, ahead of time, presentation materials for the meeting.

5.7 ANNUAL SITE VISITS

The Recipient shall host annual site visits of the AOR and the DARPA Program Manager. The purpose of this visit is to present a summary report of all work completed and milestones accomplished and to discuss ongoing or future technical tasks, data sharing, and ELSI activities

5.8 FINAL COOPERATIVE AGREEMENT REVIEW AND TECHNICAL REPORT

The Recipient shall host a final program review and provide a Final Technical Report. The purpose of this review and the report is to present a summary of all work completed and milestones accomplished and to discuss any relevant and/or related future efforts which may be pursued.

5.9 FINAL FINANCIAL STATUS REPORT

The report shall be submitted on a Standard Form 425 "Federal Financial Report (FFR)".

6.0 SECURITY

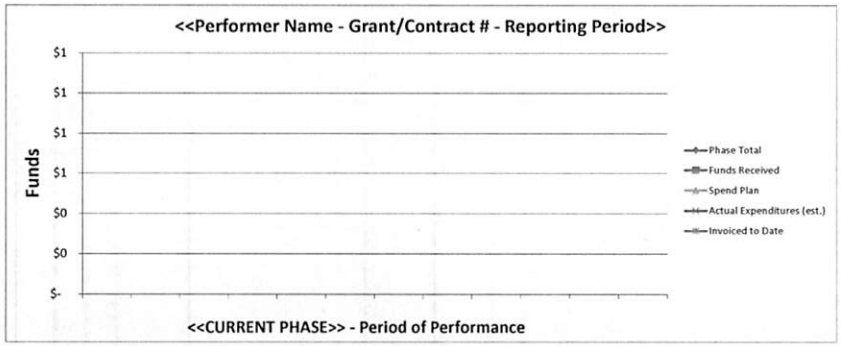
This work is unclassified.

Enclosures

(1) Monthly Financial Status Template
(2) Quarterly Technical Report

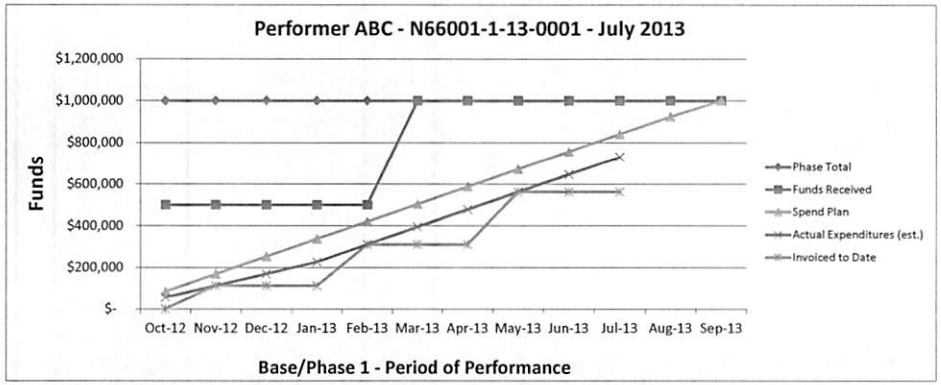
LINK TO TEMPLATE (click here)	
Please use this template to provide monthly financial updates to the DARPA Program team. As you input your data, the graph will automatically update. ***Please keep past reports in this file and create a new tab each month. We want to see all reports in the same file. Title tabs "Phase-Month-Year, " e.g., "Base - January - 2015"***	
LINK TO EXAMPLE (click here)	
An example of a completed template is also provided. The example graph illustrates a scenario where the performer is under spending. It is designed to show how this template will make it easy for Program Performers to clearly communicate the status of their effort to DARPA so that both can plan for and initiate contractual actions quickly and effectively.	
Spend Plan Data	
Period of Performance	The financial report will only cover the current phase (e.g., Base, Option 1, etc.). Use a format similar to "Sep-2013," not "Month 6." In order to plan for continuing resolution requests, DARPA may reach out to you separately to request your projected spend rate for future phases.
Phase Total	Total for current phase *(Example Graph - total is $1,000,000)* .
Funds Received	Funds awarded to date; most efforts are funded incrementally *(Example Graph - this effort received an increment for $500,000 in Oct-2012 to exercise the base, and received the remainder of their base period funding in Mar-2013 (remaining $500,000))* .
Spend Plan	Projected Expenditures must cover the entire phase.
Actual Expenditures (est.)	Actual Expenditures should not be solely based off of invoices you have submitted or received to date. Instead, it should be an accurate (to the extent that is possible) account of the expenses you have actually incurred to date. For example, if a subcontractor has incurred but hasn't invoiced $100,000 worth of work, include the $100,000 in your actual expenditures. Or a large amount of equipment valued at $50,000 that hasn't yet been invoiced should also be factored in to the actual expenditures.
Invoiced to Date	Report the invoices you have submitted to date *(Example Graph - the scenario used in the example graph submits invoices quarterly)* .
Issues/Updates Summary (if applicable)	
Use this section as an opportunity to bring issues, concerns, or updates to the attention of DARPA. For example, you can summarize reasons for over/under-spending, potential no-cost extension requests, invoicing problems, etc.	

EXHIBIT B - ENCLOSURE (1)



Spend Plan Data												
Period of Performance (Current Phase Only)												
Phase Total												
Funds Received												
Spend Plan												
Actual Expenditures (est.)												
Invoiced to Date												

Issues/Updates Summary (if applicable)



Spend Plan Data												
Period of Performance (Current Phase Only)	Oct-12	Nov-12	Dec-12	Jan-13	Feb-13	Mar-13	Apr-13	May-13	Jun-13	Jul-13	Aug-13	Sep-13
Phase Total	$ 1,000,000	$ 1,000,000	$ 1,000,000	$ 1,000,000	$ 1,000,000	$ 1,000,000	$ 1,000,000	$ 1,000,000	$ 1,000,000	$ 1,000,000	$ 1,000,000	$ 1,000,000
Funds Received	$ 500,000	$ 500,000	$ 500,000	$ 500,000	$ 500,000	$ 1,000,000	$ 1,000,000	$ 1,000,000	$ 1,000,000	$ 1,000,000	$ 1,000,000	$ 1,000,000
Spend Plan	$ 84,000	$ 168,000	$ 252,000	$ 336,000	$ 420,000	$ 504,000	$ 588,000	$ 672,000	$ 756,000	$ 840,000	$ 924,000	$ 1,000,000
Actual Expenditures (est.)	$ 56,500	$ 113,000	$ 169,550	$ 226,100	$ 310,100	$ 394,100	$ 478,100	$ 562,100	$ 646,100	$ 730,100		
Invoiced to Date	$ -	$ 113,000	$ 113,000	$ 113,000	$ 310,100	$ 310,100	$ 310,100	$ 562,100	$ 562,100	$ 562,100		

Issues/Updates Summary (if applicable)

We anticipate that we will need to request a four-month no cost extension (NCE). The NCE is necessary due to delays we experienced while getting Subcontractor #1 under contract. Although our effort's period of performance began in October 2012, the subcontract was finalized and fully-executed in February 2013, which resulted in a four-month delay from the intended start date. Subcontractor #1 is conducting a 12-month study, and cannot speed up their experiments. We would, however, like to begin work on Option 1. We intend to perform these tasks in parallel to the extended Base Period tasks (which are primarily performed by Subcontractor #1).

[Name of Prime Institution]
Quarterly Progress Report

Period Covered by the Report: [Date] through [Date]

Date of Report:

Project Title:
Contract Number:
Total Dollar Value:
Subcontractors:
Program Manager: Dr. Renee Wegrzyn, Defense Advanced Research Projects Agency, Biological Technologies Office

Submitted by:

[Name]
[Address]

Telephone:
Email:

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TABLE OF CONTENTS

1 High-Level Project Progress 4
1.1 Big Wins 4
1.2 Go/no-go Progress 4
2 Schedule – Milestones and Deliverables 5
3 Task Progress, Accomplishments, and Plans 7
4 Project Coordination, Dissemination, and Translation Efforts 9
5 Publications and Presentations 10
6 **Patents, Inventions, Disclosures** 11
Appendix I – Project Context 12

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Global Information:

- **Please do NOT wait until submitting a report to let us know if you are having a financial OR technical issue!**
- Clearly indicate if funding from another federal agency (e.g., NIH) has been used to support anything presented
- Clearly indicate if any content on it is pre-publication sensitive. Material that is not sensitive could be presented or shared by the Program Manger with the public
- Delete all instructional text from this document before submitting your report
- Support your claims with data, images, or videos in this document
- Please always update the header of this document with the period the report covers
- Name your files the following way: QR - Team Name – Month/Year Due (e.g., QR – Univ XYZ – Sep 2017)
- Due Months: June, September, December, March
- Quarterly teleconference calls will be scheduled with the Program Manager and his team

Definitions (as DARPA defines them):

- Functional block diagram: describes the functions and interrelationships of a system in a flock-block diagram style so that one can easily and thoroughly understand the system and the relationship of each of the parts to the whole. If the hardware evolves throughout your project, please provide a block diagram for each evolution (example included).
- Work-breakdown Structure (WBS): a hierarchical and incremental decomposition of the project into phases, deliverables and work packages. It is a tree structure, which shows a subdivision of effort required to achieve an objective (example included).
- Deliverable: a deliverable is a measurable and verifiable outcome or object that a project team must create and deliver according to the terms of an agreement. An intangible deliverable is a particular outcome that the team achieves. A tangible deliverable is a concrete or material object created by the team.
- Milestone: a milestone describes the status of the project as represented by an event or moment at which one or more project activities are complete. Milestones can represent the completion of key project tasks, conclusions reached, or questions answered that affect the project schedule in a major way.
- Big-win: a significant accomplishment
- Go/no-go criteria: a simple "pass-fail" way of viewing accomplishments; accomplishments that are essential for the continuation of your effort.
- SETA: Science, Engineering, and Technical Assistant (internal DARPA term for technical support staff)

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1 High-Level Project Progress

1.1 Big Wins

Briefly describe the most significant and salient accomplishment(s) that you have achieved during this ***most recent quarter***. How has this compared to your original project plan?

1.2 Go/no-go Progress

Accomplishment *Why is this significant? ID TA.*	**Month** *From Kick-off Presentation*	**Update** *What is the current status? Explain any discrepancies (behind/ahead of schedule). What is the next step?*

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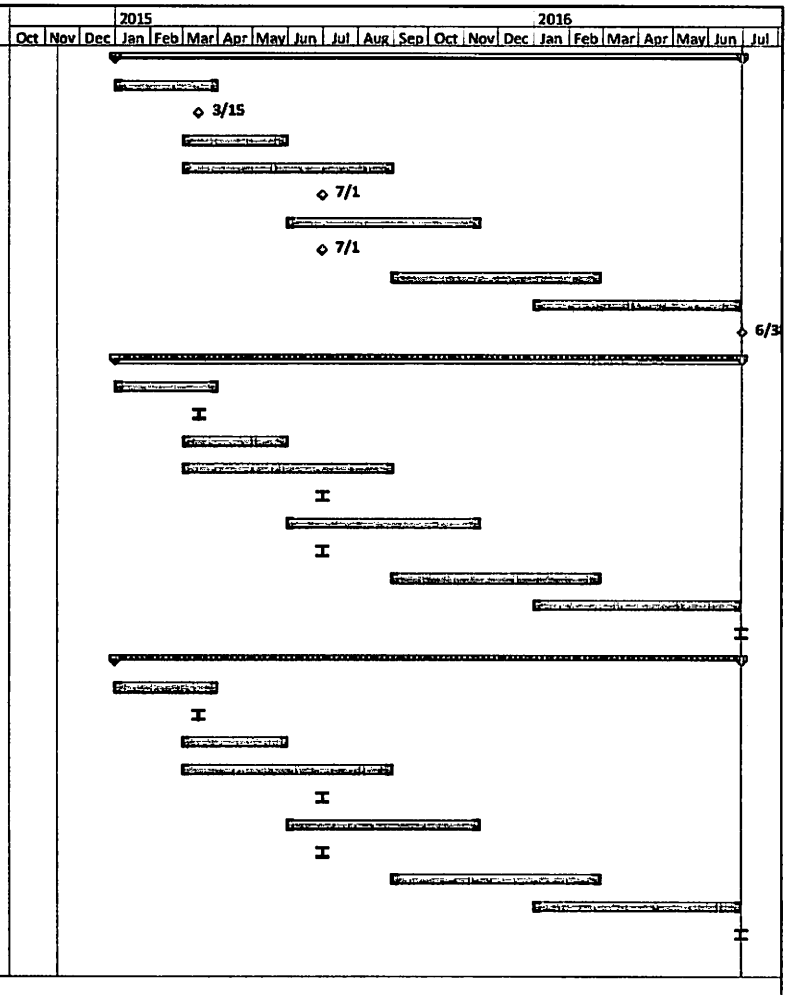
2 Schedule – Milestones and Deliverables

Include a readable high-level Gantt chart for Phase I that lists the major milestones and deliverables for each task (example included below). Use the month and year to label your chart (e.g., Mar-15), not the quarter or month (e.g., Quarter 2, Month 1). Below is an example of an acceptable chart.

ID	Task Mode	Task Name	Duration	Start	Finish	Predecessors
1		Task	391 days	Thu 1/1/15	Thu 6/30/16	
2		Subtask	64 days	Thu 1/1/15	Tue 3/31/15	
3		MS	0 days	Sun 3/15/15	Sun 3/15/15	
4		Subtask	67 days	Sun 3/1/15	Sun 5/31/15	
5		Subtask	132 days	Sun 3/1/15	Mon 8/31/15	
6		MS	0 days	Wed 7/1/15	Wed 7/1/15	
7		Subtask	122 days	Sun 5/31/15	Sun 11/15/15	
8		MS	0 days	Wed 7/1/15	Wed 7/1/15	
9		Subtask	132 days	Sun 8/30/15	Sun 2/28/16	
10		Subtask	130 days	Fri 1/1/16	Thu 6/30/16	
11		MS	0 days	Thu 6/30/16	Thu 6/30/16	
12		Task	391 days	Thu 1/1/15	Thu 6/30/16	
13		Subtask	64 days	Thu 1/1/15	Tue 3/31/15	
14		MS	1 day	Sun 3/15/15	Sun 3/15/15	
15		Subtask	67 days	Sun 3/1/15	Sun 5/31/15	
16		Subtask	132 days	Sun 3/1/15	Mon 8/31/15	
17		MS	1 day	Wed 7/1/15	Wed 7/1/15	
18		Subtask	122 days	Sun 5/31/15	Sun 11/15/15	
19		MS	1 day	Wed 7/1/15	Wed 7/1/15	
20		Subtask	132 days	Sun 8/30/15	Sun 2/28/16	
21		Subtask	130 days	Fri 1/1/16	Thu 6/30/16	
22		MS	1 day	Thu 6/30/16	Thu 6/30/16	
23		Task	391 days?	Thu 1/1/15	Thu 6/30/16	
24		Subtask	64 days	Thu 1/1/15	Tue 3/31/15	
25		MS	1 day	Sun 3/15/15	Sun 3/15/15	
26		Subtask	67 days	Sun 3/1/15	Sun 5/31/15	
27		Subtask	132 days	Sun 3/1/15	Mon 8/31/15	
28		MS	1 day	Wed 7/1/15	Wed 7/1/15	
29		Subtask	122 days	Sun 5/31/15	Sun 11/15/15	
30		MS	1 day	Wed 7/1/15	Wed 7/1/15	
31		Subtask	132 days	Sun 8/30/15	Sun 2/28/16	
32		Subtask	130 days	Fri 1/1/16	Thu 6/30/16	
33		MS	1 day	Thu 6/30/16	Thu 6/30/16	
34						



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Include a corresponding table that lists the following:

- Short text-identifier for each milestone and deliverable
- Status (on schedule, behind schedule, ahead of schedule, complete)
- If behind or ahead of schedule, explain why

Milestone/ Deliverable Description	**Responsible team members**	**Start Date**	**Due Date**	**Actual State Date**	**Actual End Date**	**Status**	**Dependencies** *Across tasks and teams(if applicable)*

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3 Task Progress, Accomplishments, and Plans

*The Program Manager wants to receive this information in a **well-organized** and **systematic** manner. He only wants updates from your **most recent quarter**, not a cumulative discussion of your project's progress to date. Back up all your claims with actual data. Highlight accomplishments to date that:*

- *The Program Manager can show his leadership to protect your program from being cut when cut directives are passed down from above*
- *Motivate funding extension and expansion of existing or follow-on programs*
- *Understand deviations from negotiated schedule and spending plan*

These reports are an opportunity to garner support from DARPA.

Identify the following for each major task in your SOW (i.e., Task 1, Task 2, Task 3, etc.); this section will form the bulk of your report:

- Task ID number mapped with SOW and TA that it supports (in example table below)
- Basic high-level description of the task (in example table below)
- Funding associated with the task (spent to date vs. remaining to spend); explain any deviations from your original spend plan (in example table below)

Task #/Title	Brief Description	% Complete	Total for Task	Total Spent	Remaining to Spend	Explain Deviations between Planned vs. Actual Expenditures

- **Describe your expected vs. actual progress towards the goals, milestones, and deliverables of the task; discuss why you have met expectations, why you didn't meet expectations, or why you have exceeded expectations; highlight significant accomplishments**
- Next steps (projected vs. actual)
- Support your claims with data, images, or videos
- Identify and describe all significant challenges and risks encountered during work towards the goals of this task
    - Identify critical dependencies across tasks and teams

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- Describe your mitigation plan
- Characterize the level of risk (high, medium, or low)
- Explain if the risk has changed since your proposal or last report
- When will you resolve the risk?

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4 Project Coordination, Dissemination, and Translation Efforts

4.1 Project Coordination

- Describe the steps you have taken to coordinate your team during this most recent quarter.
- Summarize key meetings for project planning and coordination, provide the following:
  - Meeting name, location, dates
  - Who attended from your team?
  - What was the general purpose?
  - What were the meaningful outputs?

4.2 Dissemination and Translation (if applicable)

- Include mention of any new partnerships, collaborators, users, etc. that directly resulted due to outcomes from this DARPA-supported effort
- Describe any possible consumers and commercialization pathways/partners for the results from your research

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5 Publications and Presentations

Please update the table below with any current or upcoming publications. This section will be cumulative for your effort, keep this information for all future reports.

Title, Authors	Description/Type	Status
	Presentation to Conference Name	Published
	Paper, Name of Journal	Under Review by Journal
	Letter to the Editor, Scientific Organization	In preparation

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6 Patents, Invention Disclosures, IDEs, etc...

Please update the table below with any current or upcoming patents, inventions, Investigational Device Exemption (IDE), etc... This information will be held strictly confidential. It will be cumulative for your effort, keep this information for all future reports.

Title, Authors	Description/Type	Status
	E.g. Patent; Name of Patent	Accepted
	E.g. FDA IDE	Filed/submitted
	Invention Disclosure	Preparing now

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Appendix I – Project Context

For future reports, only update this section if any information changes, indicate any changes with blue text.

Teaming and Personnel

Organizational Chart

Insert an organizational chart for your entire team

Contact Information

For each member of your team (i.e., prime and subcontractors) fill out the table of the following page to provide information about their key personnel. The short descriptive "topic" under the Role column identified for each role should correspond to the general area of expertise they will be providing. The longer descriptive "major role" column should describe the work they will be doing on the tasks and subtasks they are assigned to.

Prime Team Members and Contact Information: [Name]

Role	Full Name	Contact Information (phone and email)	Major Role(s)
PI	Name	XXX@univ.edu (888) 888-8888	
Co-I (topic)	Name	XXX@univ.edu (888) 888-8888	
Postdoc (topic)	Name	XXX@univ.edu (888) 888-8888	

Subcontract Team Members and Contact Information: [Name]

Role	Full Name	Contact Information (phone and email)	Major Role(s)
PI	Name	XXX@univ.edu (888) 888-8888	
Co-I (topic)	Name	XXX@univ.edu (888) 888-8888	
Postdoc (topic)	Name	XXX@univ.edu (888) 888-8888	

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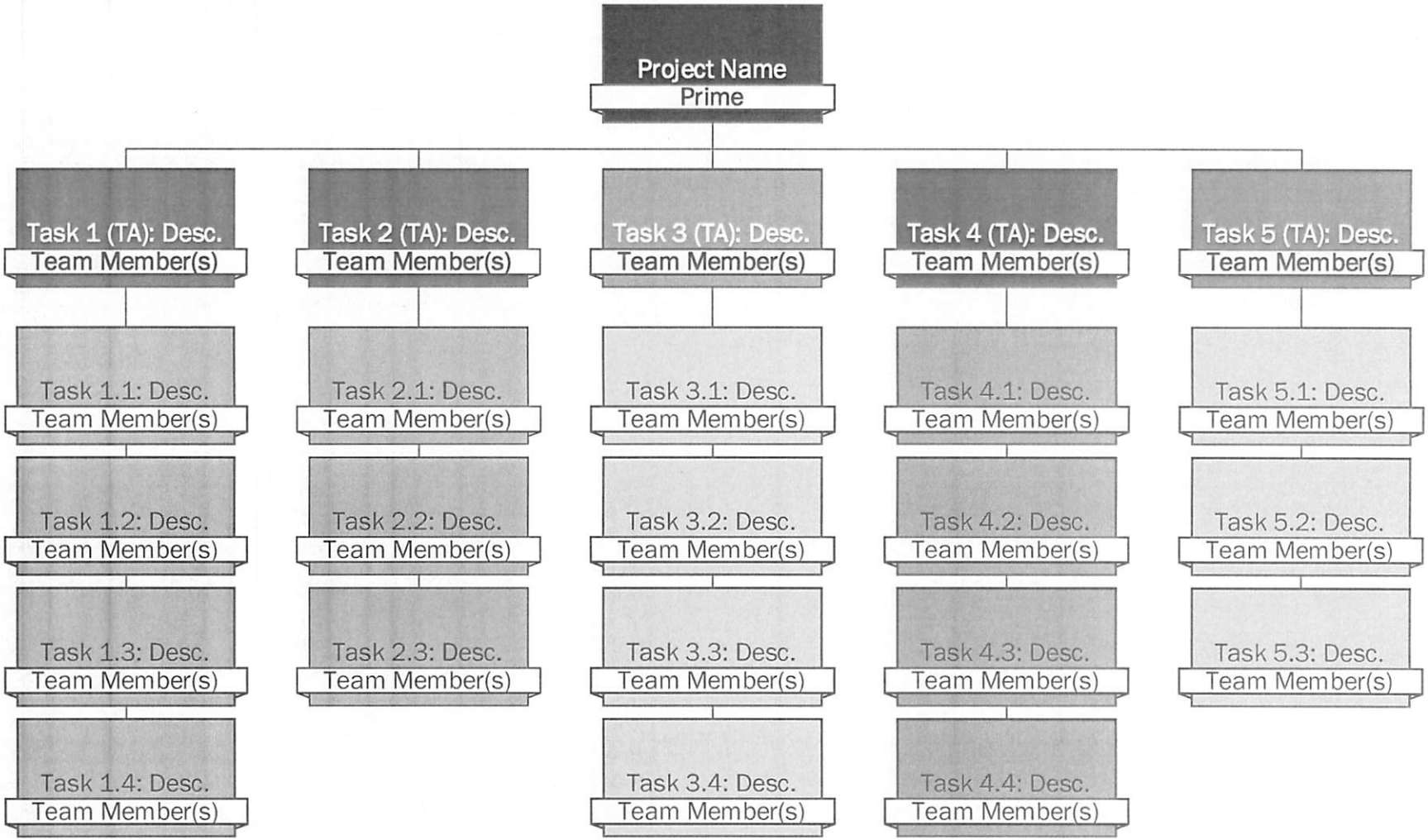
Work Breakdown Structure

Provide a WBS-style breakdown of your tasking and assign team members to each (example included below).



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DEFENSE ADVANCED RESEARCH PROJECTS AGENCY
675 NORTH RANDOLPH STREET
ARLINGTON, VA 22203-2114

Ernest Arias
Code 71750
SPAWARSYSCEN PACIFIC
53560 Hull Street
San Diego, CA 92152

SUBJECT: Appointment as Agreements Officer's Representative (AOR)

1. You are hereby appointed as the Agreements Officer's Representative for:

   Agreement Number: HR00111720046
   Recipient: North Carolina State University
   Program Description: Restoring Ecosystems and Biodiversity through Development of Safe and Effective Gene Drive Technologies

2. This appointment authorizes and designates you to perform the following duties and/or responsibilities as specified herein:

   a. Furnish plans, schedules, specifications, descriptions, and other documents to the recipient as required by the agreement.

   b. Assist the recipient in interpreting technical aspects of the agreement specifications/statement of work. Differences of opinion and interpretations which could affect the terms and conditions of the agreement will be referred to the Agreements Officer for resolution.

   c. Provide Government recommendations/approvals to the recipient promptly in all cases where the agreement calls for technical approval.

   d. Observe, monitor, and assess the recipient's performance under the terms of the agreement. This includes reporting promptly to the Agreements Officer any failures, delays, or significant deviations of performance, quality, costs, or other actions which might jeopardize agreement performance.

3. In the performance of the duties delegated to you in this letter, you are cautioned that you could be held personally liable for actions taken or directions given by you to the recipient that are beyond the authorities given to you in this letter. The duties or authorities in this letter are not delegable; therefore, you must advise the Agreements Officer or the Administrative Agreements Officer immediately when you are unable to perform these duties.

4. In your dealings with the recipient you must not give technical direction as though the recipient's employees are Government employees. You must maintain a formal, arms-length relationship with the recipient in order to avoid even an appearance that the agreement is one

for personal services. If the recipient's performance takes place in a Government facility, then to the maximum extent practicable, the recipient's work area should be physically separated from areas in which Government employees work, and communication with the recipient's employees on agreement matters should be only through that recipient employee(s) designated by the recipient to supervise them. You must not give any direction to the recipient that is not authorized by the statement of work because it is not the intent of the Government that a recipient be required to do anything that is not included in the agreement.

5. You are responsible for providing prompt notification to the Agreements Officer any significant deficiencies with respect to recipient performance or other actions which might jeopardize agreement performance.

6. You are not authorized by this letter to take any action, either directly or indirectly, that could result in a change in the pricing, quantity, quality, place of performance, delivery schedule or any other terms and conditions of the basic agreement, or to direct the accomplishment of effort which would exceed the scope of the basic agreement. You must be especially cautious in providing interpretation of the specifications/ statement of work. The agreement reached or technical direction given must be formalized in writing with copies to the Agreements Officer. You shall also notify the recipient that if he believes that the AOR's interpretation is erroneous, the recipient must notify the Agreements Officer in writing concerning the details of his position.

7. You may be held personally liable for unauthorized acts.

8. Specific duties in addition to those above are as follows:

    a. Control all government technical interfaces with the recipient.

    b. Ensure that copies of government technical correspondence are forwarded to the Agreements Officer for placement in the agreement file.

    c. Promptly furnish documentation on any requests for change, deviation, or waiver (whether generated by the Government or the recipient) to the Agreements Officer for appropriate action.

    d. Provide required review of Patent/Invention Disclosures made in I-Edison (http://www.iedison.gov).

    e. The AOR must maintain a separate file for each agreement for which he/she acts as AOR. The file should serve as a repository and record of all documents and communications between the recipient and the AOR. At a minimum, the file must include a copy of the agreement and all modifications as well as the AOR appointment letter. Examples of other file documentation may include:

    - Reports required per the agreement, e.g. interim and final technical or patent reports

- Memoranda for Record documenting important agreement discussions
- Records of formal meetings, e.g. post award conference, program reviews, etc.

f. Assist Administrative Agreements Officer and/or Agreements Officer, as requested, with closeout activities at completion of agreement period of performance.

9. You appointment as AOR for this effort expires at completion of agreement closeout activities.

10. Your good judgment in performing your duties under the agreement will have an important effect on the value of the performance obtained by the Government.

Susan K. Shean
Agreements Officer
DARPA

4-17-17
Date

ARIAS.ERNEST.1231722560
Digitally signed by ARIAS.ERNEST.1231722560
DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USN, cn=ARIAS.ERNEST.1231722560
Date: 2017.04.13 10:59:59 -07'00'

Ernest Arias
Agreements Officer's Representative
SPAWARSYSCEN PACIFIC

April 13, 2017
Date

252.227-7017 IDENTIFICATION AND ASSERTION OF USE, RELEASE, OR DISCLOSURE RESTRICTIONS (JAN 2011)

(a) The terms used in this provision are defined in following clause or clauses contained in this solicitation—

(1) If a successful offeror will be required to deliver technical data, the Rights in Technical Data--Noncommercial Items clause, or, if this solicitation contemplates a contract under the Small Business Innovation Research Program, the Rights in Noncommercial Technical Data and Computer Software--Small Business Innovation Research (SBIR) Program clause.

(2) If a successful offeror will not be required to deliver technical data, the Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation clause, or, if this solicitation contemplates a contract under the Small Business Innovation Research Program, the Rights in Noncommercial Technical Data and Computer Software – Small Business Innovation Research (SBIR) Program clause.

(b) The identification and assertion requirements in this provision apply only to technical data, including computer software documentation, or computer software to be delivered with other than unlimited rights. For contracts to be awarded under the Small Business Innovation Research Program, the notification and identification requirements do not apply to technical data or computer software that will be generated under the resulting contract. Notification and identification is not required for restrictions based solely on copyright.

(c) Offers submitted in response to this solicitation shall identify, to the extent known at the time an offer is submitted to the Government, the technical data or computer software that the Offeror, its subcontractors or suppliers, or potential subcontractors or suppliers, assert should be furnished to the Government with restrictions on use, release, or disclosure.

(d) The Offeror's assertions, including the assertions of its subcontractors or suppliers or potential subcontractors or suppliers, shall be submitted as an attachment to its offer in the following format, dated and signed by an official authorized to contractually obligate the Offeror:

Identification and Assertion of Restrictions on the Government's Use, Release, or Disclosure of Technical Data or Computer Software.

The Offeror asserts for itself, or the persons identified below, that the Government's rights to use, release, or disclose the following technical data or computer software should be restricted:

Technical Data or Computer Software to be Furnished With Restrictions*	Basis for Assertion**	Asserted Rights Category***	Name of Person Asserting Restrictions****
None	(LIST)	(LIST)	(LIST)

*For technical data (other than computer software documentation) pertaining to items, components, or processes developed at private expense, identify both the deliverable technical data and each such item, component, or process. For computer software or computer software documentation identify the software or documentation.

**Generally, development at private expense, either exclusively or partially, is the only basis for asserting restrictions. For technical data, other than computer software documentation, development refers to development of the item, component, or process to which the data pertain. The Government's rights in computer software documentation generally may not be restricted. For computer software, development refers to the software. Indicate whether development was accomplished exclusively or partially at private expense. If development was not accomplished at private expense, or for computer software documentation, enter the specific basis for asserting restrictions.

***Enter asserted rights category (e.g., government purpose license rights from a prior contract, rights in SBIR data generated under another contract, limited, restricted, or government purpose rights under this or a prior contract, or specially negotiated licenses).

****Corporation, individual, or other person, as appropriate.

*****Enter "none" when all data or software will be submitted without restrictions.

Date	4-14-2017
Printed Name and Title	Sherrie E. Settle Director Sponsored Programs NC State University
Signature	Sherrie E. Settle

(End of identification and assertion)

(e) An offeror's failure to submit, complete, or sign the notification and identification required by paragraph (d) of this provision with its offer may render the offer ineligible for award.

(f) If the Offeror is awarded a contract, the assertions identified in paragraph (d) of this provision shall be listed in an attachment to that contract. Upon request by the Contracting Officer, the Offeror shall provide sufficient information to enable the Contracting Officer to evaluate any listed assertion.

(End of provision)

252.227-7028 TECHNICAL DATA OR COMPUTER SOFTWARE PREVIOUSLY DELIVERED TO THE GOVERNMENT (JUN 1995)

The Offeror shall attach to its offer an identification of all documents or other media incorporating technical data or computer software it intends to deliver under this contract with other than unlimited rights that are identical or substantially similar to documents or other media that the Offeror has produced for, delivered to, or is obligated to deliver to the Government under any contract or subcontract. The attachment shall identify--

(a) The contract number under which the data or software were produced;

(b) The contract number under which, and the name and address of the organization to whom, the data or software were most recently delivered or will be delivered; and

(c) Any limitations on the Government's rights to use or disclose the data or software, including, when applicable, identification of the earliest date the limitations expire.

(End of clause)

[ ] Attachment submitted

[X] No Attachment required

R&D General Terms and Conditions
JUL 2016

Preamble

Applicability

This award is subject to the following DoD Research and Development general terms and conditions. These general terms and conditions do not apply to direct awards made to for-profit entities or foreign organizations/foreign public entities. However, these terms and conditions do apply to subawards made to for-profit entities and certain requirements, as specified, apply to foreign organizations or foreign public entities.

These general DoD Research and Development terms and conditions implement Office of Management and Budget (OMB) guidance, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," published in the Code of Federal Regulations (CFR) at 2 CFR part 200 and implemented by the Department of Defense (DoD) at 2 CFR part 1103, "Interim Grants and Cooperative Agreements Implementation of Guidance in 2 CFR part 200" (79 FR 76047, December 19, 2014).

Order of Precedence

Any inconsistencies in the requirements of this award shall be resolved in the following order:

a. Federal statutes
b. Federal regulations
c. 2 CFR part 200*, as modified and supplemented by DoD's interim implementation found in 2 CFR part 1103
d. Award-specific terms and conditions
e. R & D General Terms and Conditions

In case of disagreement with any requirements of this award, the recipient shall contact the grants officer in order to resolve the issue. Note, however, that performance under this award constitutes acceptance of the award including the terms and conditions.

As recipients gain operating experience with these general terms and conditions, we may find areas requiring clarification or correction. Your alerting us to potential issues therefore will help us improve both these general terms and conditions and DoD's regulatory implementation of the OMB guidance at 2 CFR part 200.

*Note that OMB amended 2 CFR 200.110(a) on September 10, 2015, to permit recipients to continue to comply with the procurement standards in previously applicable OMB guidance, rather than the procurement standards in 2 CFR 200.317-200.326, through the end of the two recipient fiscal years that begin on or after December 26, 2014. DoD implemented those previous procurement standards in DoDGARS part 32 (32 CFR part 32) for institutions of higher education, hospitals and other nonprofit organizations and in DoDGARs part 33 (32 CFR part 33) for States and local and Indian tribal governments. If you choose to use those previous procurement standards, rather than the standards in PROC Articles I and II of these R & D General Terms and Conditions, you must document that decision in your internal procurement policies.

TABLE OF CONTENTS

Part 1: Definitions 1

Section A. Purpose of this part 1

Section B. Precedence of definitions of terms in national policy requirements 1

Section C. Definitions of terms used in the Government wide cost principles or single audit requirements. 1

Section D. Definitions. 1

Part 2: Financial And Program Management 20

FMS Article I. Financial Management System Standards. (JULY 2016) 20

Section A. System standard for States 20

Section B. System standards for all recipients 20

Section C. Internal controls 21

FMS Article II. Payments. (JULY 2016) 21

Section A. Awards to States 21

Section B. Awards to institutions of higher education, nonprofit organizations, local governments, and Indian tribes 22

Section C. Electronic funds transfer and other payment procedural instructions or information. 24

FMS Article III. Allowable costs, period of availability of funds, and fee and profit. (JULY 2016) 24

Section A. Allowable costs 24

Section B. Clarifications concerning charges of publication costs. RESERVED 26

Section C. Period of availability of funds 26

Section D. Fee or profit 26

FMS Article IV. Revision of budget and program plans. (JULY 2016) 26

Section A. Approved budget 26

Section B. Revisions requiring prior approval 27

Section C. Pre-award costs, carry forward of unobligated balances, and one-time no-cost extensions 28

Section D. Procedures 28

FMS Article V. Non-Federal audits. (JULY 2016) 28

Section A. Requirements for entities subject to the Single Audit Act 28

Section B. Requirements for for-profit entities 28

FMS Article VI. Cost sharing or matching. (JULY 2016) 29
Section A. Required cost sharing or matching. 29
Section B. Allowability as cost sharing or matching 29
Section C. Allowability of unrecovered indirect costs as cost sharing or matching 30
Section D. Allowability of program income as cost sharing or matching 30
Section E. Valuation of services or property that you or subrecipients contribute or donate 30
Section F. Valuation of third-party in-kind contributions. 31
FMS Article VII. Program income. (JULY 2016) 32
Section A. Definition 32
Section B. Encouragement to earn program income 33
Section C. Costs of generating program income 33
Section D. License fees and royalties 33
Section E. Use of program income 33
Section F. Duration of accountability for program income 34
Part 3: Property Administration 35
PROP Article I. Title to Property. (JULY 2016) 35
Section A. Title to property acquired under this award. 35
Section B. Property trust relationship 35
Section C. Federally owned property 36
Section D. Federal interest in donated real property or equipment. 36
Section E. Federal interest in property improved under the award 36
PROP Article II. Property Management System. (JULY 2016) 37
Section A. Insurance coverage for real property and equipment 37
Section B. Other management system standards for a State 37
Section C. Other management system standards for an institution of higher education, nonprofit organization, local government, or Indian tribe 38
PROP Article III. Use and disposition of real property. (JULY 2016) 39
Section A. Use of real property 39
Section B. Disposition of real property 39
PROP Article IV. Use and disposition of equipment and supplies. (JULY 2016) 39
Section A. Property subject to this article 40
Section B. Requirements for a State's use and disposition of equipment 40

Section C. Use of equipment by an institution of higher education, nonprofit organization, local government, or Indian tribe.....41
Section D. Disposition of equipment by an institution of higher education, nonprofit organization, local government, or Indian tribe.....41
Section E. Use and disposition of supplies acquired under this award.....42
PROP Article V. Use and disposition of federally owned property. (July 2016).....42
Section A. Use.....42
Section B. Disposition.....43
PROP Article VI. Intangible property. (JULY 2016).....43
Section A. Assertion of copyright.....43
Section B. Inventions developed under the award.....43
Section C. Data produced under the award.....44
Section D. Use and disposition of intangible property acquired, but not developed or produced, under the award.....45
Part 4: Procurement.....46
PROC Article I. Procurement Standards for States. (JULY 2016).....46
Section A. Use of State procurement system.....46
Section B. Procurement of recovered materials.....46
Section C. Debarment and suspension.....46
Section D. Contract provisions.....46
PROC Article II. Procurement Standards for an Institution of Higher Education, Nonprofit Organization, Local Government, or Indian Tribe. (JULY 2016).....46
Section A. General procurement standards.....46
Section B. Competition.....47
Section C. Procurement methods.....47
Section D. Contracting with small and minority businesses, women's business enterprises, and labor surplus area firms.....47
Section E. Contract cost and price.....48
Section F. Contract provisions.....48
Section G. Procurement of recovered materials.....48
Section H. Review of procurement documents.....48
Section I. Bonding requirements. – RESERVED.....48
PROC Article III. Contract Provisions for Recipient Procurements. (JULY 2016).....48
Section A. Contract provisions for administrative requirements.....48

Section B. Contract provisions for national policy requirements 50
Part 5: Financial, Programmatic, and Property Reporting 53
REP Article I. Performance reporting. (JULY 2016) 53
Section A. Required reporting form, format, or data elements for interim and final performance reports. RESERVED. 53
Section B. Frequency, reporting periods, and due dates for interim performance reports. RESERVED 53
Section C. Due date and reporting period for final performance report. 53
Section D. Extensions of due dates. 53
Section E. Reporting significant developments 53
Section F. Performance reporting procedures. RESERVED 53
Section G. Site visits 53
REP Article II. Financial reporting. (JULY 2016JULY 2016) 53
Section A. Required reporting form, format, or data elements for interim and final financial reports. RESERVED 54
Section B. Interim financial reports: frequency, reporting periods, and due dates. RESERVED 54
Section C. Final financial report 54
Section D. Extensions of due dates 54
Section E. Where and how to submit financial reports. RESERVED 54
REP Article III. Reporting on property. (JULY 2016) 54
Section A. Real property 54
Section B. Equipment and supplies 55
Section C. Federally owned property. 55
Section D. Intangible property 56
REP Article IV. Reporting on subawards and executive compensation. (OCTOBER 2015) 56
Part 6: Other Administrative Requirements 57
OAR Article I. Submitting and maintaining recipient information. (JULY 2016) 57
Section A. System for Award Management 57
Section B. Reporting of Performance and Integrity Information. 57
Section C. Disclosure of evidence of integrity-related issues 59
OAR Article II. Records retention and access. (JULY 2016) 60
Section A. Records retention period 60
Section B. Extensions of retention period due to litigation, claim, or audit. 61

Section C. Records for program income earned after the end of the performance period 61
Section D. Records for joint or long-term use 61
Section E. Methods for collecting, transmitting, and storing information 62
Section F. Access to records 62
OAR Article III. Remedies and termination. (JULY 2016) 63
Section A. Remedies for noncompliance 63
Section B. Termination 64
Section C. Effects of suspension or termination of the award on allowability of costs 65
OAR Article IV. Claims, disputes and appeals. (JULY 2016) 65
Section A. Definitions 65
Section B. Submission of claims 66
Section C. Alternative dispute resolution 66
Section D. Grants officer decisions for claims you submit 66
Section E. Formal administrative appeals. 66
Section F. Representation 67
Section G. Non-exclusivity of remedies 67
OAR Article V. Collection of amounts due. (JULY 2016) 67
Section A. Establishing a debt 67
Section B. Debt delinquency and appeals 67
Section C. Demand letter, interest, and debt collection 68
OAR Article VI. Closeout. (JULY 2016) 68
Section A. Liquidation of obligations 68
Section B. Refunds of unobligated balances 68
Section C 68
Section D. Accounting for property 69
OAR Article VII. Post-closeout adjustments and continuing responsibilities. (JULY 2016) 69
Section B. Continuing responsibilities 69
Part 7: SUBAWARDS 70
SUB Article I. Distinguishing subawards and procurements. (JULY 2016) 70
Section A. Required recipient determination. 70
Section B. Considerations in making the determination 70
Section C. Effect of the determination on the next-tier transaction 70
SUB Article II. Pre-award and time of award responsibilities. (JULY 2016 71

Section A. Requirements for Unique Entity Identifiers. 71
Section B. Pre-award risk assessment 71
Section C. Subaward content 72
Section D. Subaward and executive compensation reporting 73
SUB Article III. Informational content of subawards. (JULY 2016) 73
Section A. Informational content in general 73
Section B. Federal award identification number and award date 73
Section C. Amount of Federal funds obligated 73
Section D. Total amount obligated to the subrecipient 74
Section E. Total Amount of the Federal Award 74
Section F. Federal awarding agency, pass-through entity, and awarding official 74
Section G. Indirect cost rate 74
SUB Article IV. Financial and program management requirements for subawards. (JULY 2016) 74
Section A. Purposes of this article in relation to other articles 74
Section B. Financial management standards 75
Section C. Payments 75
Section D. Allowable costs, period of availability of funds, and fee and profit. 76
Section E. Revision of budget and program plans 76
Section F. Non-Federal audits 77
Section G. Cost sharing or matching requirements 77
Section H. Program income 77
Section A. Purposes of this article in relation to other articles 78
Section B. Title to property 78
Section C. Property management system 79
Section D. Use and disposition of real property 80
Section E. Use and disposition of equipment and supplies 80
Section F. Use and disposition of federally owned property 81
Section G. Intangible property 81
SUB Article VI. Procurement procedures to include in subawards. (JULY 2016) 82
Section A. Purposes of this article in relation to other articles 82
Section B. Subaward to a State 82
Section C. Subaward to an institution of higher education, nonprofit organization, local government, or Indian Tribe 82

Section D. Subaward to a for-profit entity 82
SUB Article VII. Financial, programmatic, and property reporting requirements for subawards. (JULY 2016) 83
Section A. Purposes of this article in relation to other articles 83
Section B. Performance reporting 83
Section C. Financial reporting 83
Section D. Reporting on property 83
SUB Article VIII. Other administrative requirements for subawards. (JULY 2016) 84
Section A. Purposes of this article in relation to other articles 84
Section B. Maintenance of subrecipient information 84
Section C. Records retention and access 84
Section D. Remedies and termination 85
Section E. Disputes, hearings, and appeals 86
Section F. Collection of amounts due 86
Section G. Closeout 86
Section H. Post-closeout adjustments and continuing responsibilities 87
SUB Article IX. National policy requirements for subawards. (JULY 2016) 87
Section A. General 87
Section B. Nondiscrimination national policy requirements 87
Section C. Environmental national policy requirements 87
Section D. National policy requirements concerning live organisms 87
Section E. Other national policy requirements 88
SUB Article X. Subrecipient monitoring and related subaward administration. (JULY 2016) 88
Section A. General requirement for subrecipient monitoring 88
Section B. Subrecipient monitoring actions 88
Section C. Remedies and subaward suspension or termination 89
Section D. Subaward closeout 89
SUB Article XI. Requirements concerning subrecipients' lower-tier subawards. (JULY 2016) 90
Section A. Purpose 90
Section B. Requirements for lower-tier subawards 90
SUB Article XII. Fixed-amount subawards. (JULY 2016) 91
Section A. Limitations on use 91
Section B. Fixed-amount subawards that do not require prior approval 91

Section C. Informational content of fixed-amount subawards 93
Section D. Terms and conditions addressing administrative requirements 93
Section E. National policy requirements for fixed-amount subawards 95
Section F. Subrecipient monitoring and other post-award administration 95
Section G. Fixed-amount subawards at lower tiers 96
Part 8: National Policy Requirements 97
NP Article I. Nondiscrimination national policy requirements. (JULY 2016) 97
Section A. Cross-cutting nondiscrimination requirements. 97
Section B. Other nondiscrimination requirements. RESERVED 97
NP Article II. Environmental national policy requirements. (JULY 2016) 97
Section A. Cross-cutting environmental requirements 97
Section B. Other environmental requirements. RESERVED. 99
NP Article III. National policy requirements concerning live organisms. (JULY 2016) 99
Section A. Cross-cutting requirements concerning live organisms 99
Section B. Other requirements concerning live organisms. RESERVED 100
NP Article IV. Other national policy requirements. (JULY 2016) 101
Section A. Cross-cutting requirements. 101
Section B. Additional requirements. RESERVED. 104

Part 1: Definitions

Section A. Purpose of this part.

This part provides definitions of terms used in the General Terms and Conditions.

Section B. Precedence of definitions of terms in national policy requirements.

Some portions of this award may use a term in relation to compliance with a national policy requirement in a statute, Executive order, or other source that defines the term differently than it is defined in Section D of this part. For purposes of that particular national policy requirement, the definition of a term provided by the source of the requirement and any regulation specifically implementing it takes precedence over the definition in this part.

Section C. Definitions of terms used in the Government wide cost principles or single audit requirements.

This part includes the definition of a term used in any of the issuances listed in paragraph 1 of this section only if the General Terms and Conditions use that term directly. If the only usage is indirect—i.e., through an issuance incorporated by reference—then this part will not include a definition and a user of these terms and conditions should consult definitions in Subpart A of the OMB guidance in 2 CFR part 200 for terms used in Subparts E and F of that part.

Section D. Definitions.

1. Acquire.

Acquire means to:

a. When the term is used in connection with a DoD Component action at the prime tier, obtain property or services by purchase, lease, or barter for the direct benefit or use of the United States Government.

b. When the term is used in connection with a recipient or subrecipient action at a tier under a DoD Component's award:

(1) Purchase services;

(2) Obtain property under the award by:

(a) Purchase;

(b) Construction;

(c) Fabrication;

(d) Development

(e) The recipient or subrecipient entity's donation of the property to the project or program under the award to meet cost sharing or matching requirements (i.e., including within the entity's share of the award's project costs the value of the remaining life of the property or its fair market value, rather than charging depreciation); or

(f) Otherwise.

2. Acquisition.

Acquisition means the process of acquiring as described in:

a. Paragraph (a) of Section D.1 when used in connection with DoD Component actions at the prime tier.

b. Paragraph (b) of Section D.1 when used in connection with recipient or subrecipient actions at lower tiers under a DoD Component's award.

3. Acquisition cost.

Acquisition cost means the cost of an asset to a recipient or subrecipient, including the cost to ready the asset for its intended use.

a. For example, when used in conjunction with:

(1) The purchase of equipment, the term means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired.

(2) Equipment that a recipient or subrecipient constructs or fabricates—or software that it develops—under an award, the term includes, when capitalized in accordance with generally accepted accounting principles (GAAP):

(a) The construction and fabrication costs of that equipment; and

(b) The development costs of that software.

b. Ancillary charges, such as taxes, duty, protective in-transit insurance, freight, and installation may be included in, or excluded from, the acquisition cost in accordance with the recipient's or subrecipient's regular accounting practices.

4. Administrative offset.

Administrative offset means an action whereby money payable by the United States Government to, or held by the Government for; a recipient is withheld to satisfy a delinquent debt the recipient owes the Government.

5. Advance payment.

Advance payment means a payment that DoD or a recipient or subrecipient makes by any appropriate payment mechanism, including a predetermined payment schedule, before the recipient or subrecipient disburses the funds for project or program purposes.

6. Advanced research.

Advanced research means advanced technology development that creates new technology or demonstrates the viability of applying existing technology to new products and processes in a general way. Advanced research is most closely analogous to precompetitive technology development in the commercial sector (i.e., early phases of research and development on which commercial competitors are willing to collaborate, because the work is not so coupled to specific products and processes that the results of the work must be proprietary). It does not include development of military systems and hardware where specific requirements have been defined. It is typically funded in Advanced Technology Development (Budget Activity 3) programs within DoD's Research, Development, Test and Evaluation (RDT&E) appropriations.

7. Agreements officer.

Agreements officer means a DoD official with the authority to enter into, administer, and/or terminate Technology Investment Agreements.

8. Applied research.

Applied research means efforts that attempt to determine and exploit the potential of scientific discoveries or improvements in technology, such as new materials, devices, methods and processes. It typically is funded in Applied Research (Budget Activity 2) programs within DoD's Research, Development, Test and Evaluation (RDT&E) appropriations. Applied research often follows basic research but may not be fully distinguishable from the related basic research. The term does not include efforts whose principal aim is the design, development, or testing of specific products, systems or processes to be considered for sale or acquisition, efforts that are within the definition of "development."

9. Approved budget.

Approved budget means, in conjunction with a DoD Component award to a recipient, the most recent version of the budget the recipient submitted and the DoD Component approved (either at the time

of the initial award or subsequently), to summarize planned expenditures for the project or program under the award. It includes:

a. All Federal funding made available to the recipient under the award to use for project or program purposes.

b. Any cost sharing or matching that the recipient is required to provide under the award.

c. Any options that have been exercised but not any options that have not yet been exercised.

10. Assistance.

Assistance means the transfer of a thing of value to a recipient to carry out a public purpose of support or stimulation authorized by a law of the United States (see 31 U.S.C. 6101(3)). Grants, cooperative agreements, and technology investment agreements are examples of legal instruments that DoD Components use to provide assistance.

11. Award.

Award means a grant, cooperative agreement, technology investment agreement, or other nonprocurement instrument subject to one or more parts of the DoDGARs. Within each part of the regulations, the term includes only the types of instruments subject to that part.

12. Award administration office.

Award administration office means a DoD Component office that performs assigned post-award functions related to the administration of grants, cooperative agreements, technology investment agreements, or other nonprocurement instruments.

13. Basic research.

Basic research means efforts directed toward increasing knowledge and understanding in science and engineering, rather than the practical application of that knowledge and understanding. It typically is funded within Basic Research (Budget Activity 1) programs within DoD's Research, Development, Test and Evaluation (RDT&E) appropriations. Basic research includes:

a. Research-related, science and engineering education and training, including graduate fellowships and research traineeships; and

b. Research instrumentation and other activities designed to enhance the infrastructure for science and engineering research.

14. Capital asset.

Capital asset means a tangible or intangible asset used in operations having a useful life of more than one year which is capitalized in accordance with GAAP. Capital assets include:

a. Land, buildings (facilities), equipment, and intellectual property (including software) whether acquired by purchase, construction, manufacture, lease-purchase, exchange, or through capital leases; and

b. Additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations or alterations to capital assets that materially increase their value or useful life (not ordinary repairs and maintenance).

15. Claim.

Claim means a written demand or written assertion by one of the parties to an award seeking as a matter of right, the payment of money in a sum certain, the adjustment or interpretation of award terms, or other relief arising under or relating to the award. A routine request for payment that is not in dispute when submitted is not a claim. The submission may be converted to a claim by written notice to the grants officer if it is disputed either as to liability or amount, or is not acted upon in a reasonable time.

16. Cognizant agency for indirect costs.

Cognizant agency for indirect costs means the Federal agency responsible for reviewing, negotiating, and approving cost allocation plans and indirect cost proposals on behalf of all Federal agencies. The cognizant agency for indirect costs for a particular entity may be different than the cognizant agency for audit. The cognizant agency for indirect costs:

a. For an institution of higher education, nonprofit organization, State, or local government is assigned as described in the appendices to OMB guidance in 2 CFR part 200. See 2 CFR 200.19 for specific citations to those appendices.

b. For a for-profit entity, normally will be the agency with the largest dollar amount of pertinent business, as described in the Federal Acquisition Regulation at 48 CFR 42.003.

17. Contract.

Contract means a procurement transaction, as that term is defined in paragraph 53 of this part. A contract is a transaction into which a recipient or subrecipient enters. It is therefore distinct from the term "procurement contract," which is a transaction that a DoD Component awards at the prime tier.

18. Contracting activity.

Contracting activity means an activity to which the Head of a DoD Component has delegated broad authority regarding acquisition functions pursuant to 48 CFR 1.601.

19. Contractor.

Contractor means an entity to which a recipient or subrecipient awards a procurement transaction (also known as a contract).

20. Cooperative agreement

Cooperative agreement means a legal instrument which, consistent with 31 U.S.C. 6305, is used to enter into the same kind of relationship as a grant (see definition of "grant" in this part), except that substantial involvement is expected between the Department of Defense and the recipient when carrying out the activity contemplated by the cooperative agreement. The term does not include "cooperative research and development agreements" as defined in 15 U.S.C. 3710a.

21. Co-principal investigator.

Co-principal investigator means any one of a group of individuals whom an organization that is carrying out a research project with DoD support designates as sharing the authority and responsibility for leading and directing the research intellectually and logistically, other than the one among the group identified as the primary contact for scientific, technical, and related budgetary matters (see the definition of "principal investigator").

22. Cost allocation plan.

Cost allocation plan means either a:

a. Central service cost allocation plan, as defined at 2 CFR 200.9 and described in Appendix V to OMB guidance in 2 CFR part 200; or

b. Public assistance cost allocation plan as described in Appendix VI to 2 CFR part 200.

23. Cost sharing or matching.

Cost sharing or matching means the portion of project costs not borne by the Federal Government, unless a Federal statute authorizes use of any Federal funds for cost sharing or matching.

24. Cost-type contract.

Cost-type contract means a procurement transaction awarded by a recipient or a subrecipient at any tier under a DoD Component's grant or cooperative agreement that provides for the contractor to be paid on the basis of the actual, allowable costs it incurs (plus any fee or profit for which the contract provides).

25. Cost-type subaward.

Cost-type subaward means a subaward that:

a. A recipient or subrecipient makes to another entity at the next lower tier; and

b. Provides for payments to the entity that receives the cost-type subaward based on the actual, allowable costs it incurs in carrying out the subaward.

26. Debarment.

Debarment means an action taken by a Federal agency debarring official to exclude a person or entity from participating in covered Federal transactions, in accordance with debarment and suspension policies and procedures for:

a. Nonprocurement instruments, which are in OMB guidance at 2 CFR part 180, as implemented by the DoD at 2 CFR part 1125; or

b. Procurement contracts, which are in the Federal Acquisition Regulation at 48 CFR 9.4.

27. Debt.

Debt means any amount of money or any property owed to a Federal agency by any person, organization, or entity except another United States Federal agency. Debts include any amounts due from insured or guaranteed loans, fees, leases, rents, royalties, services, sales of real or personal property, or overpayments, penalties, damages, interest, fines and forfeitures, and all other claims and similar sources. For the purposes of this chapter, amounts due a non-appropriated fund instrumentality are not debts owed the United States.

28. Delinquent debt.

Delinquent debt means a debt:

a. That the debtor fails to pay by the date specified in the initial written notice from the agency owed the debt, normally within 30 calendar days, unless the debtor makes satisfactory payment arrangements with the agency by that date; and

b. With respect to which the debtor has elected not to exercise any available appeals or has exhausted all agency appeal processes.

29. Development.

Development means, when used in the context of "research and development," the systematic use of scientific and technical knowledge in the design, development, testing, or evaluation of potential new products, processes, or services to meet specific performance requirements or objectives. It includes the functions of design engineering, prototyping, and engineering testing. It typically is funded within

programs in Budget Activities 4 through 7 of DoD's Research, Development, Test and Evaluation (RDT&E) appropriations.

30. Direct costs.

Direct costs means any costs that are identified specifically with a particular final cost objective, such as an award, in accordance with the applicable cost principles.

31. DoD Components.

DoD Components means the Office of the Secretary of Defense; the Military Departments; the National Guard Bureau (NGB) and all Defense Agencies, DoD Field Activities, and other organizational entities within the DoD that are authorized to award or administer grants, cooperative agreements, and other non-procurement instruments.

32. Equipment.

Equipment means tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of:

a. $5,000; or

b. The recipient's or subrecipient's capitalization threshold for financial statement purposes.

33. Excepted property.

a. *Excepted property* means tangible personal property acquired in whole or in part with Federal funds under a DoD Component's awards, for which the DoD Component:

(1) Has statutory authority to vest title in recipients (or allow for vesting in subrecipients)without further obligation to the Federal Government or subject to conditions the DoD Component considers appropriate; and

(2) Elects to use that authority to do so.

b. An example of excepted property authority is contained in the Federal Grant and Cooperative Agreement Act (31 U.S.C. 6306) for tangible personal property acquired under an award to conduct basic or applied research by a nonprofit institution of higher education or nonprofit organization whose primary purpose is conducting scientific research.

34. Expenditures.

Expenditures mean charges made by a recipient or subrecipient to a project or program under an award.

a. The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied.

b. For reports prepared on a cash basis, expenditures are the sum of:

(1) Cash disbursements for direct charges for property and services;

(2) The amount of indirect expense charged;

(3) The value of third-party in-kind contributions applied; and

(4) The amount of cash advance payments and payments made to subrecipients.

c. For reports prepared on an accrual basis, expenditures are the sum of:

(1) Cash disbursements for direct charges for property and services;

(2) The amount of indirect expense incurred;

(3) The value of third-party in-kind contributions applied; and

(4) The net increase or decrease in the amounts owed by the recipient or subrecipient for:

(a) Goods and other property received;

(b) Services performed by employees, contractors, subrecipients, and other payees; and

(c) Programs for which no current services or performance are required, such as annuities, insurance claims, or other benefit payments.

35. Federal interest.

Federal interest means, in relation to real property, equipment, or supplies acquired or improved under an award or subaward, the dollar amount that is the product of the:

a. Federal share of total project costs; and

b. Current fair market value of the property, improvements, or both, to the extent the costs of acquiring or improving the property were included as project costs.

36. Federal share.

Federal share means the portion of the project costs under an award that is paid by Federal funds.

37. Fixed-amount award.

Fixed-amount award means a DoD Component grant or cooperative agreement that provides for the recipient to be paid on the basis of performance and results, rather than the actual, allowable costs the recipient incurs.

38. Fixed-amount subaward

Fixed-amount subaward means a subaward:

a. That a recipient or subrecipient makes to another entity at the next lower tier; and

b. Under which the total amount to be paid to the other entity is based on performance and results, and not on the actual, allowable costs that entity incurs.

39. Foreign organization.

Foreign organization means an entity that is:

a. A public or private organization that is located in a country other than the United States and its territories and is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance;

b. A private nongovernmental organization located in a country other than the United States and its territories that solicits and receives cash contributions from the general public;

c. A charitable organization located in a country other than the United States and its territories that is nonprofit and tax exempt under the laws of its country of domicile and operation, and is not a university, college, accredited degree-granting institution of education, private foundation, hospital, organization engaged exclusively in research or scientific activities, church, synagogue, mosque or other similar entity organized primarily for religious purposes; or

d. An organization located in a country other than the United States and its territories that is not recognized as a foreign public entity.

40. Foreign public entity.

Foreign public entity means:

a. A foreign government or foreign governmental entity;

b. A public international organization, which is an organization, entitled to enjoy privileges, exemptions, and immunities as an international organization under the International Organizations Immunities Act (22 U.S.C. 288-288f);

c. An entity owned (in whole or in part) or controlled by a foreign government; or

d. Any other entity consisting wholly or partially of one or more foreign governments or foreign governmental entities.

41. Grant.

Grant means a legal instrument which, consistent with 31 U.S.C. 6304, is used to enter into a relationship:

a. Of which the principal purpose is to transfer a thing of value to the recipient to carry out a public purpose of support or stimulation authorized by a law of the United States, rather than to acquire property or services for the DoD's direct benefit or use.

b. In which substantial involvement is not expected between the DoD and the recipient when carrying out the activity contemplated by the grant.

42. Grants officer.

Grants officer means a DoD official with the authority to enter into, administer, and/or terminate grants or cooperative agreements.

43. Indian tribe.

Indian tribe means any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. Chapter 33), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians (25 U.S.C. 450b (e)). See the annually published Bureau of Indian Affairs list of Indian Entities Recognized and Eligible to Receive Services.

44. Indirect costs (also known as "Facilities and Administrative," or F&A, costs).

Indirect costs means those costs incurred for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved.

45. Institution of higher education.

Institution of higher education has the meaning specified at 20 U.S.C. 1001.

46. Intangible property.

Intangible property means:

a. Property having no physical existence, such as trademarks, copyrights, patents and patent applications; and

b. Property such as loans, notes and other debt instruments, lease agreements, stock and other instruments of property ownership, whether the property is considered tangible or intangible.

47. Local government.

Local government means any unit of government within a State, including a:

a. County;

b. Borough;

c. Municipality;

d. City;

e. Town;

f. Township;

g. Parish;

h. Local public authority, including any public housing agency under the United States Housing Act of 1937;

i. Special district;

j. School district;

k. Intrastate district;

l. Council of governments, whether or not incorporated as a nonprofit corporation under State law; and

m. Any other agency or instrumentality of a multi-, regional, or intra-state or local government.

48. Management decision.

Management decision means a written decision issued to an audited entity by a DoD Component, another Federal agency that has audit or indirect cost cognizant or oversight responsibilities for the audited entity, or a recipient or subrecipient from which the audited entity received an award or subaward. The DoD Component, cognizant or oversight agency, recipient, or subrecipient issues the management decision to specify the corrective actions that are necessary after evaluating the audit findings and the audited entity's corrective action plan.

49. Nonprocurement instrument.

Nonprocurement instrument means a legal instrument other than a procurement contract that a DoD Component may award. Examples include an instrument of financial assistance, such as a grant or cooperative agreement, or an instrument of technical assistance, which provides services in lieu of money.

50. Nonprofit organization.

Nonprofit organization means any corporation, trust, association, cooperative, or other organization, not including an institution of higher education, that:

a. Is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest;

b. Is not organized primarily for profit; and

c. Uses net proceeds to maintain, improve, or expand the operations of the organization.

51. Obligation.

Obligation means:

a. When used in conjunction with a DoD Component's action, a legally binding agreement that will result in outlays, either immediately or in the future. Examples of actions through which a DoD Component incurs an obligation include the signature of a grant, cooperative agreement, or technology investment agreement authorizing the recipient to use funds under the award.

b. When used in conjunction with a recipient's or subrecipient's use of funds under an award or subaward, an order placed for property and services, a contract or subaward made, or a similar transaction during a given period that requires payment during the same or a future period.

52. Office of Management and Budget.

Office of Management and Budget means the Executive Office of the President, United States Office of Management and Budget.

53. Outlays.

Outlays means "expenditures," as defined in this part.

54. Participant support costs.

Participant support costs means direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences, or training projects.

55. Period of performance.

Period of performance means the time during which a recipient or subrecipient may incur new obligations to carry out the work authorized under an award or subaward, respectively.

56. Personal property.

Personal property means property other than real property. It may be tangible, having physical existence, or intangible, such as copyrights, patents, and securities.

57. Principal investigator.

Principal investigator means either:

a. The single individual whom an organization that is carrying out a research project with DoD support designates as having an appropriate level of authority and responsibility for leading and directing the research intellectually and logistically, which includes the proper conduct of the research, the appropriate use of funds, and administrative requirements such as the submission of scientific progress reports to the DoD program office; or

b. If the organization designates more than one individual as sharing that authority and responsibility, the individual within that group identified by the organization as the one with whom the DoD Component's program manager generally should communicate as the primary contact for scientific, technical, and related budgetary matters concerning the project (others within the group are "co-principal investigators," as defined in this part).

58. Procurement contract.

Procurement contract means a legal instrument which, consistent with 31 U.S.C. 6303, reflects a relationship between the Federal Government and a State, a local government, or other recipient when the principal purpose of the instrument is to acquire property or services for the direct benefit or use of the

Federal Government. A procurement contract is a prime tier transaction and therefore distinct from a recipient's or subrecipient's "procurement transaction" or "contract" as defined in this part.

59. Procurement transaction.

Procurement transaction means a legal instrument by which a recipient or subrecipient purchases property or services it needs to carry out the project or program under its prime award or subaward, respectively. A procurement transaction is distinct both from "subaward" and "procurement contract," as those terms are defined in this part.

60. Program income.

Program income means gross income earned by a recipient or subrecipient that is directly generated by a supported activity or earned as a result of an award or subaward (during the period of performance unless the award or subaward specifies continuing requirements concerning disposition of program income after the end of that period).

a. Program income includes, but is not limited to, income from:

(1) Fees for services performed;

(2) The use or rental of real or personal property for which the recipient or subrecipient is accountable under the award or subaward (whether acquired under the award or subaward, or other Federal awards from which accountability for the property was transferred);

(3) The sale of commodities or items fabricated under the award or subaward;

(4) License fees and royalties on patents and copyrights; and

(5) Payments of principal and interest on loans made with award or subaward funds.

b. Program income does not include:

(1) Interest earned on advances of Federal funds;

(2) Proceeds from the sale of real property or equipment under the award; or

(3) Unless otherwise specified in Federal statute or regulation, or the terms and conditions of the award or subaward:

(a) Rebates, credits, discounts, and interest earned on any of them; or

(b) Governmental revenues, taxes, special assessments, levies, fines, and similar revenues raised by the recipient or subrecipient.

61. Project costs.

Project costs mean the total of:

a. Allowable costs incurred under an award by the recipient, including costs of any subawards and contracts under the award; and

b. Cost sharing or matching contributions that are required under the award, which includes voluntary committed (but not voluntary uncommitted) contributions and the value of any third-party in-kind contributions.

62. Property.

Property means real property and personal property (equipment, supplies, intangible property, and debt instruments), unless stated otherwise.

63. Real property.

Real property means land, including land improvements, structures and appurtenances thereto, but excluding moveable machinery and equipment.

64. Recipient.

Recipient means an entity that receives an award directly from a DoD Component. The term does not include subrecipients.

65. Research.

Research means basic, applied, and advanced research.

66. Simplified acquisition threshold.

Simplified acquisition threshold means the dollar amount set by the Federal Acquisition Regulation at 48 CFR Subpart 2.1, which is adjusted periodically for inflation in accordance with 41 U.S.C. 1908.

67. Small award.

Small award means a DoD grant or cooperative agreement or a subaward with total value over the life of the award that does not exceed the simplified acquisition threshold.

68. State.

State means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any agency or instrumentality thereof exclusive of local governments.

69. Subaward.

Subaward means a legal instrument by which a recipient or subrecipient at any tier below a DoD Component prime award, transfers--for performance by an entity at the next lower tier--a portion of the substantive program for which the DoD Component's prime award provided financial assistance.

70. Subrecipient.

Subrecipient means an entity that receives a subaward.

71. Supplies.

Supplies means all tangible personal property, including a computing device, acquired under an award that does not meet the definition of equipment in this part.

72. Suspension.

Suspension means either:

a. When used in the context of a specific award or subaward to an entity, the temporary withdrawal of authority for that entity to obligate funds under the award or subaward, pending its taking corrective action or a decision to terminate the award or subaward.

b. When used in the context of an entity, an action by a DoD Component's suspending official under 2 CFR part 1125, DoD's regulation implementing OMB guidance on nonprocurement debarment and suspension in 2 CFR part 180, to immediately exclude the entity from participating in covered Federal Government transactions, pending completion of an investigation and any legal or debarment proceedings that ensue.

73. Technology Investment Agreement.

Technology investment agreement means one of a special class of assistance instruments used to increase involvement of commercial firms in defense research programs and for other purposes related to integration of the commercial and defense sectors of the nation's technology and industrial base. Technology investment agreements include one kind of cooperative agreement with provisions tailored for involving commercial firms, as well as one kind of assistance transaction other than a grant or cooperative agreement. Technology investment agreements are subject to, and described more fully in, 32 CFR part 37.

74. Termination.

Termination means the ending of an award or subaward, in whole or in part, at any time prior to the planned end of the period of performance.

75. Third-party in-kind contribution.

Third-party in-kind contribution means the value of a non-cash contribution (i.e., property or services) that:

a. A non-Federal third party contributes, without charge, either to a recipient or subrecipient at any tier under a DoD Component's award; and

b. Is identified, and included in the approved budget of the DoD Component's award, as a contribution being used toward meeting the award's cost sharing or matching requirements (which includes voluntary committed, but not voluntary uncommitted, contributions).

76. Total value.

Total value of a DoD grant, cooperative agreement, or TIA means the total amount of costs that are currently expected to be charged to the award over its life, which includes amounts for:

(a) The Federal share and any non-Federal cost sharing or matching required under the award; and

(b) Any options, even if not yet exercised, for which the costs have been established in the award.

77. Unique entity identifier.

Unique entity identifier means the identifier required for System for Award Management registration to uniquely identify entities with which the Federal Government does business (currently the Dun and Bradstreet Data Universal Numbering System, or DUNS, number).

78. Unobligated balance.

Unobligated balance means the amount of funds under an award or subawards that the recipient or subrecipient has not obligated. The amount is computed by subtracting the cumulative amount of the recipient's or subrecipient's unliquidated obligations and expenditures of funds from the cumulative amount of funds that it was authorized to obligate under the award or subaward.

79. Voluntary (committed or uncommitted) cost sharing.

a. *Voluntary cost sharing* means cost sharing that an entity pledges voluntarily in its application or proposal (i.e., not due to a stated cost sharing requirement in the program announcement to which the entity's application or proposal responds).

b. *Voluntary committed* cost sharing means voluntary cost sharing that a DoD Component accepts through inclusion in the approved budget for the project or program and as a binding requirement of the terms and conditions of the award made to the entity in response to its application or proposal.

c. *Voluntary uncommitted* cost sharing means voluntary cost sharing that does not meet the criteria in paragraph (b) of Section D.71.

80. Working capital advance.

Working capital advance means a payment method under which funds are advanced to a recipient or subrecipient to cover its estimated disbursement needs for a given initial period, after which payment is made by way of reimbursement.

Part 2: Financial And Program Management

FMS Article I. Financial Management System Standards. (JULY 2016)

Section A. System standard for States. As a State, you must expend and account for funds under this award in accordance with:

1. Applicable State laws; and

2. To the extent they comply with the requirements of Section B of this Article, your procedures for expending and accounting for your own State funds.

Section B. System standards for all recipients. Your financial management system must provide for:

1. Inclusion, in your accounts, of the following information about each DoD financial assistance award that you receive:

   a. That you received the award from the Department of Defense;

   b. The number and title listed in the Catalog of Federal Domestic Assistance for the DoD program under which the award was made;

   c. The DoD award number;

   d. The year (your fiscal year) in which you received the award;

2. Accurate, current, and complete disclosure of the financial results of the award needed to comply with financial and programmatic reporting requirements that are specified in REP Article I and II of these general terms and conditions, as supplemented by any award-specific terms and conditions of this award concerning reporting requirements. If you are asked at any time under this award to report financial information on an accrual basis, you:

   a. Need not establish an accrual accounting system if you maintain your records on a different basis; and

   b. May develop the accrual data based on an analysis of the data you have on hand.

3. Records that identify adequately the sources of funds for all activities funded by DoD awards, including any required cost sharing or matching, and the application of those funds. This includes funding authorizations; your obligations and expenditures of the funds; unobligated balances; property and other assets under the award; program income; and interest.

4. Effective control over, and accountability for, all funds, property, and other assets under this award. You must adequately safeguard all assets and assure they are used solely for authorized purposes (see Section C of this article for additional requirements concerning internal controls).

5. Comparisons of expenditures under this award for project or program purposes with amounts in the approved budget for those purposes.

6. **RESERVED.**

7. Written procedures:

   a. To implement requirements specified in FMS Article II, "Payments;"

   b. For determining the allowability of costs, which for this award are determined in accordance with FMS Article III, "Allowable costs, period of availability of funds, and fee or profit," of these general terms and conditions supplemented by any award-specific terms and conditions of this award that relate to allowability of costs.

Section C. Internal controls. Your system of internal controls must conform to OMB guidance in 2 CFR 200.303. With respect to paragraph (e) of §200.303, your internal control system must include measures to safeguard any information that Federal statute, Executive order, or regulation requires to be protected (e.g., personally identifiable or export controlled information), to include information generated under the award or provided to you and identified as being subject to protection.

FMS Article II. Payments. (JULY 2016)

Section A. Awards to States. If the award-specific terms and conditions of this award do not identify it as an award subject to Subpart A of 31 CFR part 205 (Department of the Treasury regulations implementing the Cash Management Improvement Act), then this award is subject to Subpart B of that part. Consistent with Subpart B of 31 CFR part 205:

1. Payment method, timing, and amounts. You must:

   a. Minimize the time between your receipt of a payment under this award and your disbursement of those funds for program purposes.

   b. Limit the amount of each advance payment request to the minimum amount you need to meet your actual, immediate cash requirements for carrying out the program or project.

   c. Submit each advance payment request approximately 10 days before you anticipate disbursing the requested amount for program purposes, so that your receipt of the funds will be as close in time as is administratively feasible to your actual cash outlay for direct program or project costs and the proportionate share of any allowable indirect costs.

2. Interest. Unlike awards subject to Subpart A of 31 CFR part 205, neither you nor we will incur any interest liability due to a difference in timing between your receipt of payments under this award and your disbursement of those funds for program purposes.

Section B. Awards to institutions of higher education, nonprofit organizations, local governments, and Indian tribes.

1. **Payment method.** Unless the award-specific terms and conditions of this award provide otherwise, you are authorized to request advance payments under this award. That authorization is contingent on your continuing to maintain, or demonstrating the willingness to maintain, written procedures that minimize the time elapsing between your receipt of each payment and your disbursement of the funds for program purposes. Note that you are not required to request advance payments and may instead, at your option, request reimbursement of funds after you disburse them for program purposes.

2. **Amounts requested.** You must:

a. Limit the amount of any advance payment request to the minimum amount needed to meet your actual, immediate cash requirements for carrying out the purpose of the approved program or project, including direct program or project costs and a proportionate share of any allowable indirect costs.

b. Exclude from any payment request amounts you are withholding from payments to contractors to assure satisfactory completion of the work. You may request those amounts when you make the payments to the contractors or to escrow accounts established to assure satisfactory completion of the work.

c. Exclude from any payment request amounts from any of the following sources that are available to you for program purposes under this award: program income, including repayments to a revolving fund; rebates; refunds; contract settlements; audit recoveries; and interest earned on any of those funds. You must disburse those funds for program purposes before requesting additional funds from us.

3. **Timing of requests.** For any advance payment you request, you should submit the request approximately 10 days before you anticipate disbursing the requested amount for program purposes. With time for agency processing of the request, that should result in payment as close as is administratively feasible to your actual disbursements for program or project purposes.

4. **Frequency of requests.** You may request payments as often as you wish unless you have been granted a waiver from requirements to receive payments by electronic funds transfer (EFT). If you have been granted a waiver from EFT requirements, the award-specific terms and conditions of this award specify the frequency with which you may submit payment requests.

5. **Withholding of payments.** We will withhold payments for allowable costs under the award at any time during the period of performance only if one or more of the following applies:

a. We suspend either payments or the award, or disallow otherwise allowable costs, as a remedy under OAR Article III due to your material failure to comply with Federal statutes, regulations, or the terms and conditions of this award. If we suspend payments and not the award, we will release withheld payments upon your subsequent compliance. If we suspend the award, then amounts of payments are subject to adjustment in accordance with the terms and conditions of OAR Article III.

b. You are delinquent in a debt to the United States as defined in OMB Circular A-129, "Policies for Federal Credit Programs and Non-Tax Receivables," in which case we may, after reasonable notice, inform you that we will not make any further payments for costs you incurred after a specified date until you correct the conditions or liquidate the indebtedness to the Federal Government.

c. The award-specific terms and conditions include additional requirements that provide for withholding of payments based on conditions identified during our pre-award risk evaluation, in which case you should have been notified about the nature of those conditions and the actions needed to remove the additional requirements.

6. **Depository requirements.**

a. There are no eligibility requirements for depositories you use for funds you receive under this award.

b. You are not required to deposit funds you receive under this award in a depository account separate from accounts in which you deposit other funds. However, FMS Article I requires that you be able to account for the receipt, obligation, and expenditure of all funds under this award.

c. You must deposit any advance payments of funds you receive under this award in insured accounts whenever possible and, unless any of the following apply, you must deposit them in interest-bearing accounts:

(1) You receive a total of less than $120,000 per year under Federal grants and cooperative agreements.

(2) You would not expect the best reasonably available interest-bearing account to earn interest in excess of $500 per year on your cash balances of advance payments under Federal grants and cooperative agreements.

(3) The best reasonably available interest-bearing account would require you to maintain an average or minimum balance higher than it would be feasible for you to do within your expected Federal and non-Federal cash balances.

(4) Foreign government or banking system precludes your use of interest-bearing accounts.

d. You may retain for administrative expenses up to $500 per year of interest that you earn in the aggregate on advance payments you receive under this award and other Federal grants and cooperative agreements. You must remit annually the rest of the interest to the Department of Health and Human Services, Payment Management System, using the procedures set forth in OMB guidance in 2 CFR 200.305 (b)(9).

Section C. Electronic funds transfer and other payment procedural instructions or information.

1. **Electronic funds transfer.** Unless the award-specific terms and conditions of this award provide otherwise, you will receive payments under this award by electronic funds transfer.

2. **RESERVED.**

FMS Article III. Allowable costs, period of availability of funds, and fee and profit. (JULY 2016)

Section A. Allowable costs. This section, with the clarification provided in Section B, specifies which Federal cost principles must be used in determining the allowability of costs charged to this award, a subrecipient's costs charged to any cost-type subaward that you make under this award, and a contractor's costs charged to any cost-type procurement transaction into which you enter under this award. These cost principles also govern the allowable costs that you or a subrecipient of a subaward at any tier below this award may consider when establishing the amount of any fixed-amount subaward or fixed-price procurement transaction at the next lower tier. The set of cost principles to be used in each case depends on the type of entity incurring the cost under the award, subaward, or contract.

1. **General case.** If you, your subrecipient, or your contractor is:

a. **An institution of higher education,** the allowability of costs must be determined in accordance with provisions of Subpart E of OMB guidance in 2 CFR part 200 other than paragraph 200.400(g), supplemented by Appendix III to that part.

b. **A hospital,** the allowability of costs must be determined in accordance with provisions of Appendix IX to 2 CFR part 200, which currently specifies the cost principles in Appendix IX to 45 CFR part 75 as the applicable cost principles.

c. **A nonprofit organization other than a hospital or institution of higher education,** the allowability of costs must be determined in accordance with provisions of Subpart E of OMB guidance in 2 CFR part 200 other than paragraph 200.400(g), supplemented by Appendices IV

and VIII to that part. In accordance with guidance in paragraph 200.401(c) a nonprofit organization listed in Appendix VIII to 2 CFR part 200 is subject to the cost principles for for-profit entities specified in paragraph 1.e of this section.

d. **A State, local government, or Indian tribe**, the allowability of costs must be determined in accordance with applicable provisions of Subpart E of OMB guidance in 2 CFR part 200 other than 2 CFR 200.400(g), supplemented by Appendices V through VII to that part.

e. **A for-profit entity (other than a hospital) or a nonprofit organization listed in Appendix VIII to 2 CFR part 200:**

(1) The allowability of costs must be determined in accordance with:

(a.) The cost principles for commercial organizations in the Federal Acquisition Regulation (FAR) at subpart 31.2 of 48 CFR part 31, as supplemented by provisions of the Defense Federal Acquisition Regulatory Supplement (DFARS) at subpart 231.2 of 48 CFR part 231; and

(b.) For a for-profit entity, the additional provisions on allowability of audit costs, in 32 CFR 34.16(f).

(2) The indirect cost rate to use in that determination is:

(a.) The for-profit entity's federally negotiated indirect cost rate if it has one.

(b.) Subject to negotiation between you and the for-profit entity if it does not have a federally negotiated indirect cost rate. The rate that you negotiate may provide for reimbursement only of costs that are allowable in accordance with the cost principles specified in paragraph A.1.e.(1) of this article.

(3) The indirect cost rate to use in that determination is:

(a.) The for-profit entity's federally negotiated indirect cost rate if it has one

(b.) Subject to negotiation between you and the for-profit entity if it does not have a federally negotiated indirect cost rate. The rate you negotiate may provide for reimbursement only of costs that are allowable in accordance with the cost principles in FAR subpart 31.2.

2. **Exception.** You may use your own cost principles in determining the allowability of a contractor's costs charged to a cost-type procurement transaction under this award—or in pricing for a fixed-price contract based on estimated costs—as long as your cost principles comply with the Federal cost principles that paragraph A.1 of this section identifies as applicable to the contractor.

Section B. Clarifications concerning charges of publication costs. RESERVED

Section C. Period of availability of funds. You may charge to this award only:

1. Allowable costs incurred during the period of performance specified in this award, including any subsequent amendments to it;

2. Any pre-award costs that you are authorized (by either the terms and conditions of FMS Article IV or the DoD awarding official) to incur prior to the start of the period of performance, at your own risk, for purposes of the program or project under this award; and

3. Costs of publishing in professional journals publications incurred after the period of performance, as permitted under paragraph 2 CFR 200.461(b)(3), if:

a. We receive the request for payment for such costs no later than the date on which REP Article II requires you to submit the final financial report to us (or, if we grant your request for an extension of the due date, that later date on which the report is due); and

b. Your reported expenditures on the final financial report include the amount you disbursed for those costs.

Section D. Fee or profit.

1. You may not receive any fee or profit under this award.

2. You may not use funds available to you under this award to pay fee or profit for an entity of any type to which you make a subaward.

3. You may pay fee or profit to an entity with which you enter into a procurement transaction to purchase goods or general support services for your use in carrying out the project or program under the award.

FMS Article IV. Revision of budget and program plans. (JULY 2016)

Section A. Approved budget. The approved budget of this award:

1. Is the most recent version of the budget that you submitted and we approved (either at the time of the initial award or a more recent amendment), to summarize planned expenditures for the project or program.

2. Includes all Federal funding that we make available to you under this award to use for program or project purposes and any cost sharing or matching that you are required to provide under this award for those same purposes.

Section B. Revisions requiring prior approval.

1. **Non-construction activities.** You must request prior approval from us for any of the following program or budget revisions in non-construction activities:

a. A change in the scope or objective of the project or program under this award, even if there is no associated budget revision that requires our prior approval.

b. A change in a key person identified in the award cover pages.

c. The approved principal investigator's or project director's disengagement from the project for more than three months, or a 25 percent reduction in his or her time devoted to the project.

d. The inclusion of direct costs that require prior approval in accordance with the applicable cost principles, as identified in FMS Article III.

(1) The requirement for prior written approval of capital expenditures for equipment that is to be used primarily in carrying out the project or program supported by the award is waived for equipment with a unit cost of $25,000 or less.

e. Reserved

f. A subaward to another entity under which it will perform a portion of the substantive project or program under the award, if it was not included in the approved budget. This does not apply to your contracts for acquisition of supplies, equipment, or general support services you need to carry out the project or program.

g. Any change in the cost sharing or matching you provide under the award, as included in the approved budget, for which FMS Article VI requires prior approval.

h. Reserved

i. The need arises for additional Federal funds to complete the project or program.

2. **Construction activities.** You must request prior approval from us for any of the following program or budget revisions in construction activities:

a. A change in the scope or objective of the project or program under this award, even if there is no associated budget revision that requires our prior approval.

b. The need arises for additional Federal funds to complete the project.

c. The inclusion of direct costs that require prior approval in accordance with the applicable cost principles, as identified in FMS Article III.

3. **Funding transfers between construction and non-construction activities.** RESERVED.

Section C. Pre-award costs, carry forward of unobligated balances, and one-time no-cost extensions. You are authorized, without requesting prior approval from us, to:

1. Charge to this award after you receive it pre-award costs that you incurred, at your own risk, up to 90 calendar days before the start date of the period of performance, as long as they are costs that would be allowable charges to the project or program under the terms and conditions of FMS Article III if they were incurred during the period of performance.

2. Carry forward an unobligated balance to a subsequent period of performance under this award.

3. **RESERVED**

Section D. Procedures.

1. We will review each request you submit for prior approval for a budget or program change and, within 30 calendar days of our receipt of your request, we will respond to you in writing to either:

   a. Notify you whether your request is approved; or

   b. Inform you that we still are considering the request, in which case we will let you know when you may expect our decision.

2. **RESERVED.**

FMS Article V. Non-Federal audits. (JULY 2016)

Section A. Requirements for entities subject to the Single Audit Act. You and each subrecipient under this award that is an institution of higher education, nonprofit organization, State, local government, or Indian tribe must comply with the audit requirements specified in Subpart F of 2 CFR part 200, which is the Office of Management and Budget implementation of the Single Audit Act, as amended (31 U.S.C. chapter 75).

Section B. Requirements for for-profit entities. Any for-profit entity that receives a subaward from you under this award is subject to the audit requirements specified in 32 CFR 34.16. Your subaward terms and conditions will require the subrecipient to provide the reports to you if it is willing to do so, so that you can resolve audit findings that pertain specifically to your subaward (e. g., disallowance of costs). If the for-profit entity is unwilling to agree to provide the auditor's report to you, contact the grants officer for this award to discuss an alternative approach for carrying out audit oversight of the subaward. If the grants officer does not provide an alternative approach within 30 days of receiving your request, you may determine an approach to ensure the for-profit subrecipient's compliance with the subaward terms and conditions, as described in OMB guidance at 2 CFR 200.501(h).

FMS Article VI. Cost sharing or matching. (JULY 2016)

Section A. Required cost sharing or matching.

1. If any cost sharing or matching is required under this award, the total amount or percentage required is shown in the award cover pages and included in the approved budget. That cost sharing or matching includes all:

   a. Cash and third party in-kind contributions.

   b. Contributions to the project or program made either by or through (if made by a third party) you and any subrecipients.

2. You must obtain our prior approval if you wish to:

   a. Change the amount or percentage of cost sharing or matching required under this award.

   b. RESERVED.

Section B. Allowability as cost sharing or matching. Each cash or third party in-kind contribution toward any cost sharing or matching required under this award, whether put forward by you or a subrecipient under a subaward that you make, is allowable as cost sharing or matching if:

1. You (or the subrecipient, if it is a subrecipient contribution) maintain records from which one may verify that the contribution was made to the project or program and, if it is a third-party in-kind contribution, its value.

2. The contribution is not counted as cost sharing or matching for any other Federal award.

3. The contribution is:

   a. Allowable under the cost principles applicable to you (or the subrecipient, if it is a subrecipient contribution) under FMS Article III of these terms and conditions; and

   b. Allocable to the project or program and reasonable.

4. The Government does not pay for the contribution through another Federal award, unless that award is under a program that has a Federal statute authorizing application of that program's Federal funds to other Federal programs' cost sharing or matching requirements.

5. The value of the contribution is not reimbursed by the Federal share of this award as either a direct or indirect cost.

6. The contribution conforms to the other terms and conditions of this award, including the award-specific terms and conditions.

Section C. Allowability of unrecovered indirect costs as cost sharing or matching. You may use your own or a subrecipient's unrecovered indirect costs as cost sharing or matching under this award. Unrecovered indirect costs means the difference between the amount of indirect costs charged to the award and the amount that you and any subrecipients could have charged in accordance with your respective approved indirect cost rates, whether those rates are negotiated or de minimis (as described in 2 CFR 200.414(f)).

Section D. Allowability of program income as cost sharing or matching. If FMS Article VII of these general terms and conditions or the award-specific terms and conditions of this award specify that you are to use some or all of the program income you earn to meet cost-sharing or matching requirements under the award, then program income is allowable as cost sharing or matching to the extent specified in those award terms and conditions.

Section E. Valuation of services or property that you or subrecipients contribute or donate. You must establish values for services or property contributed or donated toward cost sharing or matching by you or subrecipients in accordance with the provisions of this section. These contributions or donations are distinct from third-party contributions or donations to you or subrecipients, which are addressed in Section F of this article.

1. **Usual valuation of services or property that you or subrecipients contribute or donate.** Values established for contributions of services or property by you or a subrecipient must be the amounts allowable in accordance with the cost principles applicable to the entity making the contribution (i.e., you or the subrecipient), as identified in FMS Article III. For property, that generally is depreciation.

2. **Needed approvals for, and valuation of, property that you or subrecipients donate.**

   a. **Types of property that may be donated.**

      (1) **Buildings or land.** If the purposes of this award include construction, facilities acquisition, or long-term use of real property, you may donate buildings or land to the project if you obtain our prior approval. Donation of property to the project, as described in PROP Article I, means counting the value of the property toward cost sharing or matching, rather than charging depreciation.

      (2) **Other capital assets.** If you obtain our prior approval, you may donate to the project other capital assets identified in paragraphs 2 CFR 200.439(b) (1) through (3).

   b. **Usual valuation of donated property.** Unless you obtain our approval as described in paragraph E.2.c of this article, the value for the donated property must be the lesser of:

(1)The value of the remaining life of the property recorded in your accounting records at the time of donation, or

(2) The current fair market value.

c. **Approval needed for alternative valuation of property.** If you obtain our approval in the approved budget or subsequently, you may count as cost sharing or matching the current fair market value of the donated property even if it exceeds the value of the remaining life of the property recorded in your accounting records at the time of donation.

d. **Federal interest in donated property.** Donating buildings, land, or other property to the project, rather than charging depreciation, results in a Federal interest in the property in accordance with PROP Article I of these terms and conditions.

Section F. Valuation of third-party in-kind contributions.

1. **General.** If a third-party furnishes goods or services to you or subrecipients that are to be counted toward cost sharing or matching under this award, the entity to which the third party furnishes the goods or services (i.e., you or a subrecipient) must document the fair market value of those in-kind contributions and, to the extent feasible, support those values using the same methods the entity uses internally.

2. **Valuation of third-party services.** You must establish values for third-party volunteer services and services of third parties' employees furnished to you or subrecipients as follows:

a. **Volunteer services.** Volunteer services furnished by third party professional and technical personnel, consultants, and other skilled and unskilled labor must be valued in accordance with 2 CFR 200.306(e).

b. **Services of third parties' employees.** When a third party organization furnishes the services of its employees to you or a subrecipient, values for the contributions must be established in accordance with paragraph 2 CFR 200.306(f).

c. **Additional requirement for donations to nonprofit organizations.** For volunteer services or services of third parties' employees furnished to a nonprofit organization:

(1) OMB guidance in 2 CFR 200.434(e) also applies and may require the nonprofit organization to allocate a proportionate share of its applicable indirect costs to the donated services.

(2) The indirect costs that the nonprofit organization allocates to the donated services in that case must be considered project costs and may be either reimbursed under the award or counted toward required cost sharing or matching, but not both.

3. **Valuation of third-party property.** You must establish values for third-party property furnished to you or subrecipients as follows:

a. **Supplies donated by third parties.** When a third party organization donates supplies (e.g., office, laboratory, workshop, or classroom supplies), the value that may be counted toward cost sharing or matching may not exceed the fair market value of the supplies at the time of donation.

b. **Equipment, buildings, or land donated by third parties.**

(1) The value of third-party donations of equipment, buildings, or land that may be counted toward cost sharing or matching when the third party transferred title to you or a subrecipient depends on the purpose of the award in accordance with the following:

(a) If one of the purposes of the award is to assist you or the subrecipient in the acquisition of equipment, buildings, or land, you may count the aggregate fair market value of the donated property toward cost sharing or matching.

(b) If the award's purposes instead include only the support of activities that require the use of equipment, buildings, or land, you may only charge depreciation unless you obtain our prior approval to count as cost sharing or matching the fair market value of equipment or other capital assets and fair rental charges for land.

(2) The values of the donated property must be determined in accordance with the usual accounting policies of the entity to which the third party transferred title to the property, with the qualifications specified in 2 CFR 200.306(i)(1) and (2) for donated land and buildings and donated equipment, respectively.

c. **Use of space donated by third parties.** If a third party makes space available for use by you or a subrecipient, the value that you may count toward cost sharing or matching may not exceed the fair rental value of comparable space as established by an independent appraisal, as described in 2 CFR 200.306(i)(3).

d. **Equipment loaned by third parties.** If a third party loans equipment for use by you or a subrecipient, the value that you may count toward cost sharing or matching may not exceed its fair rental value.

FMS Article VII. Program income. (JULY 2016)

Section A. Definition. The term "program income" as used in this award:

1. Is gross income that:

a. You earn that is directly generated by a supported activity or earned as a result of this award; or

b. A subrecipient earns as a result of a subaward you make under this award.

2. Includes, but is not limited to, income earned under this award from:

   a. Fees for services performed;

   b. The use or rental of real or personal property acquired under any Federal award and currently administered under this award;

   c. The sale of commodities or items fabricated under this award; and

   d. License fees and royalties on patents and copyrights;

   e. Payments of principal and interest on loans made with Federal award funds.

3. Does not include for purposes of this award any:

   a. Interest earned on advance payments, disposition of which is addressed in FMS Article II;

   b. Proceeds from the sale of real property, equipment or supplies, which is addressed in PROP Articles III and IV;

   c. Rebates, credits, discounts, and interest earned on any of them; and

   d. Governmental revenues, including any taxes, special assessments, levies, fines and similar revenues you raise.

Section B. Encouragement to earn program income. You are encouraged to earn program income under this award when doing so does not interfere with the program or project the award supports.

Section C. Costs of generating program income. You may deduct costs incidental to the generation of program income from the amount that you use in accordance with Section E of this Article, as long as those costs are not charged to this award (which includes their being counted toward any cost share you are required to provide).

Section D. License fees and royalties. You have no obligations to the Federal Government with respect to program income earned under this award from license fees and royalties for patents or patent applications, copyrights, trademarks, or inventions produced under the award.

Section E. Use of program income

1. You must use any program income that you earn during the period of performance under this award to increase the amount of the award (the sum of the Federal share and any cost sharing or matching you are required to provide), thereby increasing the amount budgeted for the project. The program income must be used for the purposes and under the conditions of the award.

2. Your use of the additional funding is subject to the terms and conditions of this award, including:

   a. FMS Article II concerning your use of balances of program income before you request additional funds from us; and

   b. FMS Article III concerning allowability of costs for which the funds may be used.

3. You must report on each Federal Financial Report (SF-425) that you submit in accordance with REP Article II the program income that you earn and any that you use during the reporting period covered by that SF-425.

Section F. Duration of accountability for program income.

The requirements concerning disposition of program income in Section E of this Article apply only to program income you earn during the period of performance. There are no requirements under this award applicable to program income you earn after the end of the period of performance.

Part 3: Property Administration

PROP Article I. Title to Property. (JULY 2016)

Section A. Title to property acquired under this award.

1. **General.** Other than any property identified in paragraph A.2 of this section as excepted property:

   a. Title to real property, equipment, and supplies that you acquire (whether by purchase, construction or fabrication, development, or otherwise) and charge as direct project costs under this award vests in you, the recipient. Title to intangible property that you acquire (other than by developing or producing it) under this award also vests in you.

   b. That title is a conditional title, subject to the terms and conditions in PROP Articles II-IV, Section D of PROP Article VI, and REP Article III of this award.

   c. There is a Federal interest in the property, other than intangible property that you develop or produce under the award. For real property, equipment, and intangible property, we retain this Federal interest until final disposition of the property under PROP Article III (for real property), PROP Article IV (for equipment), or Section D of PROP Article VI (for intangible property that is acquired, other than by developing or producing it), a period that in some cases may extend beyond closeout of this award.

2. **Excepted property.** Title to all equipment purchased or fabricated with funds provided under this grant or funds you provide as cost sharing, and charged as direct costs to the project or program, shall vest with you upon acquisition without further obligation to the Federal Government subject only to the criteria below unless other conditions are imposed in the award.

   a. You use the equipment for the authorized purposes of the project or program until the property is no longer needed for those purposes.

   b. You manage the equipment as provided in PROP Article II of the general terms and conditions (see Subpart B of this part). This includes maintaining property records that include the percentage of Federal participation in the costs of the project or program under which you acquired the excepted property, so that you may deduct the Federal share if you wish to use the property in future contributions for cost sharing or matching purposes on Federal awards.

   c. The DoD Component reserves the right to transfer title to the equipment to another recipient entity if the Principal Investigator relocates his or her research program to that entity."

Section B. Property trust relationship.

1. **Basic requirement.** Other than intangible property that you develop or produce under the award, you hold any real property, equipment, or intangible property that you acquire or improve under this award, you hold title in trust for the beneficiaries of the project or program that you are carrying out under the award.

2. **Notices of record. RESERVED.**

Section C. Federally owned property. Title to any federally owned property that we provide to you under this award (or for which accountability is transferred to this award from another Federal award) remains with the Government.

Section D. Federal interest in donated real property or equipment.

If real property or equipment is acquired under this award through your donation of the property to the project or program (i.e., counting the value of the remaining life of the property recorded in your accounting records or the fair market value as permitted under FMS Article VI of this award as part of your share of project costs to meet any cost sharing or matching requirements, rather than charging depreciation):

1. The Government acquires through that donation an interest in the real property or equipment, the value of which at any given time is the product of:

   a. The Federal share of the project costs under this award; and

   b. The current fair market value of the property at that time.

2. The real property or equipment is subject to Section B of this article and the terms and conditions of PROP Articles II-IV and REP Article III that are applicable to property acquired under the award.

3. The Federal interest in the real property or equipment must be addressed at the time of property disposition.

Section E. Federal interest in property improved under the award.

1. The Government has an interest in improvements (as distinct from ordinary repairs and maintenance) you make to an item of real property or equipment if you charge the costs of the improvements as direct costs to this award.

2. We thereby acquire an interest in the property if the Government did not previously have one. If the Government already had an interest in the property, the value of that Federal interest in the property increases by the amount of the Federal interest in the improvements.

3. The property is subject to Section B of this article and the terms and conditions of PROP Articles II-IV and REP Article III that are applicable to real property or equipment acquired under the award.

4. The Federal interest in the real property or equipment must be addressed at the time of property disposition.

PROP Article II. Property Management System. (JULY 2016)

Section A. Insurance coverage for real property and equipment. You must, at a minimum, provide the equivalent insurance coverage for real property and equipment acquired or improved under this award as you provide for real property and equipment that you own.

Section B. Other management system standards for a State. 1. **Equipment.** Your property management system for equipment acquired or improved in whole or in part under this award must be in accordance with your State laws and procedures.

2. Federally **owned property.** You may use your own property management system for any federally owned property for which you are accountable, as long as it meets the following minimum standards:

a. **Records.** Your records must include for each item of federally owned property:

(1) A description of the item.

(2) The location of the item.

(3) The serial or other identification number.

(4) Which Federal agency holds title.

(5) The date you received the item.

(6) Any data on the ultimate disposition of the item, such as the date of disposal.

(7) The Federal award identification number of the award under which you are accountable for the item.

b. **Inventory.** You must take a physical inventory of federally owned property at least biennially and reconcile the results with your records.

c. **Control system.** You must:

(1)Maintain an internal property control system with adequate safeguards to prevent loss, damage, or theft of federally owned property.

(2) Investigate any loss, damage, or theft of federally owned property and promptly notify the award administration office.

d. **Maintenance.** You must maintain the property in good condition.

Section C. Other management system standards for an institution of higher education, nonprofit organization, local government, or Indian tribe. Your procedures for managing equipment (including replacement equipment) acquired or improved in whole or in part under this award and any federally owned property for which you are accountable under this award must, as a minimum, meet the requirements in this section.

1. **Records.** You must maintain records that include for each item of equipment or federally owned property:

a. A description of the item.

b. The serial or other identification number.

c. Who holds title (e.g., you or the Government and, if the latter, which Federal agency).

d. The source of funding for the equipment, including the award number, or the source of the federally owned property, including the award number of the award under which you are accountable for the property.

e. The acquisition date and cost of the equipment (or improvement to the equipment) or the date you received the federally owned property.

f. The location, use, and condition of the equipment or federally owned property.

g. Information from which one can calculate the amount of the Federal interest in the acquisition or improvement of the item (this amount is zero after you compensate us for the Federal interest in the item or improvement).

h. Any data on the ultimate disposition of the item including the date of disposal and sale price.

2. **Labelling.** You must ensure that property owned by the Federal Government is labeled to identify it as federally owned property.

3. **Inventory.** You must take a physical inventory of equipment in which there is a Federal interest under the award and reconcile the result with your records at least once every 2 years.

4. **Control system.** You must:

a. Maintain an internal property control system with adequate safeguards to prevent loss, damage, or theft of equipment and federally owned property.

b. Investigate any loss, damage, or theft and notify us if it involved equipment in which there is a Federal interest under the award or federally owned property.

5. **Maintenance.** You must maintain equipment acquired or improved in whole or in part under the award and federally owned property in good condition.

PROP Article III. Use and disposition of real property. (JULY 2016)

Section A. Use of real property.

1. You must use real property acquired or improved under this award for the originally authorized purpose as long as needed for that purpose. During that time, you may not:

a. Dispose of the property except to acquire replacement property under this award, in which case you may use the proceeds from the disposition as an offset to the cost of the replacement property; or

b. Encumber the title or other interests in the property without the approval of the award administration office identified in this award.

2. RESERVED

3. RESERVED

Section B. Disposition of real property. When you no longer need real property for the originally authorized purpose, you must obtain disposition instructions from the award administration office. Those instructions will provide for one of the following three alternatives, which are that, you:

1. Retain title after compensating us for the Federal interest in the property, which is to be computed as specified in the definition of "Federal interest."

2. Sell the property and compensate us for the Federal interest in the property, as described in 2 CFR 200.311(c) (2).

3. Transfer title to us or a third party we designate, as described in paragraph 2 CFR 200.311(c)(3).

PROP Article IV. Use and disposition of equipment and supplies. (JULY 2016)

Section A. Property subject to this article. This article specifies requirements for use and disposition of equipment and supplies. If a provision of PROP Article I or an award-specific term or condition of this award identifies any equipment or supplies as excepted property, requirements of this Article apply to that excepted property only to the extent specified in that provision of PROP Article I or the award-specific term or condition. The types of non-excepted property to which this article applies are:

1. Supplies that you acquire either by purchase or by donation as cost sharing or matching under this award; and

2. Equipment for which title is vested conditionally in you, pending resolution of a Federal interest in the equipment. That includes equipment with a conditional title resulting from your having, either under this award or under a previous award from which you transferred accountability for the equipment to this award:

a. Directly charged as project costs, in whole or in part, either the purchase or fabrication of equipment;

b. Donated the equipment to the project by counting the value of the remaining life of the property recorded in your accounting records or the fair market value toward any cost sharing or matching requirements under the award, rather than charging depreciation (see PROP Article I, Section D); or

c. Directly charged as project costs improvements to the equipment that meet the criteria given in paragraph E.1 of PROP Article I.

Section B. Requirements for a State's use and disposition of equipment. You:

1. Must use the equipment for the authorized purposes of the project or program during the period of performance, or until the property is no longer needed for those purposes.

2. May not encumber the property without the prior written approval of the award administration office.

3. Must use and dispose of the equipment in accordance with your State laws and procedures, subject to the following condition. For any item of equipment that is not loner needed for the originally authorized purpose and has a current fair market value greater than $5,000, the disposition process must include either your:

a. Payment of compensation to us in the amount of the Federal interest in the equipment; or

b. Contacting the award administration office to work out a mutually agreeable alternative that takes into account the Federal and State interests in that item of equipment. Examples of alternatives, subject to the agreement of the award administration office, include:

(1) Deferring final disposition to allow continued use of the equipment on other federally supported projects or programs, as described in 2 CFR 200.313(c)(1);

(2) Agreeing to transfer title to the Federal Government or a third party, with compensation to you for the State interest in the equipment, as descried in 2 CFR 200.313(e)(3).

Section C. Use of equipment by an institution of higher education, nonprofit organization, local government, or Indian tribe.

1. You must use the equipment for the authorized purposes of the project under this award until the equipment is no longer needed for those purposes, whether or not the project or program continues to be supported by this award.

2. May not encumber the equipment without the prior written approval of the award administration office.

3. During the time that the equipment is used for the project under this award:

a. You must make the equipment available for use on other projects or programs but only if that use will not interfere with the equipment's use as needed for the project supported by this award.

(1) First preference must be given to other projects or programs supported or previously supported by DoD Components and second preference to those supported or previously supported by other Federal agencies.

(2) Third preference is for other projects or programs not supported by the Federal Government. You should charge user fees for use of the equipment in those cases, if it is at all practicable.

b. You may use the equipment, if you need to acquire replacement equipment, as a trade-in or sell it (using sales procedures designed to ensure the highest possible return) and use the proceeds from the sale to offset the cost of the replacement equipment.

4. When the equipment is no longer needed for the project under this award, you may defer final disposition of the equipment and continue to use it on other federally sponsored projects or programs. You must give first priority to other projects or programs supported by DoD Components.

5. Notwithstanding the encouragement in FMS Article VII to earn program income, you may not use equipment in which there currently is a Federal interest--whether you acquired it under this award or are otherwise accountable for it under this award--to provide services for a fee that is less than private companies charge for equivalent services.

Section D. Disposition of equipment by an institution of higher education, nonprofit organization, local government, or Indian tribe. You must request disposition instructions from the award administration office when either original or replacement equipment acquired under this award

with a current fair market value that exceeds $5,000 is no longer needed for the original project or program or for other federally sponsored activities as described in paragraph C.4 of this article. For each item of equipment with a current fair market value of $5,000 or less, you may retain, sell, or otherwise dispose of the item with no further obligation to the Federal Government.

1. We may issue disposition instructions that:

   a. Allow you to retain or sell any item of equipment after compensating us for the Federal interest in the property, which is to be computed as specified in the definition of "Federal interest."; or

   b. Require you to transfer title to the equipment to a Federal agency or a third party, in which *case you are entitled to compensation from us for the non-Federal interest in the equipment.*

2. If we fail to provide disposition instructions for any item of equipment within 120 calendar days of receiving your request, you may retain or sell the equipment but you must compensate us for the amount of the Federal interest in the equipment.

3. If you sell the equipment:

   a. You must use sales procedures designed to ensure the highest possible return; and

   b. You may deduct and retain for selling and handling expenses either $500 or ten percent of the proceeds, whichever is less.

Section E. Use and disposition of supplies acquired under this award.

1. Use. As long as we retain a Federal interest in supplies acquired under this award either by purchase or by donation as cost sharing or matching, you may not use the supplies to provide services to other organizations for a fee that is less than private companies charge for equivalent services, notwithstanding the encouragement in FMS Article VII to earn program income.

2. Disposition. If you have a residual inventory of unused supplies with aggregate value exceeding $5,000 at the end of the period of performance under this award, and the supplies are not needed for any other Federal award, you must retain the supplies or sell them but must in either case compensate us for the amount of the Federal interest in the supplies. You may deduct and retain for selling and handling expenses either $500 or ten percent of the proceeds, whichever is less.

PROP Article V. Use and disposition of federally owned property. (July 2016)

Section A. Use. During the time that federally owned property for which you are accountable under this award is used for the project or program supported by the award, you:

1. Also may make the property available for use on other federally supported projects or programs, but only if that use will not interfere with the property's use for the project supported by this award. You must give first priority to other projects or programs supported by DoD Components.

2. May use the property for purpose other than federally supported projects or programs only with the prior approval of the awarding office or, if you request approval after the award is made, the award administration office.

Section B. Disposition. You must request disposition instructions from the award administration office for any federally owned property under this award, including any property for which a subrecipient is accountable under a subaward you make under this award, either:

1. At any time during the period of performance if the property is no longer needed for the project or program supported by this award; or

2. At the end of the period of performance.

PROP Article VI. Intangible property. (JULY 2016)

Section A. Assertion of copyright.

1. You may assert copyright in any work that is eligible for copyright protection if you acquire ownership of it under this award, either by developing it or otherwise.

2. With respect to any work in which you assert copyright, as described in paragraph A.1 of this section, The DoD reserves a royalty-free, nonexclusive and irrevocable license to:

a. Reproduce, publish, or otherwise use the work for Federal Government purposes; and

b. Authorize others to reproduce, publish, or otherwise use the work for Federal Government purposes.

Section B. Inventions developed under the award.

1. **Applicability of Government wide clause for research awards.** You must comply with the Government wide patent rights award clause published at 37 CFR 401.14, with the modifications described in paragraph B.2 of this section. DoD adopts that Government wide clause for the following entities, thereby broadening the applicability beyond types of entities included in the definition of "contractor" in 37 CFR part 401:

a. Any governmental or nonprofit entity (the types of entities subject to these general terms and conditions) receiving a DoD award for the performance of experimental, research, or developmental work;

b. Any governmental, nonprofit, or for-profit entity receiving a subaward to perform experimental, research, or developmental work under an award described in paragraph B.1.a of this section.

2. **Modifications to the wording of the Government wide clause.** DoD adopts the Government wide clause at 37 CFR 401.14, as described in paragraph B.1 of this section, with the following modifications:

a. **Terminology.** Throughout the Government wide award clause:

(1) Insert the terms "recipient" and "subrecipient (or contractor to the recipient or to a subrecipient)" to replace the terms "contractor" and "subcontractor," respectively.

(2) Insert the terms "award" and "subaward" (or contract under either the award or a subaward)" to replace the terms "contract" and "subcontract," respectively.

b. **Final report.** Add a new subparagraph (f)(5) to read, "The recipient must submit a final report listing all subject inventions made under the award or stating that there were none. The final report is due 120 calendar days after the end date of the period of performance unless you request and we grant an extension of the due date."

c. **Broadening applicability to all entities.** Delete paragraphs (g) (2) and (3) of the Government wide clause, redesignate paragraph (g) (1) as paragraph (g), and delete the phrase "to be performed by a small business firm or domestic nonprofit organization" from paragraph (g) as redesignated.

Section C. Data produced under the award.

1. **Data in general.** We have the right to:

a. Obtain, reproduce, publish, or otherwise use the data produced under this award; and

b. Authorize others to receive, reproduce, publish, or otherwise use the data produced under this award for Federal Government purposes.

2. **Research data requested under the Freedom of Information Act (FOIA).**

a. If we receive a request under the FOIA for "research data" that are related to "published research findings" produced under this award and that were "used by the Federal Government in developing an agency action that has the force and effect of law," you must provide the data to us within a reasonable time after we request it from you, so that the data can be made available to the public through procedures established under the FOIA.

b. For purposes of the requirement in paragraph C.2.a of this section, 2 CFR 200.315(e) provides definitions of the phrases "published research findings," "used by the Federal Government in developing an agency action that has the force and effect of law," and "research data."

Section D. Use and disposition of intangible property acquired, but not developed or produced, under the award.

1. **Applicability**. This section applies to a patent, patent application, copyright, or other intangible property acquired, but not developed or produced, under this award.

2. **Use**. You:

a. Must use the intangible property for the authorized purpose under this award until the intangible property is no longer needed for that purpose, whether or not that purpose is still being supported by this award.

b. May not encumber the intangible property without the prior written approval of the award administration office.

3. **Disposition.** When the intangible property is no longer needed for the originally authorized purpose, you must contact the award administration office to arrange for disposition in accordance with the procedures specified for disposition of equipment in either section B or D of PROP Article IV, as applicable.

Part 4: Procurement

PROC Article I. Procurement Standards for States. (JULY 2016)

Section A. Use of State procurement system. Subject only to the conditions in Sections B through D of this article, you must use the same policies and procedures to procure supplies, equipment, real property, and services under this award that you use when you procure those items for State purposes using non-Federal funds.

Section B. Procurement of recovered materials. You must comply with the Resource Conservation and Recovery Act requirements described in OMB guidance in 2 CFR 200.322.

Section C. Debarment and suspension. You must comply with restrictions on awarding procurement transactions to excluded or disqualified parties and other requirements specified by OMB guidelines on nonprocurement debarment and suspension at 2 CFR part 180, as implemented by DoD at 2 CFR part 1125.

Section D. Contract provisions. You must include provisions in your procurement transactions under this award to require the contractors' compliance with the requirements specified in PROC Article III, as applicable.

PROC Article II. Procurement Standards for an Institution of Higher Education, Nonprofit Organization, Local Government, or Indian Tribe. (JULY 2016)

Section A. General procurement standards.

1. For procurement under this award, you must comply with the following paragraphs of OMB guidance in 2 CFR 200.318:

   a. 200.318(a) concerning documented procurement procedures;

   b. 200.318(b) concerning oversight of contractors;

   c. 200.318(c) concerning standards of conduct and conflicts of interest;

   d. 200.318(e) concerning intergovernmental or inter-entity agreements;

   e. 200.318(g) concerning value engineering;

   f. 200.318(i) concerning procurement records;

   g. 200.318(j) concerning time and material type contracts; and

h. 200.318(k) concerning settlement of issues arising out of procurements.

2. You must comply with OMB guidance in 2 CFR 200.318(d) concerning purchases of unnecessary or duplicative items with the following clarifications if this award supports research or research-related training:

a. You must avoid purchasing items that are unnecessarily duplicative (as opposed to items that are merely duplicative, as it is normal for a recipient carrying out research or research-related training activities to have many duplicative items being used simultaneously in different projects).

b. You are not required to conduct equipment surveys to comply with the requirement to avoid purchasing unnecessarily duplicative equipment under this award.

c. Your compliance with the policy on shared use of equipment purchased under this award in accordance with the implementation in PROP Article IV of OMB guidance at 2 CFR 200.313(c)(2), will help avoid purchases of unnecessarily duplicative items.

3. You are encouraged, as described in 2 CFR 200.318(f), to use Federal excess or surplus property in lieu of purchasing new equipment and property whenever such use is feasible and reduces project costs, with the following clarification. The encouragement to use Federal excess or surplus property is contingent not only on its being feasible but also on its not reducing the efficiency or effectiveness with which you can achieve the award's purposes. For example, the encouragement does not extend to use of older models of excess or surplus equipment under a research or research related training award to an institution of higher education when use of current models would accelerate data acquisition or enable better training of future scientists and engineers in the latest research techniques.

4. You must do business only with responsible contractors who are able to perform, as described in OMB guidance in 2 CFR 200.318(h). Related to that, you must comply with restrictions on awarding procurement transactions to exclude or disqualified parties and other requirements specified by OMB guidelines on nonprocurement debarment and suspension at 2 CFR part 180, as implemented by DoD at 2 CFR part 1125.

Section B. Competition. You must award procurement transactions under this DoD award in accordance with the competition requirements described in OMB guidance in 2 CFR 200.319.

Section C. Procurement methods. You must award procurement transactions under this award using methods described in OMB guidance in 2 CFR 200.320.

Section D. Contracting with small and minority businesses, women's business enterprises, and labor surplus area firms. You must take the affirmative steps described in OMB guidance in 2 CFR 200.321, using the applicable cost principles specified in FMS Article III, when awarding procurement transactions under this award.

Section E. Contract cost and price. You must follow the procedures related to costs and price that are described in OMB guidance in 2 CFR 200.323.

Section F. Contract provisions. You must include provisions in your contracts to require the contractors' compliance with the requirements of PROC Article III of this award, as applicable.

Section G. Procurement of recovered materials. – If you are a political subdivision of a State, you must comply with the Resource Conservation and Recovery Act requirements described in OMB guidance in 2 CFR 200.322.

Section H. Review of procurement documents. Upon our request, you must make available:

1. Technical specifications on proposed procurements, as described in 2 CFR 200.324(a).

2. Pre-procurement documents for our review, as described in 2 CFR 200.324(b) unless you are exempt from that requirement under 2 CFR 200.234(c).

Section I. Bonding requirements. – RESERVED.

PROC Article III. Contract Provisions for Recipient Procurements. (JULY 2016)

Section A. Contract provisions for administrative requirements.

1. **Remedies.** In any contract under this award for an amount in excess of the simplified acquisition threshold, you must provide for administrative, contractual, or legal remedies, including any appropriate sanctions and penalties, when the contractor violates or breaches the contract terms.

2. **Termination.** In any contract for an amount in excess of $10,000, you must specify: conditions under which you may terminate the contract for cause or convenience; the procedures for termination; and the basis to be used for settlement.

3. **Allowable costs under cost-type contracts.** In any cost-type contract with an entity, you must include a clause to permit the entity to charge to the contract only costs that are allowable under the cost principles that FMS Article VIII identifies as applicable to that type of entity, as supplemented by any award-specific terms and conditions related to allowability of costs that are included in this award. Your contract clause may permit the contractor to use its own cost principles in determining the allowability of its costs charged to the contract, as long as its cost principles comply with the applicable Federal cost principles supplemented by any award-specific terms and conditions of this award.

4. **Rights in copyright and data.** You must include in each contract under this award a provision requiring that the contractor:

   a. Grant the Government a royalty-free, nonexclusive and irrevocable right to:

(1) Reproduce, publish, or otherwise use for Federal purposes any work that is subject to copyright and that the contractor develops, or acquires ownership of, under this award;

(2) Authorize others to reproduce, publish, or otherwise use such work for Federal purposes; and

b. Grant the Government the right to:

(1) Obtain, reproduce, publish, or otherwise use data produced under this award;

(2) Authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes; and

c. Include The Government in each subcontract it makes the requirements described in:

(1) Paragraphs A.4.a.(1) and (2) of this section, to provide for Government rights in any works subject to copyright that the subcontractor develops, or acquires ownership of, under this award;

(2) Paragraphs A.4.b.(1) and (2) of this section, to provide for Government rights in any data that the subcontractor produces under this award.

5. **Access to records.**

a. In any negotiated, cost-type or time and materials contract for an amount in excess of the simplified acquisition threshold, you must provide for access to any of the contractor's books, documents, papers, and records that are directly pertinent to that contract, to enable and support audits, examinations, excerpts, and transcriptions. The contract provision must provide access to those records for all of the following and their duly authorized representatives:

(1) You;

(2) Us as the Federal awarding agency, including our Inspector General; and

(3) The Comptroller General of the United States.

b. In any audit services contract for performance of an audit required by the Single Audit Act, as implemented by OMB in Subpart F of 2 CFR part 200, you must provide for the access to audit documentation described in 2 CFR 200.517(b).

6. **Records retention.**

a. In any negotiated, cost-type or time and materials contract for an amount in excess of the simplified acquisition threshold, you must provide for retention of all records that are directly

pertinent to that contract for three years after you make final payment and all pending matters are closed.

b. In any audit services contract for performance of an audit required by the Single Audit Act, as implemented by OMB in Subpart F of 2 CFR part 200, you must provide for the retention of audit documentation described in 2 CFR 200.517(a).

7. **Reporting.** In any contract awarded under this award, you must include any provision for the contractor's reporting to you that may be needed in order for you to meet your requirements under this award to report to us.

Section B. Contract provisions for national policy requirements.

1. **Equal employment opportunity.** You must include the clause provided in 41 CFR 60-1.4(b) in any "federally assisted construction contract" (as defined in 41 CFR 60-1.3) under this award unless provisions of 41 CFR part 60-1 exempt the contract from the requirement. The clause will require the contractor to comply with equal opportunity requirements in 41 CFR Chapter 60.

2. **Wage Rate Requirements (Construction) – RESERVED.**

3. **Copeland Act prohibition on kickbacks.** In each contract under this award to construct, complete, or repair a building or work, you must:

a. Include a provision requiring the contractor to comply with the anti-kickback provisions of the Copeland Act (18 U.S.C. 874 and 40 U.S.C. 3145), as supplemented by Department of Labor regulations at 29 CFR part 3, "Contractors and Subcontractors on Public Building or Public Work Financed in Whole or in Part by Loans or Grants from the United States."

b. Report all suspected or reported violations to the award administration office identified in the award notice cover sheet of this award.

4. **Contract Work Hours and Safety Standards Act for work involving mechanics or laborers.** In each contract for an amount greater than $100,000 that involves the employment of mechanics or laborers and is not a type of contract excepted under 40 U.S.C. 3701, you must include the clauses specified in Department of Labor (DoL) regulations at 29 CFR 5.5(b) to require use of wage standards that comply with the Contract Work Hours and Safety Standards Act (40 CFR, Subtitle II, Part A, Chapter 37), as implemented by the DoL at 29 CFR part 5, "Labor Standards Provisions Applicable to Contracts Governing Federally Financed and Assisted Construction."

5. **Patents and inventions.** If you procure the services of a nonprofit organization, small business firm, or other entity for the performance of experimental, developmental or research work, you must include in the contract the clause that Section B of PROP Article VI specifies to establish requirements for the contractor with respect to subject inventions resulting from the contract and provide for Government rights in those inventions.

6. **Clean air and water requirements.** You must:

a. In each contract for an amount greater than $150,000 under this award, include a clause requiring the contractor to comply with applicable provisions of the Clean Air Act (42 U.S.C. 7401-7671q), Federal Water Pollution Control Act (33 U.S.C. 1251-1387), and standards, orders, or regulations issued under those acts; and

b. Report any violations of the Acts, standards, orders, or regulations to both the award administration office identified in the award notice cover sheet of this award and the appropriate regional office of the Environmental Protection Agency.

7. **Nonprocurement suspension and debarment.** Unless you have an alternate method for requiring the contractor's compliance, you must include a clause in each contract for an amount equal to or greater than $25,000 and in each contract for federally required audit services to require the contractor to comply with Office of Management and Budget guidance on nonprocurement suspension and debarment in 2 CFR part 180, Subpart C, as implemented by Department of Defense regulations at 2 CFR part 1125.

8. **Byrd Amendment anti-lobbying requirements.** In each contract for an amount exceeding $100,000, you must include a clause requiring the contractor to submit to you the certification and any disclosure forms regarding lobbying that are required under 31 U.S.C. 3152, as implemented by the Department of Defense at 32 CFR part 28.

9. **Purchase of recovered materials by States or political subdivisions of States.** In each contract under which the contractor may purchase items designated in Environmental Protection Agency (EPA) regulations in 40 CFR part 247, subpart B, you must include a clause requiring the contractor to comply with applicable requirements in those EPA regulations, which implement Section 6002 of the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6962).

10. **Fly America requirements.** In each contract under which funds provided under this award might be used to participate in costs of international air travel or transportation for people or property, you must include a clause to require the contractor to:

a. Comply with the International Air Transportation Fair Competitive Practices Act of 1974 (49 U.S.C. 40118, also known as the "Fly America" Act), as implemented by the General Services Administration at 41 CFR 301-10.131 through 301-10.143, which provides that U.S Government-financed international air travel and transportation of personal effects or property must use a U.S. Flag air carrier or be performed under a cost-sharing arrangement with a U.S. carrier, if such service is available; and

b. Include the requirements of the Fly America Act in all subcontracts that might involve international air transportation.

11. **Cargo preference for United States flag vessels.** In each contract under which equipment, material, or commodities may be shipped by oceangoing vessels, you must include the clause specified in Department of Transportation regulations at 46 CFR 381.7(b) to require that at least 50 percent of equipment, materials or commodities purchased or otherwise obtained with Federal funds under this award, and transported by ocean vessel, be transported on privately owned U.S.-flag commercial vessels, if available."

Part 5: Financial, Programmatic, and Property Reporting

REP Article I. Performance reporting. (JULY 2016)

Section A. Required reporting form, format, or data elements for interim and final performance reports. RESERVED.

Section B. Frequency, reporting periods, and due dates for interim performance reports. RESERVED.

Section C. Due date and reporting period for final performance report.

1. **Due date.** You must submit the final performance report under this award no later than 120 calendar days after the end date of the period of performance unless we approve an extension of that due date as described in Section D of this article.

2. **Reporting period.** Final reports for research awards must be cumulative (i.e., each final report should cover the entire period of performance under the award and not just the period since the previous interim performance report).

Section D. Extensions of due dates. You may request extensions of the due dates that Sections B and C of this Article specify for interim and final reports. You must provide the reasons for your request and we will approve extensions that are adequately justified.

Section E. Reporting significant developments. You must report the following information to us as soon as you become aware of it:

1. Problems, delays, or adverse conditions that will materially impair your ability to meet the objectives of this award. This disclosure must include a statement of the action taken, or contemplated, and any assistance needed to resolve the situation.

2. Favorable developments which will enable you to meet schedules and objectives sooner or at less cost than anticipated or produce more or different beneficial results than originally planned.

Section F. Performance reporting procedures. RESERVED.

Section G. Site visits. We reserve the right to make site visits as warranted to monitor program performance under this award.

REP Article II. Financial reporting. (JULY 2016JULY 2016)

Section A. Required reporting form, format, or data elements for interim and final financial reports. RESERVED.

Section B. Interim financial reports: frequency, reporting periods, and due dates. RESERVED.

Section C. Final financial report. You must submit the final financial report under this award no later than 120 calendar days after the end date of the period of performance.

Section D. Extensions of due dates. You may request extensions of the due dates that Sections B and C of this Article specify for interim and final reports, respectively. You must provide the reasons for your request, and we will approve extensions that are adequately justified.

Section E. Where and how to submit financial reports. RESERVED.

REP Article III. Reporting on property. (JULY 2016)

Section A. Real property. Paragraphs A.1 through A.4 apply to real property for which you are accountable under this award, for as long as there is a Federal interest in the property (whether that interest is due to you or a subrecipient having acquired or improved the property under this award, or a transfer of the accountability for the property to this award from another award).

1. **Periodic status reports.** You must submit periodic status reports, as follows:

    a. Frequency and duration of reporting requirement. **RESERVED.**

    b. Due dates. **RESERVED.**

    c. Other submission instructions. **RESERVED.**

2. **Notifications of critical changes.** You must notify the award administration office of any critical change in the status of real property as soon as feasible after you become aware of it. A critical change is any event with a significant adverse impact on the condition or value of the property, such as damage due to fire; flood, hurricane, or other severe weather; earthquake; or accident.

3. **Requests for disposition instructions.** You must comply with applicable requirements in PROP Article III to request disposition instructions, either during the period of performance or at closeout.

4. **Closeout accounting.** You must account to the award administration office for real property at the time of closeout of the award, as required by Section D of OAR Article VI.

Section B. Equipment and supplies. Paragraphs B.1 through B.4 apply to equipment or supplies for which you are accountable under this award and in which there is a Federal interest (whether that interest is due to you or a subrecipient having acquired or improved the property under this award, or a transfer of the accountability for the property to this award from another award).

1. **Periodic status report.** There is no requirement for periodic reporting during the period of performance.

2. **Notifications of loss, damage, or theft.** You must comply with applicable requirements in PROP Article II governing your property management system to promptly notify the award administration office of any loss, damage or theft of equipment.

3. **Requests for disposition instructions.** You must comply with applicable requirements in PROP Article IV to request disposition instructions for equipment, either during the period of performance or at closeout.

4. **Closeout accounting.**

   a. **Equipment.** You must account to the award administration office for equipment at the time of closeout of this award, as required by Section D of OAR Article VI.

   b. **Supplies.** If you have a residual inventory of unused supplies that meets the criteria specified in paragraph E.2 of PROP Article IV, you must as part of your closeout accounting arrange with the award administration office for the compensation that paragraph specifies for the Federal interest in the supplies.

Section C. Federally owned property. Paragraphs C.1 through C.4 apply to federally owned property for which you are accountable under this award.

1. **Annual inventory.** You must submit annually to the award administration office an inventory of federally owned property.

2. **Notifications of loss, damage, or theft.** As provided in PROP Article II governing your property management system, you must promptly notify the award administration office of any loss, damage, or theft of federally owned property.

3. **Requests for disposition instructions.** You must comply with requirements in Section B of PROP Article V to request disposition instructions, either during the period of performance or at closeout.

4. **Closeout accounting.** Your requests for disposition instructions for federally owned property, as described in paragraph C.3 of this section, satisfy the need to account for federally owned property at closeout (see Section D of OAR Article VI).

Section D. Intangible property. Paragraphs D.1 through D.3 apply to intangible property for which you are accountable under this award.

1. **Inventions developed under the award.** You must submit all reports on subject inventions developed under this award that are required by the modified Government wide patent rights award provision specified in Section B of PROP Article VI, which include a disclosure of each subject invention and a final report listing all such subject inventions.

2. **Copyrights and data.** You are not required to submit periodic reports about data produced under this award or about works for which you acquired ownership under this award, either by development or otherwise, and in which copyright was asserted. However, because the Federal Government has the rights in the works and data that Sections A and C of PROP Article VI specify, you must provide information about the works and data if we request it.

3. **Intangible property acquired, but not developed or produced, under the award.** You must comply with requirements in Section D of PROP Article VI to request disposition instructions for intangible property acquired, but not developed or produced, under the award.

REP Article IV. Reporting on subawards and executive compensation. (OCTOBER 2015)

You must report information about subawards and executive compensation as specified in the award term in Appendix A to 2 CFR part 170, "Reporting subaward and executive compensation information," modified as follows:

1. To accommodate any future designation of a different Government wide Web site for reporting subaward information, the Web site "http://www.fsrs.gov" cited in paragraphs a.2.i. and a.3 of the award provision is replaced by the phrase "http://www.fsrs.gov or successor OMB-designated Web site for reporting subaward information";

2. To accommodate any future designation of a different Government wide Web site for reporting executive compensation information, the Web site "http://www.sam.gov" cited in paragraph b.2.i. of the award provision is replaced by the phrase "https://www.sam.gov or successor OMB-designated Web site for reporting information on total compensation"; and

3. The reference to "Sec. ___.210 of the attachment to OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations" in paragraph e.3.ii of the award term is replaced by "2 CFR 200.330, as implemented in SUB Article I of this award."

Part 6: Other Administrative Requirements

OAR Article I. Submitting and maintaining recipient information. (JULY 2016)

Section A. System for Award Management.

1. Unless you are exempted from this requirement based on the criteria provided in OMB guidance in section 25.110 of 2 CFR part 25, you must maintain the currency of information about yourself in the system the Federal Government specifies as the repository for information about its business partners (currently the System for Award Management).

2. You must maintain the information in that system until you submit the final financial report required under this award or receive the final payment, whichever is later.

3. You must review and update the information at least annually after your initial registration in the system and more frequently if required by changes in your information. The one exception is the integrity and performance information that you report through the System for Award Management to the designated performance and integrity information system, in accordance with Section B of this article. That information must be reviewed and updated at least semiannually, as described in paragraph B.4 of that section.

Section B. Reporting of Performance and Integrity Information.

1. General reporting requirement. If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal agencies exceeds $10,000,000 for any period of time during the period of performance of this award, then during that period of time you must maintain the currency of information that you are required by paragraph B.2 of this section to report to the information system designated by the Federal Government for that purpose. Note that:

a. This reporting is required under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313).

b. As required by section 3010 of Public Law 111-212, all performance and integrity information posted in the designated information system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available.

c. The currently designated information system is the Federal Awardee Performance and Integrity Information System (FAPIIS). Recipient information is submitted to that system through the System for Award Management, as described in paragraph B.3 of this section.

2. Proceedings about which you must report. Submit the information that the designated information system requires about each proceeding that:

a. Is in connection with the award or performance of a grant, cooperative agreement, or procurement contract from the Federal Government;

b. Reached its final disposition during the most recent 5 year period; and

c. Is one of the following:

(1) A criminal proceeding that resulted in a conviction, as defined in paragraph B.5. of this section;

(2) A civil proceeding that resulted in a finding of fault and liability and payment of a monetary fine, penalty, reimbursement, restitution, or damages of $5,000 or more;

(3) An administrative proceeding, as defined in paragraph B.5. of this section, that resulted in a finding of fault and liability and your payment of either monetary fine or penalty of $5,000 or more or a reimbursement, restitution, or damages in excess of $100,000; or

(4) Any other criminal, civil, or administrative proceeding if:

(a) It could have led to an outcome described in paragraph B.2.c.(1), (2), or (3) of this section;

(b) It had a different disposition arrived at by consent or compromise with an acknowledgment of fault on your part; and

(c) The requirement in this section to disclose information about the proceeding does not conflict with applicable laws and regulations.

3. Reporting procedures. Submit the required information about types of proceedings described in paragraph B.2 of this section to the Entity Management functional area of the System for Award Management.

a. Current procedures are to submit the information as part of the maintenance of your information in the System for Award Management that Section A of this article requires.

b. You do not need to submit the information again under this award if you already reported current information to the System for Award Management under another Federal grant, cooperative agreement, or procurement contract.

4. Reporting frequency. During any period of time when you are subject to the requirement in paragraph B.1 of this section, you must report to FAPIIS no less frequently than semiannually following your initial report of any proceedings for the most recent 5-year period, either to provide new information about any proceeding(s) that you have not reported previously or affirm that there is no new information to report.

5. **Definitions.** For purposes of this section:

a. *Administrative proceeding* means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals proceedings, and Armed Services Board of Contract Appeals proceedings). This includes proceedings at the Federal and State level but only in connection with performance of a Federal contract, grant, or cooperative agreement. It does not include audits, site visits, corrective plans, or inspection of deliverables.

b. *Conviction* means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, and includes a conviction entered upon a plea of nolo contendere.

c. *Total value of currently active grants, cooperative agreements, and procurement contracts* includes:

(1) Only the Federal share of the funding under any Federal agency award with a recipient cost share or match; and

(2) Value of all expected funding increments and options, even if not yet exercised, under each Federal agency award.

Section C. Disclosure of evidence of integrity-related issues.

1. **Disclosure requirement.** At any time during the period of performance of this award, if you have credible evidence that a covered person committed a covered action (see paragraphs C.2 and C.3 of this section) that may affect this award, you must disclose the evidence in writing to the Office of the Inspector General, DoD, with a copy to the grants officer identified in the cover pages.

2. **Covered person.** As the term is used in this section, "covered person" means a principal, employee, or agent of either you or a subrecipient under this award, where:

a. "Principal" means:

(1) An officer, director, owner, partner, principal investigator, or other person with management or supervisory responsibilities that relate to this award; or

(2) A consultant or other person, whether or not employed by you or a subrecipient or paid with funds under this award, who:

(a) Is in a position to handle funds under this award;

(b) Is in a position to influence or control the use of those funds; or

(c) Occupies a technical or professional position capable of substantially influencing the development or outcome of an activity required to perform the project or program under this award.

b. "Agent" means any individual who acts on behalf of, or who is authorized to commit you or the subrecipient, whether or not employed by you or the subrecipient.

3. **Covered action.** As the term is used in this section, "covered action" means a violation of Federal criminal law in Title 18 of the United States Code involving fraud, bribery, or a gratuity violation.

4. **Safeguarding of the information.**

a. To the extent permitted by law and regulation, we will:

(1) Safeguard and treat information you disclose to us as confidential if you mark the information as "confidential" or "proprietary."

(2) Not release the information to the public in response to a Freedom of Information Act (5 U.S.C. 552) request without notifying you in advance.

b. We may transfer documents you provide to us to any other department or agency within the Executive Branch of the Federal Government if the information relates to matters within that organization's jurisdiction.

OAR Article II. Records retention and access. (JULY 2016)

Section A. Records retention period. Except as provided in Sections B through D of this article:

1. You must keep records related to any real property and equipment acquired, in whole or in part, using Federal funds under the award for three years after final disposition of the property. For any item of excepted property with a current fair market value greater than $5,000, and for which final disposition was not a condition of the title vesting, you must keep whatever records you need for as long as necessary to ensure that you can deduct the Federal share if you later use the property in contributions for cost sharing or matching purposes under any Federal award.

2. You must keep records related to rate proposals for indirect or facilities and administration costs, cost allocation plans, and supporting records such as indirect cost rate computations and any similar accounting computations of the rate at which a particular group of costs is chargeable (such as computer usage chargeback or composite fringe benefit rates) as follows:

a. If you are required to submit a proposal, plan, or other computations to your Federal cognizant agency for indirect costs, as the basis for negotiation of a rate, you must keep the submitted

materials and supporting records for 3 years from the date on which you were required to submit the materials.

b. If you are not required to submit a proposal, plan, or other computations as the basis for negotiation, you must keep the proposal, plan, other computations, and supporting records for three years from the end of the fiscal year or other accounting period covered by the proposal, plan, or other computation.

3. You must keep other financial records, supporting documents, statistical records, and other records pertinent to this award for a period of three years from the date you submit your final financial report under the award.

Section B. Extensions of retention period due to litigation, claim, or audit.

1. If any litigation, claim, or audit begins before the end of the three-year retention period specified in section A of this article and the final action related to the litigation, claim, or audit is not taken before the end of that three-year period, you must retain all records related to this award that may be involved in the litigation, claim, or audit until all findings involving the records have been resolved and final action taken.

2. We may disallow costs and recover funds under this award based on an audit or other review of records during the record retention period, including any extension to that retention period that we required in a written notification to you.

Section C. Records for program income earned after the end of the performance period. In accordance with Section F of FMS Article VII, there are no requirements under this award applicable to program income you earn after the end of the period of performance and therefore no associated records retention requirements.

Section D. Records for joint or long-term use.

1. **Joint use.** To avoid duplicate recordkeeping for records that you and we both need to use on a continuous basis, we may ask you to make special arrangements with us, by mutual agreement, to make records available for joint and continuous use.

2. **Long-term use.** If we determine that some records will be needed longer than the three-year period specified in section A of this article, we may request that you either:

a. Retain the records for a longer period of time; or

b. Transfer the records to our custody for long-term retention.

3. **Retention requirements for transferred records.** For any records transferred to our custody, you are not subject to the records retention requirements in Section A of this article.

Section E. Methods for collecting, transmitting, and storing information.

1. You should, whenever practicable, collect, transmit, and store information related to this award in open and machine readable formats rather than in closed formats or on paper. However, if you request it, we will:

a. Provide award related-information to you on paper; and

b. Accept award related-information from you on paper. In that case, we will not require more than an original and two copies.

2. When your original records are in an electronic form that cannot be altered, you do not need to create and retain paper copies of those records.

3. When your original records are on paper, you may substitute electronic versions produced through duplication or using other forms of electronic media, provided that:

a. You conduct periodic quality control reviews of the records;

b. You provide reasonable safeguards against alteration of the records; and

c. The records remain readable.

Section F. Access to records.

1. **Scope of Government access rights.**

a. We as the awarding agency, the Federal Government Inspectors General, the Comptroller General of the United States, and any of our authorized representatives have the right of access to any documents, papers, or other records you have that are pertinent to this award, in order to make audits, examinations, excerpts, and transcripts.

b. This right also includes timely and reasonable access to your personnel for the purposes of interview and discussion related to the records.

c. As described in OMB guidance at 2 CFR 200.336(b), the access to records described in this section will include access to the true name of a victim of a crime only under extraordinary and rare circumstances.

(1) You are required to provide that access only in response to a court order or subpoena pursuant to a bona fide confidential investigation, or in response to a request duly authorized by the head of the DoD Component or his or her designee; and

(2) You must take appropriate steps to protect this sensitive information.

2. **Duration of Government access rights.** We have the access rights described in paragraph F.1 of this section as long as you retain the records.

3. **Public access.**

a. You must comply with requirements to protect information that Federal statute, Executive order, or regulation requires to be protected (e.g., personally identifiable or export controlled information), to include both information generated under this award and information provided to you and identified as being subject to protection. Other than those limitations on dissemination of information, we place no restrictions on you that limit public access to your records pertinent to this award.

b. We do not place any requirements on you to permit public access to your records separate from any Federal, State, or local statute that may require you to do so.

c. The Federal Freedom of Information Act (FOIA, 5 U.S.C. 552) does not apply to records in your possession but records you provide to us generally will be subject to FOIA, with the applicable exemptions.

OAR Article III. Remedies and termination. (JULY 2016)

Section A. Remedies for noncompliance.

1. If you materially fail to comply with a term or condition of this award or an applicable Federal statute or regulation, we may amend this award to impose specific additional conditions as described in OMB guidance in 2 CFR 200.207. If we determine that the imposition of those additional conditions is insufficient to remedy the noncompliance, we may take one or more of the following actions that we deem appropriate to the circumstances:

a. Temporarily withhold cash payments pending:

(1) Your correction of the deficiency; or

(2) Our taking more severe enforcement action.

b. Disallow (that is, deny both use of funds and any applicable cost-sharing or matching credit for) all or part of the cost of the activity or action not in compliance;

c. Suspend or terminate this award, in whole or in part (suspension of an award is a separate and distinct action from suspension of a person under 2 CFR parts 180 and 1125, as noted in paragraph A.3 of this article);

d. Withhold further awards to you for the project or program that is not in compliance;

e. Take any other action legally available to us under the circumstances.

2. You may raise an objection to our taking any remedy we take under paragraph A.1 of this section and will be given an opportunity to provide information and documentation challenging the action. The procedures are those specified in OAR Article IV for claims and disputes.

3. Our use of any remedy under paragraph A.1 of this section, including suspension or termination of the award, does not preclude our referring the noncompliance to a suspension and debarment official and asking that official to consider initiating a suspension or debarment action under 2 CFR part 1125, the DoD implementation of OMB guidance at 2 CFR part 180.

Section B. Termination.

1. This award may be terminated in whole or in part as follows:

a. **Unilaterally by the Government.** We will provide a notice of termination if we unilaterally terminate this award in whole or in part, which we may do for either of the following reasons:

(1) Your failure to comply with the award terms and conditions. If we terminate the award for that reason, we will report the termination to the Federal Awardee Performance and Integrity Information System (FAPIIS). In accordance with 41 U.S.C. §2313, each Federal awarding official must review and consider the information in FAPIIS with regard to any proposal or offer before awarding a grant or contract.

(2) The program office does not have funding for an upcoming increment if this award is incrementally funded. In that case, the Government's financial obligation does not exceed the amount currently obligated under the award.

b. **By mutual agreement.** Upon written notification of termination to you and with your consent, we may terminate this award, in whole or in part, for any reason. In that case, you and we must agree to:

(1) The termination conditions, including the effective date; and

(2) In the case of a partial termination, the portion to be terminated.

c. **Unilaterally by the recipient.** You may unilaterally terminate this award, in whole or in part, by sending us written notification that states:

(1) The reasons for the termination;

(2) The effective date; and

(3) In the case of partial termination, the portion to be terminated. In that case, however, we may terminate the award in its entirety if we determine that the remaining portion of the award will not accomplish the purposes for which we made the award.

2. If this award is terminated in its entirety before the end of the performance period, you must complete the closeout actions for which you are responsible under OAR Article VI. The due date for each action is to be measured relative to the date of termination instead of the end date of the performance period as OAR Article VI specifies.

3. If this award is only partially terminated before the end of the performance period, with a reduced or modified portion of the award continuing through the end of the performance period, then closeout actions will occur at the end of the performance period as specified in OAR Article VI.

4. You will continue to have all of the post-closeout responsibilities that OAR Article VII specifies for you if this award is wholly or partially terminated before the end of the performance period.

Section C. Effects of suspension or termination of the award on allowability of costs. If we suspend or terminate this award prior to the end of the period of performance, costs resulting from obligations that you incurred:

1. Before the effective date of the suspension or termination are allowable if:

a. You properly incurred those obligations;

b. You did not incur the obligations in anticipation of the suspension or termination;

c. In the case of termination, the costs resulted from obligations that were noncancellable after the termination; and

d. The costs would have been allowable if we had not suspended or terminated the award and it had expired normally at the end of the period of performance.

2. During the suspension or after the termination are not allowable unless we expressly authorize them, either in the notice of suspension or termination or subsequently.

OAR Article IV. Claims, disputes and appeals. (JULY 2016)

Section A. Definitions.

1. **Claim.** The definition of the term "claim," as it is used in this article, is in Part 1, Definitions.

2. **Grant Appeal Authority. RESERVED.**

Section B. Submission of claims.

1. **Your claims.** To submit a claim arising out of this award, you must submit it in writing to the grants officer for decision; specify the nature and basis for the relief you are requesting, and include all data that supports your claim.

2. **Government claims.** You will receive a written grants officer's decision if a DoD claim arises out of this award.

Section C. Alternative dispute resolution.

1. We encourage resolution of all issues related to this award by mutual agreement between you and the grants officer.

2. If you and the grants officer are unable to resolve an issue through unassisted negotiations, we encourage use of Alternative Dispute Resolution (ADR) procedures to try to do so. ADR procedures are any voluntary means, such as mini-trials or mediation, used to resolve issues in controversy. ADR procedures may be used prior to submission of a claim or at any other time prior to the Grant Appeal Authority's decision on any appeal you submit.

Section D. Grants officer decisions for claims you submit.

1. Within 60 calendar days of receiving your claim, the grants officer will either:

a. Transmit a written decision that:

(1) Identifies data on which the decision is based; and

(2) Identifies and provides the mailing address for the Grant Appeal Authority to whom you would submit an appeal of the decision if you elect to do so; or

b. If more time is required to render a written decision, notify you of a specific date when he or she will render the decision and inform you of the reason for delaying it.

2. The grants officer's decision will be final unless you decide to appeal, in which case we encourage use of ADR procedures as noted in Section C of this article.

Section E. Formal administrative appeals.

1. **Right to appeal.** You have the right to appeal a grants officer's decision to the Grant Appeal Authority identified in Section A of this article.

2. **Notice of appeal.** You may appeal a grants officer's decision within 90 calendar days of receiving the decision by submitting a written notice of appeal to the Grant Appeal Authority and grants officer. If you elect to use ADR procedures, you are allowed an additional 60 calendar days to submit the written notice of appeal to them.

3. **Appeal file.** Within 30 calendar days of the grants officer's receipt of your notice of appeal, you should receive the appeal file with copies of all documents relevant to the appeal. You may supplement the file with other documents you deem relevant and with a memorandum in support of your position for the Grant Appeal Authority's consideration. The Grant Appeal Authority may request additional information from you.

4. **Decision.** Unless the Grant Appeal Authority decides to conduct fact-finding procedures or an oral hearing on the appeal, the appeal will be decided solely on the basis of the written record. Any fact-finding or hearing will be conducted using procedures that the Grant Appeal Authority deems appropriate.

Section F. Representation. You may be represented by counsel or any other designated representative in any claim, appeal, or ADR proceeding, as long as the representative is not otherwise prohibited by law or regulation from appearing before the DoD Component concerned.

Section G. Non-exclusivity of remedies. Nothing in this article is intended to limit your right to any remedy under the law.

OAR Article V. Collection of amounts due. (JULY 2016)

Section A. Establishing a debt.

1. Any amount paid to you in excess of the amount to which you are determined to be entitled under the terms and conditions of this award constitutes a debt to the Federal Government.

2. A grants officer will attempt to resolve any claim of your indebtedness arising out of this award by mutual agreement.

3. If the grants officer fails to resolve the claim in that manner, you will receive a written notice of the grants officer's decision formally determining the debt, as described in paragraph B.2 of OAR Article IV. The notice will describe the debt, including the amount, name and address of the official who determined the debt, and a copy of that official's determination.

Section B. Debt delinquency and appeals.

1. Within 30 calendar days of the grants officer's decision, you must either pay the amount owed to the address provided in the written notice or inform the grants officer that you intend to appeal the decision.

2. If you elect not to appeal, any amounts not paid within 30 calendar days of the grants officer's decision will be a delinquent debt.

3. If you elect to appeal the grants officer's decision, you will have 90 calendar days after receipt of the grants officer's decision to file your appeal unless Alternative Dispute Resolution (ADR) procedures are used, as described in section C of OAR Article IV, in which case you will have 150 calendar days.

Section C. Demand letter, interest, and debt collection.

1. If within 30 calendar days of the grants officer's decision, you neither pay the amount due nor provide notice of your intent to appeal the grants officer's decision, the grants officer will send you a demand letter identifying a payment office that will be responsible for any further debt collection activity.

2. If you do not pay by the due date specified in the written demand letter, the Federal Government may collect part or all of the debt by:

a. Making an administrative offset against your requests for reimbursements under Federal awards;

b. Withholding advance payments otherwise due to you; and

c. Any other action permitted by Federal statute.

3. The debt will bear interest, and may include penalties and other administrative costs, in accordance with applicable provisions of the DoD Financial Management Regulation (DoD 7000.14-R), which implements the Federal Claims Collection Standards. The date from which interest is computed is not extended by litigation or the filing of any form of appeal.

OAR Article VI. Closeout. (JULY 2016)

Section A. Liquidation of obligations. Unless the award administration office authorizes an extension of the due date, you must liquidate all obligations that you incurred under this award not later than 120 calendar days after the end date of the period of performance.

Section B. Refunds of unobligated balances. You must promptly refund to the award administration office any balances of unobligated cash that we have advanced or paid to you and not authorized you to use on other projects.

Section C. You must submit the:

1. Final performance report under this award no later than the date specified in Section C of REP Article I, subject to any extensions granted under Section D of that article;

2. Final financial report under this award no later than the date specified in Section C of REP Article II, subject to any extensions granted under Section D of that article.

3. Final report listing subject inventions made under the award no later than the date specified in Section B of PROP Article VI; and

4. Other final reports that are required under this award no later than 120 calendar days after the end date of the period of performance, unless you request an extension of the due date and the award administration office approves the request.

Section D. Accounting for property. You must account for any real property, equipment, supplies, and intangible property that you and any subrecipients acquired or improved under the award, in accordance with PROP Articles I through IV and VI. Your requests for disposition instructions for any federally owned property, as required by PROP Article V, meet the need described in OMB guidance at 2 CFR 200.343(f) to account for that property at closeout.

OAR Article VII. Post-closeout adjustments and continuing responsibilities. (JULY 2016)

Section A. Adjustments. The closeout of this award does not affect:

1. Our right to disallow costs and recover funds on the basis of a later audit or other review, as long as we make the determination that the costs are disallowed and notify you about that determination as specified in paragraph B.2 of OAR Article II of these terms and conditions.

2. Your obligation to return any funds due to the Federal Government as a result of later refunds, corrections, or other transactions (to include any adjustments in final indirect cost rates).

Section B. Continuing responsibilities. After closeout of this award, you must continue to comply with terms and conditions of this award that have applicability beyond closeout, including requirements concerning:

1. Audits, as specified in FMS Article V that cover periods of time during which you expended funds under this award.

2. Management, use, and disposition of any real property or equipment acquired or improved under this award in which we continue to have a Federal interest after closeout, as specified in PROP Articles I through IV.

3. Retention of, and access to, records related to this award, as specified in OAR Article II.

Part 7: SUBAWARDS

SUB Article I. Distinguishing subawards and procurements. (JULY 2016)

Section A. Required recipient determination. For each transaction into which you enter with another entity at the next tier below this award, you must determine whether the transaction is a subaward or procurement.

Section B. Considerations in making the determination.

1. The primary purpose of the transaction between you and the other entity is the key factor you must use to determine whether the transaction is a subaward or procurement.

   a. The transaction is a subaward and the other entity therefore a subrecipient if the transaction's primary purpose is for you to transfer—for performance by the other entity—a portion of the substantive program for which we are providing financial assistance to you through this award. You will continue to be accountable to us for performance of the program under the award, including portions performed by any subrecipients.

   b. The transaction is a procurement and the other entity therefore your contractor if the transaction's primary purpose is for you to purchase goods or services that you need to perform the substantive program supported by this award. The distinction from a subaward is the contractor is not performing a portion of the substantive program as a result of the transaction.

2. What you call the transaction is not a factor in distinguishing a subaward from a procurement. If the transaction meets the criterion in paragraph B.1.a of this article, it is a subaward for purposes of the requirements of this award even if you call and consider the transaction a "contract."

Section C. Effect of the determination on the next-tier transaction.

1. **Process for awarding the transaction.** One important consequence of your determining whether a next-tier transaction is a subaward or procurement is that there are different requirements governing the pre-award and time of award processes that you use to award the transaction.

   a. SUB Article II of this award specifies pre-award and time of award responsibilities for subawards.

   b. PROC Articles I and II of this award govern pre-award and time of award process for awarding procurement transactions.

2. **Transaction terms and conditions.** A second important consequence of your determining whether a next-tier transaction is a subaward or procurement is that the terms and conditions you include in a subaward differ from those you include in a procurement transaction.

a. Section C of SUB Article II of this award addresses requirements you must include in subaward terms and conditions. Those requirements are generally either identical with or directly related to requirements in the general terms and conditions of this award with which you must comply. They include national policy requirements as well as administrative requirements in areas such as financial and programmatic management, property administration, procurement, and reporting.

b. PROC Article III of this award lists requirements you must include in a procurement transaction when applicable to the procurement.

SUB Article II. Pre-award and time of award responsibilities. (JULY 2016)

Section A. Requirements for Unique Entity Identifiers.

1. **Definition of "entity."** For purposes of the Unique Entity Identifier requirements in paragraphs A.2 and 3 of this section, "entity" has the meaning given in paragraph C.3 of the Appendix to OMB guidance in 2 CFR part 25.

2. **Pre-notification of potential subrecipients.** You must notify potential subrecipients that no entity may receive a subaward from you under this award unless it has provided its unique entity identifier to you.

3. **Restriction on making subawards.**

a. General. You may not make a subaward to an entity unless the entity has provided its unique entity identifier to you.

b. Exception. You may make a subaward to an entity that has not provided its Unique Entity Identifier to you in rare cases in which you requested and we approved an exemption from the requirement for the entity to provide a unique entity identifier, based on the criteria in paragraph 25.110 (d) of OMB guidance in 2 CFR part 25.

Section B. Pre-award risk assessment.

1. Before making a subaward to an entity, you must perform a risk assessment of the prospective subrecipient, as described in 2 CFR 200.331(b). OMB guidance in 2 CFR 200.205(c) provides examples of factors you may consider in evaluating risk.

2. As part of the risk assessment under paragraph B.1 of this article, you must:

a. Verify that neither the prospective subrecipient nor its principals under the subaward are excluded or disqualified from participating in the transaction, in accordance with requirements in Subpart C of OMB guidance in 2 CFR part 180, as implemented by DoD at 2 CFR part 1125; and

b. If warranted by risks you identify, determine whether to impose award-specific terms and conditions in the subaward to mitigate the risks.

(1) These award-specific terms and conditions may be in addition to, or differ from, the terms and conditions that SUB Articles IV through IX of this award require you to include in subawards.

(2) They may include items such as those listed in OMB guidance in 2 CFR 200.207(a) (1) through (6).

(3) Your procedures for imposing and removing the additional or different requirements must comply with the procedural guidance in 2 CFR 200.207(b) and (c).

Section C. Subaward content.

1. **Cost-type subawards.**

a. SUB Article III of this award specifies informational content that you must include in each cost-type subaward.

b. SUB Articles IV through VIII specify administrative requirements that you must include:

(1) As applicable, in each cost-type subaward to:

(a) A domestic U.S. entity (i.e., an entity other than a foreign public entity or a foreign organization); or

(b) An organizational unit of a foreign organization if that unit has a place of business in the United States; and

(c) To the maximum extent practicable in each cost-type subaward to a foreign public entity or an organizational unit of a foreign organization that does not have a place of business in the United States. However, absent our prior approval, you may not allow that foreign entity or organization to acquire real property or equipment under a subaward.

c. SUB Article IX of this award specifies national policy requirements that you must include, as applicable, in each cost-type subaward.

2. **Fixed-amount type subawards.** SUB Article XII of this award specifies informational content and administrative and national policy requirements that you must include in any fixed-amount subaward that you make.

3. **Additional subaward terms and conditions.** You may include other requirements in your subawards that you need in order to meet your responsibilities under this award for performance of the program or project (including portions performed by subrecipients) and compliance with applicable administrative and national policy requirements.

Section D. Subaward and executive compensation reporting. You must report subaward obligating actions and information on subrecipients' executive compensation as required by REP Article IV of this award.

SUB Article III. Informational content of subawards. (JULY 2016)

Section A. Informational content in general. You must include in each subaward (and each subsequent amendment to a subaward that alters the amount of the subaward) the information specified in OMB guidance in 2 CFR 200.331(a) (1), "Federal Award Identification," with the clarifications provided in Sections B through G of this article.

Section B. Federal award identification number and award date. The "Federal Award Identification Number" and "Federal Award Date" described in 2 CFR 200.331(a) (1) (iii) and (iv), respectively, are the award number and award date for this award to you. You must provide the information in a way that makes it clear that the subaward is under this DoD award.

Section C. Amount of Federal funds obligated.

1. The "Amount of Federal Funds Obligated by this action by the pass-through entity to the subrecipient" that is described in 2 CFR 200.331(a) (1) (vi) is either:

a. The amount of your obligation to the subrecipient, if the terms and conditions of this award do not require you to provide any cost sharing or matching for the project or program the award supports; or

b. The amount of the Federal share of your subaward obligation if this award does require cost sharing or matching, which in that case is the product of:

(1) The Federal share of total project costs under this DoD award to you, as a percentage of those total project costs; and

(2) The total amount of project costs obligated for the subaward action.

2. Note that the total project costs of the award and subaward, as used in paragraphs C.1.b.(1) and (2) of this section include any cost sharing or matching that you or the subrecipient provides if you are counting it toward the cost sharing required under this award.

Section D. Total amount obligated to the subrecipient. The "Total amount of Federal Funds Obligated to the Subrecipient by the pass-through entity including the current obligation," as described in 2 CFR 200.331(a) (1) (vii), is the cumulative amount to date of the amounts described in Section C of this article.

Section E. Total Amount of the Federal Award. The "Total Amount of the Federal Award committed to the subrecipient by the pass-through entity," as described in 2 CFR 200.331(a)(1)(viii), is the total amount through the end of the subaward that you and the subrecipient mutually agreed upon, to include: funding obligated to date, any future anticipated funding increments, and any options you may exercise in the future.

Section F. Federal awarding agency, pass-through entity, and awarding official. The "Name of Federal awarding agency" and "pass-through entity," as those terms are used in 2 CFR 200.331(a) (1) (x) are the DoD and the business name associated with your registration in the System for Award Management. In that same paragraph of 2 CFR part 200, the "awarding official" is the individual in your organization who made the subaward.

Section G. Indirect cost rate. With respect to the requirement in 2 CFR 200.331(a) (1) (xiii) for the subaward to include the "Indirect cost rate for the Federal award:"

1. The rate the subaward must include is the subrecipient's rate, whether it is a rate set by negotiation with a Federal Government agency or you, or is the de minimis rate described in 2 CFR 200.414(f).

2. You are required to include the indirect cost rate only if the subrecipient is willing to share that information with you and assents that information about its rate is not proprietary. If a subrecipient is not willing to share information about its indirect cost rate with you, consult the grants officer for this award to explore alternative ways to assess the reasonableness of costs of the subaward.

SUB Article IV. Financial and program management requirements for subawards. (JULY 2016)

Section A. Purposes of this article in relation to other articles.

1. This article specifies administrative requirements concerning financial and program management that you must include in the terms and conditions of each cost-type subaward that you make under this award to a domestic entity.

2. It thereby addresses the flow down to subrecipients of requirements with which you must comply under FMS Articles I through VII of this award.

3. SUB Article XII of this award addresses which of these administrative requirements you must include in any fixed-amount subaward that you make, if you are authorized to make fixed-amount subawards under this award.

Section B. Financial management standards. You must include in any subaward you make under this award the requirements of:

1. Sections A through C of FMS Article I of this award if the subrecipient is a State;

2. Sections B and C of FMS Article I if the subrecipient is an institution of higher education, nonprofit organization, local government, or Indian tribe; or

3. 32 CFR 34.11 if the subrecipient is a for-profit entity.

Section C. Payments.

1. **Subawards to States.** You must include the provisions of Section A of FMS Article II of this award in each subaward you make to a State;

2. **Subawards to institutions of higher education, nonprofit organizations, local governments, and Indian tribes.** The following paragraphs specify requirements you must include in subawards to institutions of higher education, nonprofit organizations, local governments, and Indian tribes.

a. **Payment method.**

(1) If you are authorized to request advance payments under this award, you must authorize a subrecipient to request advance payments unless:

(a) It does not maintain, or demonstrate the willingness to maintain, written procedures that minimize the time elapsing between its receipt of each payment and its disbursement of the funds for program purposes;

(b) You impose a requirement for the subrecipient to be paid by reimbursement as a result of your risk evaluation of the subrecipient under SUB Article II of this award.

(c) The subaward is for construction.

(2) If you do not authorize advance payments for one of the reasons given in paragraph C.2.a.1 of this article, you must specify either reimbursement or working capital advances as the payment method in accordance with OMB guidance in 2 CFR 200.305(b)(3) and (4).

b. **Payment timing and amount.**

(1) **Advances.** You must limit advance payments to the minimum amounts needed and time the payments to be in accordance with the subrecipient's actual, immediate cash requirements in carrying out the program or project under the subaward. The timing and amount of your advance payments to the subrecipient must be as close as is

administratively feasible to the subrecipient's actual disbursements for direct program or project costs and the proportionate share of any allowable indirect costs. Your subawards also must include the requirements of paragraphs B.2.b and c of FMS Article II to specify costs subrecipients must exclude from amounts of their advance payment requests.

(2) **Reimbursements or working capital advances.** You must follow OMB guidance in 2 CFR 200.305(b) (3) and (4) concerning timing and amount of reimbursements or working capital advances.

c. **Frequency of requests.** You must allow the subrecipient to request advance payments or reimbursements, including those associated with the working capital advance payment method, as often as it wishes if you pay using electronic funds transfers and at least monthly otherwise.

d. **Other requirements.**

(1) In any subaward that was subject to our consent, you must include the requirements of paragraph B.5 of FMS Article II of this award concerning withholding of payments.

(2) You must include the provisions of paragraph B.6 of FMS Article II concerning depositories in each subaward that authorizes the subrecipient to request advance payments.

3. **Subawards to for-profit entities.** The provision concerning payments in each subaward you make to a for-profit entity must conform to the requirements in 32 CFR 34.12.

Section D. Allowable costs, period of availability of funds, and fee and profit.

1. You must include in each cost-type subaward a requirement that the allowability of costs under the subaward (and any lower-tier subawards or procurement transactions into which the subrecipient enters) must be determined in accordance with the applicable cost principles identified in Section A of FMS Article III of this award.

2. You must specify in each subaward the period of availability of funds for any project or program purpose so that the period neither begins before nor ends after the period during which you may use funds available to you under this award for that same project or program purpose.

3. You must include in each subaward the provisions concerning fee or profit that are in Section D of FMS Article III of this award.

Section E. Revision of budget and program plans. You must include in each subaward provisions requiring the subrecipient to request your approval for any change in the subaward budget or program that would cause a budget or program change under this award for which Section B of FMS Article IV requires you to first obtain our prior approval. You may not approve any budget or program revision that is inconsistent with the purpose or terms and conditions of this award.

Section F. Non-Federal audits. You must include a provision in each cost-type subaward that you make under this award to require the subrecipient entity to comply with the audit requirements applicable to that entity, as specified in either Section A or Section B of FMS Article V.

Section G. Cost sharing or matching requirements. If you make a subaward under which the subrecipient may provide contributions or donations of cash or third-party in-kind contributions to be counted toward any cost sharing or matching that is required under this award, you must include provisions in that subaward to specify:

1. The criteria governing the allowability as cost sharing or matching of the types of cash or third-party in-kind contributions that the subrecipient may contribute or donate. Those criteria are specified in:

   a. Sections B through D of FMS Article VI of this award if the subaward is to a State, institution of higher education, nonprofit organization, local government, or Indian tribe.

   b. The provisions of 32 CFR 34.13(a) if the subaward is to a for-profit entity.

2. The methods for determining and documenting the values of those contributions or donations to be counted as cost sharing or matching. Those methods are specified in:

   a. Sections E and F of FMS Article VI of this award if the subaward is to a State, institution of higher education, nonprofit organization, local government, or Indian tribe.

   b. The provisions of 32 CFR 34.13(b) if the subaward is to a for-profit entity.

Section H. Program income. In each subaward, you must include requirements concerning program income, as follows:

1. In each subaward to a State, institution of higher education, nonprofit organization, local government, or Indian tribe:

   a. You must require the subrecipient to account to you when it earns any program income under the subaward or uses it, so that you can prepare reports you are required to submit to us. If the award-specific terms and conditions of this award specify that you are accountable for program income earned after the period of performance, you must include a corresponding requirement in your subawards.

   b. You must include the provisions of Sections A through D of FMS Article VII of this award.

   c. You must specify that program income earned by the subrecipient be used in one of the following ways:

      (1) Added to the approved budget of the subaward, which includes any required cost sharing or matching.

(2) Used to meet the cost sharing or matching requirement of the subaward.

(3) Deducted from the total allowable costs of the subaward in determining the net allowable costs.

d. Note, however, you still must comply with the alternative specified in Section E of FMS Article VII and any applicable award-specific terms and conditions for the total amount of program income earned, which includes amounts earned by you and your subrecipients. For example, if we authorize you to use the addition alternative, you may specify that a subrecipient use that alternative or another of the alternatives specified in paragraph 1.c above.

e. Regardless of the alternative for use of program income that you specify under a subaward(s), you must report the program income earned under the subaward and the use of the program on each Federal Financial Report you are required to submit in accordance with REP Article II

2. In each subaward to a for-profit entity, you must include the provisions of 32 CFR 34.14, with the appropriate method specified for disposition of program income.

SUB Article V. Property requirements for subawards. (JULY 2016)

Section A. Purposes of this article in relation to other articles.

1. This article specifies administrative requirements concerning property that you must include in the terms and conditions of each subaward that you make under this award.

2. It thereby addresses the flow down to subrecipients of requirements with which you must comply under PROP Articles I through VI of this award.

3. SUB Article XII of this award addresses which of these administrative requirements you must include in any fixed-amount subaward that you make, if you are authorized to make fixed-amount subawards under this award.

Section B. Title to property.

1. **Subawards to institutions of higher education, nonprofit organizations, States, local governments, or Indian tribes.**

a. General. You must include terms and conditions in each subaward to flow down to the subrecipient the provisions of:

(1) Paragraph A.1 of PROP Article I concerning vesting of title to property acquired under the subaward unless paragraph B.1.b of this section provides otherwise.

(2) Sections B through E of PROP Article I that are applicable to types of property that the subrecipient may acquire, improve, donate, or for which it may otherwise be accountable under the subaward.

b. **Exceptions. Reserved**

2. **Subawards to for-profit entities.**

a. **Real property and equipment.** You must obtain the prior approval of the DoD grants officer before permitting any for-profit subrecipient to acquire or improve real property or equipment in whole or in part with Federal funds.

(1) If the grants officer does not grant the approval, you must include a subaward provision that prohibits the entity from using Federal funds provided under the subaward to acquire or improve real property or equipment.

(2) If the approval is granted, you must include a subaward provision specifying that title vesting and Federal interest are governed by provisions of 32 CFR 34.21(b) and (c).

b. **Supplies.** You must include a subaward provision specifying that vesting of title to supplies is governed by provisions of 32 CFR 34.24 (a), subject to the use and disposition requirements of 32 CFR 34.24 (b).

c. **Federally owned property.** You must include a subaward provision in any subaward to a for-profit entity under which the entity may be accountable for federally owned property, to state that title to such property will remain vested in the Federal Government.

Section C. Property management system. If you make a subaward under which the subrecipient either may acquire or improve equipment, or may be accountable for federally owned property, you must include in the subaward:

1. If the subrecipient is a State, applicable provisions of:

a. Section A of PROP Article II concerning insurance for real property and equipment.

b. Section B of PROP Article II concerning other property management system standards.

2. If the subrecipient is an institution of higher education, nonprofit organization, local government, or Indian tribe, applicable provisions of:

a. Section A of PROP Article II concerning insurance for real property and equipment.

b. Section C of PROP Article II concerning other property management system standards.

3. Applicable provisions of 32 CFR 34.22(a) and 34.23 if the subrecipient is a for-profit entity and:

   a. The entity may be accountable under the subaward for federally owned property; or

   b. You obtained the grants officer's prior approval for the entity's acquisition of equipment under the subaward.

Section D. Use and disposition of real property. If the subrecipient of a subaward you make under this award may acquire or improve real property, then you must include in the subaward:

1. **Use.** The requirements concerning use of real property:

   a. In Section A of PROP Article III if the subaward is to an institution of higher education, nonprofit organization, State, local government, or Indian tribe, unless the award-specific terms and conditions of this award provide otherwise;

   b. In 32 CFR 34.21(d) if the subaward is to a for-profit entity and you obtained the grants officer's prior approval for the entity's acquisition of real property under the subaward; and

2. **Disposition.** Provisions to require the subrecipient to request disposition instructions through you when the property is no longer needed for its originally authorized purpose, so that you can meet your responsibilities to us under Section B of PROP Article III to address the Federal interest in the property.

Section E. Use and disposition of equipment and supplies. If you make a subaward under which the subrecipient may acquire or improve equipment, or acquire supplies, you must include in the subaward, as applicable:

1. If the subaward is to a State:

   a. The requirements in Sections B and E of PROP Article IV concerning use and disposition of equipment and supplies, except that you must require the State to contact you instead of the award administration office when it is ready to arrange disposition of equipment or address the Federal interest in supplies; and

   b. Provisions such as those in Section A of PROP Article IV that make clear the applicability of those requirements.

2. If the subaward is to an institution of higher education, nonprofit organization, local government, or Indian tribe:

   a. The requirements in Sections C and E of PROP Article IV concerning use of equipment and use and disposition of supplies;

   b. Provisions such as those in Section A of PROP Article IV that make clear the applicability of those requirements; and

c. Provisions to require the subrecipient to request disposition instructions from you when equipment is no longer needed for its originally authorized purpose, so that you can meet your responsibilities to us under Section B or D of PROP Article IV to address the Federal interest in the equipment.

3. If the subaward is to a for-profit entity:

a. The requirements concerning use and disposition of supplies in 32 CFR 34.24(b);

b. And you obtained the grants officer's prior approval for the entity's acquisition of equipment under the subaward:

(1) The requirements concerning use of equipment in 32 CFR 34.21(d); and

(2) Provisions such as those in Section A of PROP Article IV that make clear the applicability of those requirements; and
(3) Provisions to require the subrecipient to request disposition instructions from you when equipment is no longer needed for its originally authorized purpose, so that you can meet your responsibilities to us under Section B or D of PROP Article IV to address the Federal interest in the equipment.

Section F. Use and disposition of federally owned property. If you make a subaward under which the subrecipient may be accountable for federally owned property, you must include subaward provisions specifying that the subrecipient:

1. May use the property for purposes specified in paragraph A.1 of PROP Article V;

2. Must submit requests through you for the award administration office's approval to use the property for other purposes, as described in paragraph A.2 of PROP Article V;

3. Must request the award administration office's disposition instructions through you when the property is no longer needed for subaward purposes or the subaward ends.

Section G. Intangible property. You must include in a subaward provisions specifying the requirements of:

1. Sections A through D of PROP Article VI if the subaward is to an institution of higher education, nonprofit organization, State, local government, or Indian tribe.

2. Section A of PROP Article VI as it applies to works developed under the subaward, Section B of PROP Article VI, and paragraph C.1 of Section C of PROP Article VI, if the subaward is to a for-profit entity.

SUB Article VI. Procurement procedures to include in subawards. (JULY 2016)

Section A. Purposes of this article in relation to other articles.

1. This article specifies administrative requirements concerning procurement procedures that you must include in the terms and conditions of each subaward that you make under this award.

2. It thereby addresses the flow down to subrecipients of requirements with which you must comply under PROC Articles I through III of this award.

3. SUB Article XII of this award addresses which of these administrative requirements you must include in any fixed-amount subaward that you make, if you are authorized to make fixed-amount subawards under this award.

Section B. Subaward to a State. In any subaward that you make to a State, you must include the requirements of PROC Article I and applicable sections of PROC Article III of this award.

Section C. Subaward to an institution of higher education, nonprofit organization, local government, or Indian Tribe. In any subaward that you make to an institution of higher education, nonprofit organization, local government, or Indian tribe:

1. You must include the requirements of Sections A through G of PROC Article II and applicable sections of PROC Article III of this award.

2. You must include the requirement for the subrecipient to make available to you, upon request:

   a. Technical specifications of proposed procurements, under the conditions described in OMB guidance 2 CFR 200.324(a); and

   b. Other procurement documents for pre-procurement review, under the conditions described in OMB guidance at 2 CFR 200.324(b).

3. If it is possible that, under a subaward you make, the subrecipient may award a construction or facility improvement contract with a value in excess of the simplified acquisition threshold, you must include provisions in the subaward to require the subrecipient to comply with at least the minimum requirements for bidders' bid guarantees and contractors' performance and payment bonds described in 2 CFR 200.325(a) through (c), unless you determine that the subrecipient's bonding policy and requirements are adequate to protect Federal interests.

Section D. Subaward to a for-profit entity. In any subaward you make to a for-profit entity, you must include the requirements in 32 CFR 34.31.

SUB Article VII. Financial, programmatic, and property reporting requirements for subawards. (JULY 2016)

Section A. Purposes of this article in relation to other articles.

1. This article specifies administrative requirements concerning reporting that you must include in the terms and conditions of each subaward that you make under this award.

2. It thereby addresses the flow down to subrecipients of requirements with which you must comply under REP Articles I through III of this award.

3. SUB Article XII of this award addresses which of these administrative requirements you must include in any fixed-amount subaward that you make, if you are authorized to make fixed-amount subawards under this award.

Section B. Performance reporting.

1. You must include terms and conditions in each subaward to require the subrecipient to provide any performance information you need, by the time you need it, to comply with the performance reporting requirements in REP Article I and other terms and conditions of this award.

2. You may specify a form, format, or data elements the subrecipient uses to provide the information to you (you need not require the subrecipient to use the same form, format, or data elements this article specifies for your reporting to us).

Section C. Financial reporting.

1. You must include terms and conditions in each subaward to require the subrecipient to provide any financial information you need, by the time you need it, to comply with the financial reporting requirements in REP Article II and other terms and conditions of this award.

2. You may specify a form, format, or data elements the subrecipient uses to provide the information to you (you need not require the subrecipient to use the same form, format, or data elements that REP Article II specifies for your reporting to us).

Section D. Reporting on property.

1. Each subaward you make under this award must include provisions concerning property reporting as described in paragraph D.2 of this section if the subrecipient may, under the subaward:

a. Acquire or improve real property or equipment;

b. Acquire supplies or intangible property; or

c. Be accountable for federally owned property.

2. The subaward provisions must require the subrecipient to give you the information you need about the property in order to meet your responsibilities to us under Sections A through D of REP Article III and PROP Articles II through VI.

SUB Article VIII. Other administrative requirements for subawards. (JULY 2016)

Section A. Purposes of this article in relation to other articles.

1. This article specifies other administrative requirements that you either must or should include in the terms and conditions of each subaward that you make under this award.

2. It thereby addresses the flow down to subrecipients of requirements with which you must comply under OAR Articles I through VII of this award.

3. SUB Article XII of this award addresses which of these administrative requirements you must include in any fixed-amount subaward that you make, if you are authorized to make fixed-amount subawards under this award.

Section B. Maintenance of subrecipient information. You must include the substance of the provision in Section C of OAR Article I in any subaward that will have a total value of $5 million or more over the life of the subaward. The provision must require the subrecipient's disclosure of any credible evidence directly to the Inspector General, DoD.

Section C. Records retention and access. In each subaward you make under this award,

1. If the subaward is to an institution of higher education, nonprofit organization, State, local government, or Indian tribe:

a. You must include the requirements of Section A of OAR Article II with the additional condition that, for any subrecipient under this award that does not have a federally approved rate for indirect or facilities and administrative costs and that does not use the de minimis rate described in 2 CFR 200.414(f), you must:

(1) Require the subrecipient to keep records that support its indirect or facilities and administrative costs charged to the subaward for three years from the end of the fiscal year (or other accounting period) to which the costs apply; and

(2) Keep any plan or computation the subrecipient submits to you to serve as a basis for your determining the reasonableness and allowability of indirect or facilities and administrative costs of the subaward, for three years from the end of the fiscal year (or other accounting period) to which the proposal, plan, or computation applies.

b. You must include the requirements of Sections B, C, and F of OAR Article II.

c. You must include provisions that enable you to comply with the requirements of Section D of OAR Article II concerning records for joint or long-term use.

d. You must include provisions that establish the same rights and responsibilities for the subrecipient under the subaward that Section E of OAR Article II establishes for you under this award.

e. You may not impose any other record retention or access requirements on the subrecipient.

2. If the subaward is to a for-profit entity, you must include the records retention and access provisions of 32 CFR part 34.42.

Section D. Remedies and termination. The terms and conditions of each subaward you make under this award should specify your rights and responsibilities and those of the subrecipient if you take a remedial action to address a subrecipient's noncompliance with an applicable Federal statute or regulation or the terms and conditions of your subaward. Each subaward's terms and conditions should:

1. Identify remedial actions you may take to address the subrecipient's noncompliance. Available remedies are described in:

a. OMB guidance in 2 CFR 200.338 for a subaward to an institution of higher education, nonprofit organization, State, local government, or Indian tribe; and

b. 32 CFR 34.52 for a subaward to a for-profit entity.

2. With respect to termination specifically:

a. Identify conditions under which you, the subrecipient, or both (by mutual agreement) may terminate the subaward, in whole or in part, as described in:

(1) OMB guidance in 2 CFR 200.339(a) for a subaward to an institution of higher education, nonprofit organization, State, local government, or Indian tribe; and

(2) 32 CFR 34.51 for a subaward to a for-profit entity.

b. Inform the subrecipient that you will provide it with a notice of termination if you unilaterally terminate the award

c. Specify that you and the subrecipient remain responsible for applicable requirements addressed in Sections G and H of this article concerning closeout, post-closeout adjustments, and continuing responsibilities.

3. With respect to either suspension or termination of the subaward, inform the subrecipient about the criteria that you will use to either allow or disallow subaward costs, which are in:

a. Section C of OAR Article III for a subaward to an institution of higher education, nonprofit organization, State, local government, or Indian tribe; and

b. 32 CFR 34.52(c) for a subaward to a for-profit entity.

Section E. Disputes, hearings, and appeals. Each subaward's terms and conditions should specify any rights the subrecipient has to a hearing, appeal, or other administrative proceeding if it disputes a decision you render in administering its subaward. You must comply with any statute or regulation that affords the subrecipient an opportunity for a hearing, appeal, or other administrative proceeding and is applicable to the dispute.

Section F. Collection of amounts due. Although your subaward terms and conditions do not need to include any of the requirements of OAR Article V because those requirements do not flow down to subrecipients, you should consider including provisions to specify what you would need from the subrecipient if you owed a debt to the Government under this award that is related to its subaward.

Section G. Closeout.

1. In each subaward that you make to an institution of higher education, nonprofit organization, State, local government, or Indian tribe, you must include provisions to require the subrecipient to:

a. Liquidate all obligations that it incurred under the subaward not later than 90 calendar days after the end date of the period of performance of either the subaward or this award, whichever is earlier, unless you grant an extension.

b. Promptly refund to you any balances of unobligated cash that you advanced or paid to the subrecipient, unless you received authorization from the DoD award administration office for the subrecipient's use of those funds on other projects.

c. Submit to you:

(1) Any information you need from the subrecipient to meet your responsibilities to us for an accounting of property, under Section D of OAR Article VI; and

(2) Not later than 90 calendar days after the end date of the subaward period of performance, unless you grant the subrecipient an extension, any information you need to meet your responsibilities to us for final reports, under Section C of OAR Article VI.

2. In each subaward that you make to a for-profit entity you must include the terms and conditions that you deem necessary for you to be able to comply with the requirements in OAR Article VI.

Section H. Post-closeout adjustments and continuing responsibilities.

You must include provisions in each subaward to require the subrecipient to provide what you need in order to comply with the requirements of OAR Article VII.

SUB Article IX. National policy requirements for subawards. (JULY 2016)

Section A. General.

1. You must include provisions in the terms and conditions of each subaward you make to require the subrecipient entity's compliance with each of the national policy requirements in Sections B through E of this article that you determine is applicable, given the type of entity receiving the subaward and activities it will be carrying out under the subaward.

2. If an entity to which you are about to make a subaward will not accept an award provision requiring its compliance with a national policy requirement that you determine to be applicable, you must alert the award administration office immediately. You may not omit an applicable national policy requirement in order to make the subaward.

3. If at any time during the performance of a subaward, you learn that—or receive a credible allegation that—the subrecipient is not complying with an applicable national policy requirement, you must alert the award administration office immediately.

Section B. Nondiscrimination national policy requirements. You must include provisions in each subaward to require the subrecipient's compliance with the nondiscrimination national policy requirements specified in paragraphs A.1 through A.5 of NP Article I, as applicable.

Section C. Environmental national policy requirements. You must include provisions in each subaward to require that:

1. The subrecipients comply with the Clean Air and Clean Water Acts specified in paragraph A.1 of NP Article II, as applicable.

2. Provide any information you need, when you need it, in order to comply with the requirement to immediately notify us of potential environmental impacts specified in paragraph A.2 of NP Article II, as applicable, due to activities under the award (which includes subaward activities).

Section D. National policy requirements concerning live organisms. You must include provisions in each subaward to require the subrecipient's compliance with the national policy requirements concerning human subjects and animals that are specified in paragraphs A.1 and A.2 of NP Article III, as applicable.

Section E. Other national policy requirements. You must include provisions in each subaward to require the subrecipient's compliance with the national policy requirements in the following portions of NP Article IV of this award, as applicable:

1. Paragraph A.1 on debarment and suspension.

2. Paragraphs A.3.a and b on lobbying.

3. Paragraphs A.4 through A.17 on officials not to benefit, Hatch Act, native American graves protection and repatriation, fly America Act, use of United States flag vessels, research misconduct, military recruiters and Reserve Officers Training Corps, historic preservation, relocation and real property acquisition, confidentiality of patient records, Pro-Children Act, Constitution Day, trafficking in persons, and whistleblower protections.

SUB Article X. Subrecipient monitoring and related subaward administration. (JULY 2016)

Section A. General requirement for subrecipient monitoring. You must do the post-award monitoring of the subrecipient's activities under each subaward that is needed in order for you to ensure, to the best of your ability to do so, that:

1. The subrecipient carries out the portion of the substantive program under this award that, as described in paragraph B.1.a of SUB Article I:

   a. Your subaward transferred for the subrecipient's performance, which is the subaward's primary purpose; and

   b. For which you are accountable to us.

2. The subrecipient is using project funds under the subaward (including any cost sharing or matching the subrecipient provides that is counted as project funds in the approved budget of this award) for authorized purposes.

3. The subrecipient's performance under the subaward is in compliance with applicable Federal statutes and regulations, and the terms and conditions of your subaward.

Section B. Subrecipient monitoring actions.

1. **Required monitoring actions.** You must, as part of your post-award monitoring of each subrecipient:

   a. Review the financial and programmatic information that your subaward terms and conditions require the subrecipient to provide, in accordance with Sections B and C of SUB Article VII of this award.

b. Follow up and ensure that the subrecipient takes timely and appropriate action to remedy deficiencies detected through any means, including audits and on-site reviews.

c. With respect to audits of subrecipients that are required under FMS Article V of this award:

(1) Verify that the subrecipient is audited in accordance with those requirements, as applicable (note that Section F of SUB Article IV requires you to include those audit requirements for the subrecipient in the subaward's terms and conditions).

(2) Resolve and issue a management decision for audit findings that pertain to your subaward. Doing so is a requirement under either Section A or B of FMS Article V of this award (Section B requires that explicitly and Section A does so by implementing OMB guidance in 2 CFR 200.521, as well as other portions of Subpart F of that part).

(3) Consider whether you need to adjust your own records related to this award based on results of audits, on-site reviews or other monitoring of the subrecipient and, as applicable, notify the award administration office.

2. **Other monitoring actions.** OMB guidance in 2 CFR 200.331(e)(1) through (3) describe other actions that may be useful as part of your subrecipient monitoring program, depending on the outcomes of the pre-award risk assessment you conducted in accordance with Section B of SUB Article II.

Section C. Remedies and subaward suspension or termination. With respect to any subaward under this award, you must:

1. Consider whether you need to take any remedial action if you determine that the subrecipient is noncompliant with an applicable Federal statute or regulation or the terms and conditions of your subaward, as described in Section D of SUB Article VIII.

2. Provide a notice of termination to the subrecipient if you terminate its subaward prior to the end of the period of performance.

3. In the case of either suspension or termination of a subaward prior to the end of the period of performance, allow or disallow subaward costs in accordance with Section C of OAR Article III.

Section D. Subaward closeout.

1. You will close out each subaward that you make under this award when you either:

a. Determine that the subrecipient has completed its programmatic performance under the subaward and all applicable administrative actions; or

b. Terminate the subaward, if you do so prior to completion of the subrecipient's programmatic performance.

2. With respect to the closeout of each subaward:

   a. You must pay the subrecipient promptly for allowable and reimbursable costs.

   b. Consistent with the terms and conditions of the subaward, you must make a settlement for any upward or downward adjustments to the Federal share of costs after you receive the information you need from the subrecipient to close out the subaward.

   c. You should complete the closeout of the subaward no later than one year after you receive and accept the final reports and other information from the subrecipient that you need to close out the subaward.

SUB Article XI. Requirements concerning subrecipients' lower-tier subawards. (JULY 2016)

Section A. Purpose. This article specifies requirements you must include in any cost-type subaward under which you determine that the subrecipient of your subaward may make lower-tier cost-type subawards to other entities.

Section B. Requirements for lower-tier subawards. Your cost-type subaward terms and conditions must require your subrecipient, with respect to each lower-tier cost-type subaward that it makes, to:

1. Ensure that the lower-tier transaction is a subaward, rather than a procurement, by making the determination that SUB Article I of this award requires you to make for your subawards.

2. Conduct the pre-award risk assessment of its intended subrecipient that Section B of SUB Article II of this award requires you to make for your subawards.

3. Include in any cost-type subaward it makes at the next tier:

   a. The informational content that SUB Article III specifies;

   b. The administrative requirements that SUB Articles IV through VIII of this award specify, as applicable;

   c. The national policy requirements that SUB Article IX of this award specifies, as applicable; and

   d. The requirements of this article if the next-tier subrecipient may make even lower-tier cost-type subawards to other entities.

4. Carry out the subrecipient monitoring and other post-award administration responsibilities specified in SUB Article X of this award.

SUB Article XII. Fixed-amount subawards. (JULY 2016)

Section A. Limitations on use.

1. You may not use a fixed-amount subaward:

   a. If the total value over the life of the subaward will exceed the simplified acquisition threshold.

   b. Unless the project or program scope is specific, with definite outcomes, and you are able to establish a reasonable estimate of the actual costs of accomplishing those outcomes.

   c. If you will predetermine a set amount or percentage of cost sharing or matching that the subrecipient must provide under its subaward.

   d. If the subrecipient will be acquiring any real property or equipment under the subaward.

2. For fixed-amount subawards not prohibited by paragraph 1 of this section and except as provided in Section B of this article, you must obtain our prior approval before making a fixed-amount type of subaward.

   a. If Section B of FMS Article IV requires you to obtain our prior approval before you make any subaward, and you do not identify the subaward as a fixed-amount subaward when you obtain that approval, then you must subsequently request separate approval before awarding it as a fixed-amount type of subaward.

   b. If a subaward is identified as a fixed-amount type of subaward in the budget you submit for our approval, then our approval of the budget is the required prior approval.

Section B. Fixed-amount subawards that does not require prior approval. You are not required to obtain our prior approval before using a fixed-amount type of subaward if:

1. The subaward is to either:

   a. A foreign public entity; or

   b. An organizational unit of a foreign organization, if that unit does not have a place of business in the United States, regardless of whether another organizational unit of that foreign organization has one.

2. You determine that the portion of the project or program under this award which the subrecipient will be carrying out under the subaward has one or more specific outcomes with the following characteristics:

a. You can define the outcomes well enough to specify them at the time you make the subaward. Note that:

(1) Outcomes are distinct from inputs needed to achieve the outcomes, such as amounts or percentages of time that subrecipient employees or other participants will spend on the project or program.

(2) The inherently unpredictable nature of basic or applied research makes it rarely, if ever, possible to define specific research outcomes in advance, which makes fixed-amount subawards inappropriate for research. Note that technical performance reports serve to document research outcomes but are not themselves outcomes, notwithstanding the definition of "performance goals" in OMB guidance at 2 CFR 200.76.

b. The accomplishment of each outcome will be observable and verifiable by you when it occurs, so that you will not need to rely solely on the subrecipient's assurance of that accomplishment.

c. The subrecipient associates its projected costs with outcomes in the proposal it submits to you, and you are confident that the costs of accomplishment of the outcomes will equal or exceed the subaward amount. This requires either that you have a high degree of confidence:

(1). In your estimate of the costs associated with accomplishing the well-defined and observable outcomes, based on the prospective subrecipient's proposal (and using the applicable cost principles in FMS Article III as a guide); or

(2). That those costs will be within a finite range, rather than a specific amount, so that you may provide an amount of funding under the subaward that does not exceed the lower end of the range, with the provision that the subrecipient agrees to provide any balance above that amount that ultimately is needed to accomplish the outcomes. Your subaward then would include a term or condition to reflect the subrecipient's agreement to provide that balance (which would be in an amount to be post-determined, when the outcomes are accomplished). Note that this is distinct from a situation in which you predetermine a set amount or percentage of cost sharing or matching that the subrecipient must provide under its subaward, a situation in which paragraph A.1.c of this article prohibits use of a fixed-amount subaward.

3. The subaward is based on a fixed rate per unit of outcome (or "unit cost") and you have both the confidence:

a. That is described in paragraph B.2.c of this article in the estimated costs associated with each unit of outcome; and

b. In the subrecipient's guarantee that it can accomplish at least the number of units of outcome on which your total subaward amount will be based (i.e., the product of the unit cost and the number of units of outcome the subrecipient guarantees to accomplish).

c. Note, however, that not every fixed rate subaward is also a fixed-amount subaward. If you have confidence in the unit cost but not also in the subrecipient's ability to guarantee the number of units of outcome that it will accomplish, then you should set a not-to-exceed award amount based on the number of units desired and reduce the subaward amount at the end if the subrecipient accomplishes fewer than that number. Examples of activities for which it may be appropriate to award this type of fixed rate subaward that is not a fixed-amount subaward include:

   (1) A clinical trial for which the unit cost is the cost of treating each participant. The not-to-exceed amount would be based on the number of participants the subrecipient planned to recruit and the final award on the number who actually participated, documentation for which would be subject to audit.

   (2) Labor costs for performance of a portion of the program under this award by an entity that treats its indirect cost rate as proprietary information. The unit cost in that case may be "loaded" labor rates for the entity's employees that include indirect costs. The final award amount would depend on the number of labor hours the firm's employees expended under the subaward, documentation for which may be audited without exposing proprietary details associated with the actual costs.

Section C. Informational content of fixed-amount subawards. You must include in each fixed-amount subaward the informational content, other than the indirect cost rate, that is described in SUB Article III of this award.

Section D. Terms and conditions addressing administrative requirements.

1. **General.** This section:

   a. Specifies the minimum set of terms and conditions addressing administrative requirements that you must include in fixed-amount subawards, in lieu of the more extensive set specified in SUB Articles IV through X for cost-type subawards:

      (1) In each fixed-amount subaward to an entity other than a foreign organization, as applicable; and

      (2) To the maximum extent practicable, in each fixed-amount subaward to a foreign organization.

   b. Does not preclude your including other requirements that you need in order to meet your responsibilities under this award for performance of the program or project (including portions

performed by subrecipients) and compliance with applicable administrative and national policy requirements.

2. **Financial and program management requirements.**

   a. **Financial management system standards.** For a subaward to other than a for-profit entity, your subaward must require the subrecipient to include the information specified in paragraph B.1 of FMS Article I in its financial management system, for the purposes of the non-federal audits required by paragraph 2.d of this section.

   b. **Payments.** Your payments must be based on accomplishment of the outcomes and associated costs that you used to establish the award amount, rather than on subrecipient expenditures for project or program purposes. Milestone payments before the end of the subaward's period of performance may be appropriate if there are outcomes that the subrecipient will accomplish at different times during that period.

   c. **Revision of budget and program plans.** If our prior approval was required under paragraph A.2 of this article for use of a fixed-amount type of subaward, then you must:

      (1) Request our prior approval for any change in principal investigator, project leader, project partner, or scope or objective of the subaward; and

      (2) Therefore include a requirement in the subaward for the subrecipient to request that approval through you.

   d. **Non-federal audits.** You must include the requirement for non-Federal audits described in Section F of SUB Article IV. The audits are intended to focus on compliance with the performance requirements in the subaward terms and conditions and not to review actual costs as they would for a cost-type subaward.

   e. **Certification of completion.** You must include the requirement for the subrecipient to provide you with a certification at the end of the project as specified in 2 CFR 200.201(b) (3).

3. **Property requirements.**

   a. **Federally owned property.** If the subrecipient will be accountable for federally owned property, you must include the property management system, use, and disposition requirements described in Sections C and F of SUB Article V that are applicable to federally owned property.

   b. **Intangible property.** You must include the applicable requirements concerning intangible property, as described in Section G of SUB Article V.

4. **Reporting requirements.** You must include requirements for performance reporting that you need in order to meet your responsibilities under this award for reporting to us.

5. **Other administrative requirements.**

a. **Integrity-related information.** You must include the substance of the provision in Section C of OAR Article I in any subaward that you anticipate will have a total value of $5 million or more over the life of the subaward. The provision must require the subrecipient's disclosure of any credible evidence directly to the Inspector General, DoD.

b. **Records retention and access.**

(1) You must include the requirements for records retention and access in paragraph A.3 and Sections B and F of OAR Article II, as applicable, if the subaward is to an institution of higher education, nonprofit organization, State, local government, or Indian tribe. You may not impose any other records retention or access requirements on the subrecipient.

(2) You must include the corresponding requirements of 32 CFR 34.42 if the subaward is to a for-profit entity.

c. **Remedies and termination.** You must include:

(1) The requirements concerning remedies and termination that are described in paragraphs D.1 and 2 of SUB Article VIII;

(2) Provisions addressing any hearing and appeal rights the subrecipient has, as described in Section E of SUB Article VIII; and

(3) Terms and conditions addressing adjustment of the amount of the subaward if it is terminated before the subrecipient accomplish all of the specified outcomes.

d. **Continuing responsibilities.** You must include requirements concerning continuing responsibilities for audits and records retention and access that are described in paragraphs B.1 and 3 of OAR Article VII.

e. **Collection of amounts due.** You should consider including the requirements concerning collection of amounts due, as described in Section F of SUB Article VIII.

Section E. National policy requirements for fixed-amount subawards. You must include in the terms and conditions of each fixed-amount subaward the national policy requirements that SUB Article IX of this award specifies, as applicable.

Section F. Subrecipient monitoring and other post-award administration. You must carry out the subrecipient monitoring and post-award administration actions specified in SUB Article X, as applicable.

Section G. Fixed-amount subawards at lower tiers.

1. **Authority.**

   a. If Section B of this article authorizes you to use a fixed-amount type of subaward without our prior approval in some situations, a cost-type subaward that you make may authorize the subrecipient to use fixed-amount subawards at the next lower tier in those same situations without our prior approval.

   b. If you wish to allow a subrecipient of a cost-type subaward to use fixed-amount subawards at the next tier in other situations (i.e., situations in which this article requires you to obtain our prior approval before using a fixed-amount type of subaward), your subaward terms and conditions must require the subrecipient to submit a request through you to obtain our prior approval for use of that type of subaward.

2. **Subaward requirements.** If your subrecipient is authorized to use lower-tier fixed-amount subawards, as described in paragraphs 1.a and b of this section, your subaward's terms and conditions must:

   a. Require the subrecipient, before it makes any lower-tier fixed-amount subaward, to:

      (1) Ensure that the lower-tier transaction is a subaward, rather than a procurement, by making the determination that SUB Article I of this award requires you to make for your subawards.

      (2) Conduct the pre-award risk assessment of its intended subrecipient that Section B of SUB Article II of this award requires you to make for your subawards.

Include the requirements specified in Sections A through F of this article.

Part 8: National Policy Requirements

NP Article I. Nondiscrimination national policy requirements. (JULY 2016)

Section A. Cross-cutting nondiscrimination requirements. By signing this agreement or accepting funds under this agreement, you assure that you will comply with applicable provisions of the national policies prohibiting discrimination:

1. On the basis of race, color, or national origin, in Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), as implemented by Department of Defense (DoD) regulations at 32 CFR part 195.

2. On the basis of gender, blindness, or visual impairment, in Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), as implemented by DoD regulations at 32 CFR part 196.

3. On the basis of age, in the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), as implemented by Department of Health and Human Services regulations at 45 CFR part 90.

4. On the basis of disability, in the Rehabilitation Act of 1973 (29 U.S.C. 794), as implemented by Department of Justice regulations at 28 CFR part 41 and DoD regulations at 32 CFR part 56.

5. On the basis of disability in the Architectural Barriers Act of 1968 (42 U.S.C. 4151 et seq.) related to physically handicapped persons' ready access to, and use of, buildings and facilities for which Federal funds are used in design, construction, or alteration.

Section B. Other nondiscrimination requirements. RESERVED.

NP Article II. Environmental national policy requirements. (JULY 2016)

Section A. Cross-cutting environmental requirements. You must:

1. You must comply with all applicable Federal environmental laws and regulations. The laws and regulations identified in this section are not intended to be a complete list.

2. Comply with applicable provisions of the Clean Air Act (42 U.S.C. 7401, et seq.) and Clean Water Act (33 U.S.C. 1251, et seq.).

3. Comply with applicable provisions of the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. 4821-4846), as implemented by the Department of Housing and Urban Development at 24 CFR part 35. The requirements concern lead-based paint in buildings owned by the Federal Government or housing receiving Federal assistance.

4. Immediately identify to us, as the Federal awarding agency, any potential impact that you find this award may have on:

a. The quality of the "human environment", as defined in 40 CFR 1508.14, including wetlands; and provide any help we may need to comply with the National Environmental Policy Act (NEPA, at 42 U.S.C. 4321 et seq.), the regulations at 40 CFR 1500-1508, and E.O. 12114, if applicable; and assist us to prepare Environmental Impact Statements or other environmental documentation. In such cases, you may take no action that will have an environmental impact (e.g., physical disturbance of a site such as breaking of ground) or limit the choice of reasonable alternatives to the proposed action until we provide written notification of Federal compliance with NEPA or E.O. 12114.

b. Flood-prone areas, and provide any help we may need to comply with the National Flood Insurance Act of 1968, as amended by the Flood Disaster Protection Act of 1973 (42 U.S.C. 4001 et seq.), which require flood insurance, when available, for federally assisted construction or acquisition in flood-prone areas.

c. A land or water use or natural resource of a coastal zone that is part of a federally approved State coastal zone management plan and provide any help we may need to comply with the Coastal Zone Management Act of 1972 (16 U.S.C. 1451, et seq.) including preparation of a Federal agency Coastal Consistency Determination.

d. Coastal barriers along the Atlantic and Gulf coasts and Great Lakes' shores, and provide help we may need to comply with the Coastal Barrier Resources Act (16 U.S.C. 3501 et seq.), concerning preservation of barrier resources.

e. Any existing or proposed component of the National Wild and Scenic Rivers system, and provide any help we may need to comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. 1271 et seq.).

f. Underground sources of drinking water in areas that have an aquifer that is the sole or principal drinking water source, and provide any help we may need to comply with the Safe Drinking Water Act (42 U.S.C. 300f et seq.).

5. You must comply fully with the Endangered Species Act of 1973, as amended (ESA, at 16 U.S.C. 1531 et seq.), and implementing regulations of the Departments of the Interior (50 CFR parts 10-24) and Commerce (50 CFR parts 217-227). You also must provide any help we may need in complying with the consultation requirements of ESA section 7 (16 U.S.C. 1536) applicable to Federal agencies or any regulatory authorization we may need based on the award of this grant. This is not in lieu of responsibilities you have to comply with provisions of the Act that apply directly to you as a U.S. entity, independent of receiving this award.

6. You must fully comply with the Marine Mammal Protection Act of 1972, as amended (MMPA, at 16 U.S.C. 1361 et seq.) and provide any assistance we may need in obtaining any required MMPA permit based on an award of this grant.

Section B. Other environmental requirements. RESERVED.

NP Article III. National policy requirements concerning live organisms. (JULY 2016)

Section A. Cross-cutting requirements concerning live organisms. You must:

1. Human subjects.

a. You must protect the rights and welfare of individuals who participate as human subjects in research under this award and comply with the requirements at 32 CFR part 219, DoD Instruction (DoDI) 3216.02, 10 U.S.C. 980, and when applicable, Food and Drug Administration (FDA) regulations.

b. You must not begin performance of research involving human subjects, also known as human subjects research (HSR), that is covered under 32 CFR part 219, or that meets exemption criteria under 32 CFR 219.101(b), until you receive a formal notification of approval from a DoD Human Research Protection Official (HRPO). Approval to perform HSR under this award is received after the HRPO has performed a review of your documentation of planned HSR activities and has officially furnished a concurrence with your determination as presented in the documentation.

c. In order for the HRPO to accomplish this concurrence review, you must provide sufficient documentation to enable his or her assessment as follows:

i. If the HSR meets an exemption criteria under 32 CFR 219.101(b), the documentation must include a citation of the exemption category under 32 CFR 219.101(b) and a rationale statement.

ii. If your activity is determined as "non-exempt research involving human subjects", the documentation must include:

A. Assurance of Compliance (i.e., Department of Health and Human Services Office for Human Research Protections (OHRP) Federal Wide Assurance (FWA)) appropriate for the scope of work or program plan; and

B. Institutional Review Board (IRB) approval, as well as all documentation reviewed by the IRB to make their determination.

d. The HRPO retains final judgment on what activities constitute HSR, whether an exempt category applies, whether the risk determination is appropriate, and whether the planned HSR activities comply with the requirements in paragraph 1.a of this section.

e. You must notify the HRPO immediately of any suspensions or terminations of the Assurance of Compliance.

f. DoD staff, consultants, and advisory groups may independently review and inspect your research and research procedures involving human subjects and, based on such findings, DoD may prohibit research that presents unacceptable hazards or otherwise fails to comply with DoD requirements.

g. Definitions for terms used in paragraph 1 of this article are found in DoDI 3216.02.

2. Animals.

a. Prior to initiating any animal work under the award, you must:

i. Register your research, development, test, and evaluation or training facility with the Secretary of Agriculture in accordance with 7 U.S.C. 2136 and 9 CFR section 2.30, unless otherwise exempt from this requirement by meeting the conditions in 7 U.S.C. 2136 and 9 CFR parts 1-4 for the duration of the activity.

ii. Have your proposed animal use approved in accordance with Department of Defense Instruction (DoDI) 3216.01, Use of Animals in DoD Programs by a DoD Component Headquarters Oversight Office.

iii. Furnish evidence of such registration and approval to the grants officer.

b. You must make the animals on which the research is being conducted, and all premises, facilities, vehicles, equipment, and records that support animal care and use available during business hours and at other times mutually agreeable to you, the United States Department of Agriculture Office of Animal and Plant Health Inspection Service (USDA/APHIS) representative, personnel representing the DoD component oversight offices, as well as the grants officer, to ascertain that you are compliant with 7 U.S.C. 2131 et seq., 9 CFR parts 1-4, and DoDI 3216.01.

c. Your care and use of animals must conform with the pertinent laws of the United States, regulations of the Department of Agriculture, and regulations, policies, and procedures of the Department of Defense (see 7 U.S.C. 2131 et seq., 9 CFR parts 1-4, and DoDI 3216.01).

d. You must acquire animals in accordance with DoDI 3216.01.

3. Use of Remedies.

Failure to comply with the applicable requirements in paragraphs 1-2 of this section may result in the DoD Component's use of remedies, e.g., wholly or partially terminating or suspending the award, temporarily withholding payment under the award pending correction of the deficiency, or disallowing all or part of the cost of the activity or action (including the federal share and any required cost sharing or matching) that is not in compliance. See OAR Article III.

Section B. Other requirements concerning live organisms. RESERVED

NP Article IV. Other national policy requirements. (JULY 2016)

Section A. Cross-cutting requirements.

1. Debarment and suspension. You must comply with requirements regarding debarment and suspension in Subpart C of 2 CFR part 180, as adopted by DoD at 2 CFR part 1125. This includes requirements concerning your principals under this award, as well as requirements concerning your procurement transactions and subawards that are implemented in PROC Articles I through III and SUB Article II.

2. Drug-free workplace. You must comply with drug-free workplace requirements in Subpart B of 2 CFR part 26, which is the DoD implementation of 41 U.S.C. chapter 81, "Drug-Free Workplace."

3. Lobbying.

a. You must comply with the restrictions on lobbying in 31 U.S.C. 1352, as implemented by DoD at 32 CFR part 28, and submit all disclosures required by that statute and regulation.

b. You must comply with the prohibition in 18 U.S.C. 1913 on the use of Federal funds, absent express Congressional authorization, to pay directly or indirectly for any service, advertisement or other written matter, telephone communication, or other device intended to influence at any time a Member of Congress or official of any government concerning any legislation, law, policy, appropriation, or ratification.

c. If you are a nonprofit organization described in section 501(c)(4) of title 26, United States Code (the Internal Revenue Code of 1968), you may not engage in lobbying activities as defined in the Lobbying Disclosure Act of 1995 (2 U.S.C., chapter 26). If we determine that you have engaged in lobbying activities, we will cease all payments to you under this and other awards and terminate the awards unilaterally for material failure to comply with the award terms and conditions.

4. Officials not to benefit. You must comply with the requirement that no member of Congress shall be admitted to any share or part of this agreement, or to any benefit arising from it, in accordance with 41 U.S.C. 6306.

5. Hatch Act. If applicable, you must comply with the provisions of the Hatch Act (5 U.S.C. 1501-1508) concerning political activities of certain State and local government employees, as implemented by the Office of Personnel Management at 5 CFR part 151, which limits political activity of employees or officers of State or local governments whose employment is connected to an activity financed in whole or part with Federal funds.

6. Native American graves protection and repatriation. If you control or possess Native American remains and associated funerary objects, you must comply with the requirements of 43 CFR part 10, the Department of the Interior implementation of the Native American Graves Protection and Repatriation Act of 1990 (25 U.S.C., chapter 32).

7. Fly America Act. You must comply with the International Air Transportation Fair Competitive Practices Act of 1974 (49 U.S.C. 40118), commonly referred to as the "Fly America Act," and implementing regulations at 41 CFR 301-10.131 through 301-10.143. The law and regulations require that U.S. Government financed international air travel and transportation of personal effects or property must use a U.S. Flag air carrier or be performed under a cost sharing arrangement with a U.S. carrier, if such service is available.

8. Use of United States-flag vessels. You must comply with the following requirements of the Department of Transportation at 46 CFR 381.7, in regulations implementing the Cargo Preference Act of 1954:

a. Pursuant to Pub. L. 83-664 (46 U.S.C. 55305), at least 50 percent of any equipment, materials or commodities procured, contracted for or otherwise obtained with funds under this award, and which may be transported by ocean vessel, must be transported on privately owned United States-flag commercial vessels, if available.

b. Within 20 days following the date of loading for shipments originating within the United States or within 30 working days following the date of loading for shipments originating outside the United States, a legible copy of a rated, "on-board" commercial ocean bill-of-lading in English for each shipment of cargo described in paragraph 8.a of this section must be furnished to both our award administrator (through you in the case of your contractor's bill-of-lading) and to the Division of National Cargo, Office of Market Development, Maritime Administration, Washington, DC 20590.

9. Research misconduct. You must comply with requirements concerning research misconduct in Enclosure 4 to DoD Instruction 3210.7, "Research Integrity and Misconduct." The Instruction implements the Government wide research misconduct policy that the Office of Science and Technology Policy published in the Federal Register (65 FR 76260, December 6, 2000, available through the U.S. Government Printing Office web site: http://www.gpo.gov/fdscys/browse/collection.action?Code=FR).

10. Requirements for an Institution of Higher Education Concerning Military Recruiters and Reserve Officers Training Corps (ROTC).

a. As a condition for receiving funds available to the DoD under this award, you agree that you are not an institution of higher education (as defined in 32 CFR part 216) that has a policy or practice that either prohibits, or in effect prevents:

i. The Secretary of a Military Department from maintaining, establishing, or operating a unit of the Senior Reserve Officers Training Corps (ROTC)—in accordance with 10 U.S.C. 654 and other applicable Federal laws—at that institution (or any subelement of that institution);

ii. Any student at that institution (or any subelement of that institution) from enrolling in a unit of the Senior ROTC at another institution of higher education.

iii. The Secretary of a Military Department or Secretary of Homeland Security from gaining access to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of military recruiting in a manner that is at least equal in quality and scope to the access to campuses and to students that is provided to any other employer; or

iv. Access by military recruiters for purposes of military recruiting to the names of students (who are 17 years of age or older and enrolled at that institution or any subelement of that institution); their addresses, telephone listings, dates and places of birth, levels of education, academic majors, and degrees received; and the most recent educational institutions in which they were enrolled.

b. If you are determined, using the procedures in 32 CFR part 216, to be such an institution of higher education during the period of performance of this award, we:

i. Will cease all payments to you of DoD funds under this award and all other DoD grants and cooperative agreements; and

ii. May suspend or terminate those awards unilaterally for material failure to comply with the award terms and conditions.

11. Historic preservation. You must identify to us any:

a. Property listed or eligible for listing on the National Register of Historic Places that will be affected by this award, and provide any help we may need, with respect to this award, to comply with Section 106 of the National Historic Preservation Act of 1966 (54 U.S.C. 306108), as implemented by the Advisory Council on Historic Preservation regulations at 36 CFR part 800 and Executive Order 11593, "Identification and Protection of Historic Properties," [3 CFR, 1971-1975 Comp., p. 559]. Impacts to historical properties are included in the definition of "human environment" that require impact assessment under NEPA (See NP Article II, Section A).

b. Potential under this award for irreparable loss or destruction of significant scientific, prehistorical, historical, or archeological data, and provide any help we may need, with respect to this award, to comply with the Archaeological and Historic Preservation Act of 1974 (54 U.S.C. chapter 3125).

12. Relocation and real property acquisition. You must comply with applicable provisions of 49 CFR part 24, which implements the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (42 U.S.C. 4601, et seq.) and provides for fair and equitable treatment of persons displaced by federally assisted programs or persons whose property is acquired as a result of such programs.

13. Confidentiality of patient records. You must keep confidential any records that you maintain of the identity, diagnosis, prognosis, or treatment of any patient in connection with any program or activity relating to substance abuse education, prevention, training, treatment, or rehabilitation that is assisted directly or indirectly under this award, in accordance with 42 U.S.C. 290dd-2.

14. Pro-Children Act.

You must comply with applicable restrictions in the Pro-Children Act of 1994 (Title 20, Chapter 68, Subchapter X, Part B of the U.S. Code) on smoking in any indoor facility:

a. Constructed, operated, or maintained under this award and used for routine or regular provision of kindergarten, elementary, or secondary education or library services to children under the age of 18.

b. Owned, leased, or contracted for and used under this award for the routine provision of federally funded health care, day care, or early childhood development (Head Start) services to children under the age of 18.

15. Constitution Day. You must comply with Public Law 108-447, Div. J, Title I, Sec. 111 (36 U.S.C. 106 note), which requires each educational institution receiving Federal funds in a Federal fiscal year to hold an educational program on the United States Constitution on September 17th during that year for the students served by the educational institution.

16. Trafficking in persons. You must comply with requirements concerning trafficking in persons specified in the award term at 2 CFR 175.15(b), as applicable.

17. Whistleblower protections. You must comply with 10 U.S.C. 2409, including the:

a. Prohibition on reprisals against employees disclosing certain types of information to specified persons or bodies; and

b. Requirement to notify your employees in writing, in the predominant native language of the workforce, of their rights and protections under that statute.

Section B. Additional requirements. RESERVED.