From: Raul Medina
To: Fred Gould; tim.harvey-samuel@pirbright.ac.uk; Nicole Gutzmann; Zach Adelman; Zachary Brown; Jayce Sudweeks; Elizabeth Heitman; Thompson, Paul; Sarah Carter; Bradbury, Steven P [NREM]
Cc: Jennifer Kuzma
Subject: ESA Symposium Invitation: Status Update
Date: Thursday, March 08, 2018 9:00:07 AM

Dear Potential Speakers,

The ESA Symposia Committee read our Symposium proposal and did not select it as one of the only 6 Program Symposia chosen for this year. However, they are considering it as a **Member or Section Symposium.** They have not finished their deliberations yet so we still don't know if our proposal will make it into the Annual Meeting program this year but my feeling is that we have a good chance to make it.

I will keep you informed.

Cheers

Raul

Dr. Raul F. Medina
Professor
Department of Entomology
Texas A&M University
TAMU 2475
College Station, TX 77843
USA
Phone: +1-301-335-4464

From: Raul Medina
Sent: Friday, February 2, 2018 10:43 AM
To: Fred Gould; [redacted]; Nicole Gutzmann; Zach Adelman; Zachary Brown; Jayce Sudweeks; Elizabeth Heitman; Thompson, Paul; Sarah Carter; Bradbury, Steven P [NREM]
Cc: Jennifer Kuzma
Subject: ESA Symposium Invitation: Thanks

Dear Potential Speakers,

Jennifer and I submitted our proposal for the ESA Symposium on Biotech and

Pest Control this past Wednesday.

Lets keep our fingers crossed so they accept our proposal!

If they accept our symposium, I will email you to re-confirm your participation. If for any reason you can not join us as a speaker, I will ask you for recommendations so I can ask the people you recommend to feel the space left by your talk.

Hopefully they will accept our symposium and you will all be able to make it as a speaker.

Thanks so much for your support!

Below is our symposium proposal:

Cheers

Raul

This message serves as a confirmation that your submission for the Entomology 2018 was received as noted below:

Title: A Changing World: Biotechnology and the Future of Pest Control

Summary Statement: The goal of this proposed program symposium is to discuss the changing world of pest control as a result of recent developments in biotechnology. Improvements in the efficiency and ease to conduct gene editing, the possibility of using gene drives to control pest species, and the realization of the crucial role played by microorganisms in the biology of most pest species, have offered novel targets and opened innovative ways to conduct pest control. Successful implementation of pest control practices using novel biotechnology products will require discussions on risks and benefits, as well as economic, social, ethical and regulatory aspects. The proposed

symposium will encourage participants to consider the importance of each of these angles in the design of pest control practices and regulations that yield societal benefits while minimizing risks.

Speakers:

1- Fred Gould (Professor, North Carolina State University): Genetic pest control: prospects and challenges

2-Tim Harvey-Samuel (The Pirbright Institute): An introduction to Gene-Drives for insect pest control

3- Nicole Gutzman (PhD student, North Carolina State University): Responsible innovation in gene drive research, what does it mean for researchers?

4-Zach Adelman (Texas A&M University): Laboratory containment of genetically-modified arthropods; gene drive and beyond

5- Jennifer Kuzma (Distinguished Professor, North Carolina State University): Value systems and their influence in the design of science-based policy

6- Zachary Brown (Assistant Professor, North Carolina State University): What does the U.S. public think about using gene drives in agriculture? And what do they want know?

7- Jayce Sudweeks (PhD student, North Carolina State University): Genetically Modified Mosquitos- Ok in Brazil, But Not The US: Do Policy Narratives About Genetically Modified Mosquitoes Have an Influence on Release Decisions

8-Elizabeth Heitman (Professor, UT Southwestern Medical Center): Ethics of gene drive for pest control

9- Paul Thompson (Professor, Michigan State University): Gene Drives for Agricultural Pest Control: A Preliminary Analysis of the Social Risks

10- Sarah Carter (Science Policy Consultant): Regulatory Challenges for Advanced Biotech Solutions

11-Steve Bradbury (Professor, Iowa State University): Advancing Regulatory Science in Anticipation of Future Biotechnology Products

Dr. Raul F. Medina
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From:	Raul Medina
To:	Fred Gould; tim.harvey-samuel@pirbright.ac.uk; Nicole Gutzmann; Zach Adelman; Zachary Brown; Jayce Sudweeks; Elizabeth Heitman; Thompson, Paul; Sarah Carter; Bradbury, Steven P [NREM]
Cc:	Jennifer Kuzma
Subject:	ESA Symposium Invitation: Thanks
Date:	Friday, February 02, 2018 10:44:12 AM

Dear Potential Speakers,

Jennifer and I submitted our proposal for the ESA Symposium on Biotech and Pest Control this past Wednesday.

Lets keep our fingers crossed so they accept our proposal!

If they accept our symposium, I will email you to re-confirm your participation. If for any reason you can not join us as a speaker, I will ask you for recommendations so I can ask the people you recommend to feel the space left by your talk.

Hopefully they will accept our symposium and you will all be able to make it as a speaker.

Thanks so much for your support!

Below is our symposium proposal:

Cheers

Raul

This message serves as a confirmation that your submission for the Entomology 2018 was received as noted below:

Title: A Changing World: Biotechnology and the Future of Pest Control

Summary Statement: The goal of this proposed program symposium is to

discuss the changing world of pest control as a result of recent developments in biotechnology. Improvements in the efficiency and ease to conduct gene editing, the possibility of using gene drives to control pest species, and the realization of the crucial role played by microorganisms in the biology of most pest species, have offered novel targets and opened innovative ways to conduct pest control. Successful implementation of pest control practices using novel biotechnology products will require discussions on risks and benefits, as well as economic, social, ethical and regulatory aspects. The proposed symposium will encourage participants to consider the importance of each of these angles in the design of pest control practices and regulations that yield societal benefits while minimizing risks.

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Dr. Raul F. Medina
Professor
Department of Entomology
Texas A&M University
TAMU 2475
College Station, TX 77843
USA
Phone: +1-301-335-4464

From: Goldsmith, Carol
To: Zach Adelman; Elizabeth Heitman
Cc: Portney, Kent E
Subject: FW: AFRI Social Implications meeting opportunity
Date: Tuesday, February 20, 2018 4:33:51 PM
Attachments: image002.png
FY 2018 BRAG PD Meeting Invite Letter.docx

Zach and Liz,

I am sharing with you the attached invitation to attend a PD meeting for grant awardees. The date has not yet been set, but there is an RSVP deadline of March 23.
Please note the we are expected to pay for travel from the grant, but we did not budget for this travel.
Perhaps once the date is set is a good time to determine who's available to go and who all should attend. And of course, if you are unable to make the trip, we can still include any questions you might have, as noted in the email below.

Carol L. Goldsmith, MPA
Senior Research Associate and Institute Manager
Institute for Science, Technology and Public Policy

20 YEARS EDUCATING PUBLIC SERVANTS

The Bush School OF GOVERNMENT & PUBLIC SERVICE TEXAS A&M UNIVERSITY

From: Portney, Kent E
Sent: Friday, February 09, 2018 3:20 PM
To: Goldsmith, Carol <clgoldsmith@tamu.edu>
Subject: FW: AFRI Social Implications meeting opportunity

Here is the invitation I just received from the AFRI program for a grantees' meeting.

- kp

From the office of:

Kent E. Portney, Professor and Director, Institute for Science, Technology and Public Policy
The George H. W. Bush School of Government and Public Service
Allen 1113A
Texas A&M University
College Station, TX 77843-4155
Email: kportney@tamu.edu
Web page addresses:
http://bush.tamu.edu/faculty/kportney/

http://tiny.cc/portney
http://www.ourgreencities.com
Blog address:
http://ourgreencities.typepad.com
Office phone: 979-458-8031

The Bush School
OF GOVERNMENT & PUBLIC SERVICE
TEXAS A&M UNIVERSITY

From: Dean, Wesley - NIFA [mailto:Wesley.Dean@nifa.usda.gov]
Sent: Friday, February 09, 2018 1:55 PM
To: Portney, Kent E <kportney@tamu.edu>
Cc: Hong, Agnes - NIFA <Agnes.Hong@nifa.usda.gov>; Kwok, Shing - NIFA <skwok@nifa.usda.gov>; Matukumalli, Lakshmi - NIFA <lmatukumalli@nifa.usda.gov>; Shoemaker, Robbin - NIFA <rshoemaker@nifa.usda.gov>; Zycherman, Ariela - NIFA <Ariela.Zycherman@nifa.usda.gov>; Kaleikau, Edward - NIFA <EKALEIKAU@nifa.usda.gov>
Subject: AFRI Social Implications meeting opportunity

Dear Kent,

We would like to extend to you and the other A1642 grantees an invitation to attend the project directors' meeting for the Biotechnology Risk Assessment Grants (BRAG) Program.

This is not a required meeting, but it will provide you an opportunity to network with A1642 and BRAG awardees, and U.S. federal regulatory scientists from USDA APHIS-BRS, FDA, and EPA agencies. We are currently working on the agenda and will invite speakers to present by late March/early April. Those who are not asked to prepare an oral presentation are requested to provide poster projects (2.5' x 3.5'). The schedule will be a mixture of federal regulator talks, selected PD project updates and progress, and a discussion and poster session in the afternoon. The agenda will be sent out as the date approaches.

Please let me know if you would like to attend by Friday, March 23rd, COB regarding your:

1. Full name and organization (How you'd like it to be printed on your name tag)
2. If you will be bringing a Co-PD/student with you
3. Questions you may have regarding biotechnology regulatory issues or risk assessments for federal regulators

We will collate your questions and provide the questions that the federal regulators may have for you in advance so it can be a productive discussion.

I am carbon copying Shing Kwok, Lakshmi Matukumalli, and Agnes Hong who are respectively the two National Program Leaders and the Program Specialist for the BRAG program, and Robbin Shoemaker, Edward Kaleikau, and Ariela Zycherman who are the National Program Leaders for the A1642 program.

Thank you,

Wesley Dean
Robbin Shoemaker,
Edward Kaleikau,
and
Ariela Zycherman

Wesley R. Dean, Ph.D.
National Program Leader
Institute of Food Production and Sustainability
Division of Agricultural Systems
202-689-4286
3321 Waterfront Centre
http://www.nifa.usda.gov

Information Regarding Annual Project Director's (PD) Meeting for Biotechnology Risk Assessment Grants (BRAG) Program

The annual PD meeting for the BRAG program will be held at the following date and location:

Date: May, 22rd, 2018; Tuesday (8:30 AM-5 PM)

Location: USDA APHIS-BRS
Animal and Plant Health Inspection Service
Oklahoma Memorial Conference Center
4700 River Road
Riverdale, MD 20737

Details for preparing for the PD Meeting:

Travel – PDs are responsible for making their own travel/hotel arrangements to Riverdale, MD, and are responsible for covering expenses from their grant.

Oral Presentations – A few projects will be invited to make oral presentations. National Program Leaders will send invitations and reach out with further instructions by March 29th.

Poster Presentations – All other projects should plan to present a poster (2.5' length x 3.5' width) that summarizes the goals, objectives, outcomes, and/or impacts of your funded work

Acknowledgement of Funding - As you prepare for this meeting and others, please remember to properly acknowledge National Institute of Food and Agriculture (NIFA) funding. Proper acknowledgement of your NIFA, AFRI funding in posters, abstracts, project websites, published manuscripts, presentations, press releases, etc. is critical for the success of the agency's programs. Please use the following language to acknowledge NIFA, AFRI support, as appropriate: "This project was supported by the Social Implications of Emerging Technologies program no XXXX-XXXXX-XXXXX from the U.S. Department of Agriculture". We also expect that you will use our agency's identifier in all of your slide and poster presentations resulting from your A1642 award.

Flight Information: Airport closest to APHIS-BRS is Washington Reagan International (DCA) Airport (15 miles away), or Baltimore Washington International (BWI) Airport (25 miles away).

If you are flying into DCA, the most convenient/economical way to get to hotels (see below) near APHIS-BRS is to take the metro GREEN line just outside the airport towards GREENBELT/FORT TOTTEN. Exit either COLLEGE PARK or GREENBELT, depending on your hotel. From the metro exit, you can pick up a taxi to your hotel. Alternatively, you can take a shuttle service or taxi directly to your hotel from the airport.

If you are flying into BWI, the most convenient method of getting to your hotel is to take a shuttle service or taxi directly from the airport to your hotel.

Parking Information: There are no fees to park at the APHIS building; however, the parking lot is secured with entry gates. Visitors should pull up to the gate and press the button on the speaker and state that they are attendees of the "USDA Biotechnology Risk Assessments Grant (BRAG) PD Meeting." Security will open gates for you to enter the lot. When entering the building, all visitors must go through a security screening and check in at the Guard Desk with a valid identification to receive a visitor pass.

For more directions and visitors information, please visit the USDA APHIS website here:
https://www.aphis.usda.gov/aphis/banner/contactus/directions-to-aphis-headquarters

Hotel accommodations:
Participants will be responsible for obtaining their own lodging accommodations.
Each of the following suggested hotels provides a free shuttle service to the USDA-APHIS building (but please check with the hotels to ensure this service is still available before making reservations):

Hilton Garden Inn
7810 Walker Drive, Greenbelt, MD
301-474-7400
www.hiltongardeninn.com

Comfort Inn & Suites College Park
9020 Baltimore Avenue, College Park, MD
301-441-8110
www.comfortinn.com

Clarion Inn College Park
8601 Baltimore Ave, College Park, MD
301-474-2800
www.cpmdinn.com

Holiday Inn
7200 Hanover Drive, Greenbelt, MD
301-982-7000
www.higreenbelt.com

From: Portney, Kent E
To: Elizabeth Heitman; Zach Adelman
Cc: Goldsmith, Carol
Subject: FW: AFRI Social Implications meeting opportunity
Date: Friday, March 23, 2018 2:25:39 PM
Attachments: image002.png
FY 2018 BRAG PD Meeting Invite Letter.docx

The travel details for the May meeting are in the attachment from Wesley Dean.

- Kent

From the office of:

Kent E. Portney, Professor
Bob Bullock Chair of Public Policy and Finance
Director, Institute for Science, Technology and Public Policy
The George H. W. Bush School of Government and Public Service
Allen 1113A
Texas A&M University
College Station, TX 77843-4155
Email: kportney@tamu.edu
Web page addresses:
http://bush.tamu.edu/faculty/kportney/
http://tiny.cc/portney
http://www.ourgreencities.com
Blog address:
http://ourgreencities.typepad.com
Office phone: 979-458-8031

The Bush School
OF GOVERNMENT & PUBLIC SERVICE
TEXAS A&M UNIVERSITY

From: Dean, Wesley - NIFA [mailto:Wesley.Dean@nifa.usda.gov]
Sent: Friday, February 09, 2018 1:55 PM
To: Portney, Kent E <kportney@tamu.edu>
Cc: Hong, Agnes - NIFA <Agnes.Hong@nifa.usda.gov>; Kwok, Shing - NIFA <skwok@nifa.usda.gov>; Matukumalli, Lakshmi - NIFA <lmatukumalli@nifa.usda.gov>; Shoemaker, Robbin - NIFA <rshoemaker@nifa.usda.gov>; Zycherman, Ariela - NIFA <Ariela.Zycherman@nifa.usda.gov>; Kaleikau, Edward - NIFA <EKALEIKAU@nifa.usda.gov>
Subject: AFRI Social Implications meeting opportunity

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We will collate your questions and provide the questions that the federal regulators may have for you in advance so it can be a productive discussion.

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Thank you,

Wesley Dean
Robbin Shoemaker,
Edward Kaleikau,
and
Ariela Zycherman

Wesley R. Dean, Ph.D.
National Program Leader
Institute of Food Production and Sustainability
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202-689-4286
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delete the email immediately.

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301-474-2800
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Holiday Inn
7200 Hanover Drive, Greenbelt, MD
301-982-7000
www.higreenbelt.com

From: Goldsmith, Carol
To: Portney, Kent E; David Kerns; Zach Adelman; Elizabeth Heitman
Cc: Johnston Vasquez, Elizabeth K
Subject: FW: almost there... NIFA 2017-08610
Date: Tuesday, March 06, 2018 9:50:02 AM
Importance: High

FYI on where we are with the award on this.

I will put together more details on the justification for the travel and work with Elizabeth on submitting the response.

Carol L. Goldsmith, MPA
Senior Research Associate and Institute Manager
Institute for Science, Technology and Public Policy

From: Berna, Jose - NIFA [mailto:JBERNA@nifa.usda.gov]
Sent: Tuesday, March 06, 2018 9:43 AM
To: Goldsmith, Carol <clgoldsmith@tamu.edu>
Cc: Johnston Vasquez, Elizabeth K <evasquez@tamu.edu>; Berna, Jose - NIFA <JBERNA@nifa.usda.gov>
Subject: almost there... NIFA 2017-08610
Importance: High

Hello Carol,

I hope you're doing well....

We are only one step away to approve this proposal. However, my signing officer wants to have a bit more information regarding the travel costs in relation to the 'Community Outreach Meetings in multiple locations throughout Texas' in the amount of $36,000. How did you arrive at this dollar amount? Perhaps you can provide the destination(s), number of travelers and other travel description related to this travel.

Also, there is $13,988 under the Texas A&M AgriLife Extension Service allocated for travel costs. We also like to obtain further breakdown on this cost. The justification you originally provided wasn't very thorough.

If you could provide me this information within the next hour or two, we'll be able to wrap things up on our end and approve this award by this afternoon.

Let me know if you have any questions.

Thank you so much!
JB
202-401-6509

From: Berna, Jose - NIFA [mailto:JBERNA@nifa.usda.gov]
Sent: Wednesday, February 21, 2018 4:30 PM
To: srs-awards@tamu.edu
Cc: Portney, Kent E <kportney@tamu.edu>; Berna, Jose - NIFA <JBERNA@nifa.usda.gov>
Subject: NIFA 2017-08610

Hello,

I'm currently conducting an administrative review for the referenced proposal, entitled: "Gene Drive Applications to Agriculture in Texas: Knowledge, Perceptions, and Values". In order for me to continue this reviewing process, I need you to send me the following information:

1. The IRB for Human Subjects is still pending.

2. Under "Materials & Supplies" for $2,100 – What type of materials will you be requesting?

3. You have requested "Catering" services for a Project Team Meeting for $3,762. Unfortunately, 'catering' services are not allowed, such activity is considered to be an entertainment cost. You need to remove this line-item from your budget. Now, you may charge 'light meals' as long as this activity maintains the continuity of these meetings and to do otherwise will impose strenuous conditions on the meeting participants. Breakfast and/or dinners are generally not allowable either because no continuity of the meeting exists.

4. I noticed you have indicated "Contractors" for $62,265 (GFK Custom Research, LLC). I'm under the impression that these contractors should

be treated as Subcontractors within your proposed budget and has to be in the same group as the other two sub-recipients (Univ. of Texas Southwestern Medical Center, and the Texas A&M AgriLife Extension). If you could please provide a broader explanation along with a signed Letter of Commitment, and Statement of Work. If they are indeed a sub-recipient, they must submit a 3-Year Budget, along with a budget justification, and reallocate this line-item under Subcontractors group in your budget and budget narrative.

5. Under UTSMC (Subrecipient): They have requested "Gift Cards" to compensate each patient ($400). Please have them remove these 'gift cards' as these are not allowable. Federal funds are not used to offer targeted program participants incentives (e.g., gift cards) to entice participation. This cost is prohibited under OMB Circulars. Have them remove this cost from their budget accordingly.

6. The Texas A&M AgriLife Extension's budget narrative was missing.

7. All Subrecipient's Letters of Commitment were missing. Make sure to have them send you these letters of collaboration and that these are signed by their Authorized Representatives.

If you could please coordinate the delivery of this information directly to my attention by February 27, 2018, so I'm able to continue this reviewing process.

Feel free to contact me via email if you have any questions or concerns.

Thank you so much!!

José A. Berna
Grants Management Specialist

Awards Management Division
Office of Grants and Financial Management
National Institute of Food and Agriculture
U. S. Department of Agriculture
Room 2130
800 9th Street., SW
Washington, D.C. 20024
Telephone: (202) 401-6509
E-mail: jberna@nifa.usda.gov

For faster service, inquiries regarding ASAP Payment Accounts should be directed to the Financial Management Division at asapcustomerservice@nifa.usda.gov.

Investing in Science, Securing Our Future

From: Goldsmith, Carol
To: Portney, Kent E; Elizabeth Heitman; Zach Adelman; David Kerns
Subject: FW: Award No. 2018-67023-27676
Date: Thursday, March 29, 2018 1:57:48 PM

So we have clarification that an approval from the IRB based on the expert interviews with note of further IRB approvals and updates will meet the assurance requirement to release the funds. Kent suggested, and I agree, that we break the expert interviews into two parts – the Texas Ag officials and the Mexican officials, and proceed with a protocol that covers the Texas officials, which we can then amend to add the Mexican officials, or have that separate. The IRB here is on board with this.

Liz, I've started a submission form for the A&M IRB. I'll share that with you tomorrow. I'll be out from noon tomorrow until around 1:00 on Tuesday. Let me know when we can chat after I return.

Carol

From: Dean, Wesley - NIFA [mailto:Wesley.Dean@nifa.usda.gov]
Sent: Thursday, March 29, 2018 10:49 AM
To: Goldsmith, Carol <clgoldsmith@tamu.edu>
Subject: RE: Award No. 2018-67023-27676

Hi Carol,

I just spoke with Jose and his team leader Evan and we do need an assurance number to release funds. In the meantime, TAMU has the 90 day expenditure authority.

Is the assurance number still pending? If so, what Jose needs is a new version of the form without a tick in the pending box.

I pulled out your proposal to look at the data collection schedule. It looks like your preliminary stage will feature these less structured discussions. Perhaps you could get an assurance based on that from IRB with the understanding that you have to return to IRB for further approvals/updates as you develop new data collection protocols.

Let me know if this helps.

Best,

Wesley

Wesley R. Dean, Ph.D.
National Program Leader
Institute of Food Production and Sustainability
Division of Agricultural Systems
202-689-4286
3321 Waterfront Centre
http://www.nifa.usda.gov

From: Goldsmith, Carol [mailto:clgoldsmith@tamu.edu]
Sent: Monday, March 26, 2018 4:52 PM
To: Dean, Wesley - NIFA <Wesley.Dean@nifa.usda.gov>
Subject: RE: Award No. 2018-67023-27676

Thank you.

Carol L. Goldsmith, MPA
Senior Research Associate and Institute Manager
Institute for Science, Technology and Public Policy

From: Dean, Wesley - NIFA [mailto:Wesley.Dean@nifa.usda.gov]
Sent: Monday, March 26, 2018 3:51 PM
To: Goldsmith, Carol <clgoldsmith@tamu.edu>
Subject: RE: Award No. 2018-67023-27676

Hi Carol,

I'm going to catch up with Jose and his director when they're all in the office, likely this Thursday, and then we'll get back to you.

Best,

Wesley

Wesley R. Dean, Ph.D.
National Program Leader
Institute of Food Production and Sustainability
Division of Agricultural Systems
202-689-4286
3321 Waterfront Centre
http://www.nifa.usda.gov

From: Goldsmith, Carol [mailto:clgoldsmith@tamu.edu]
Sent: Monday, March 26, 2018 3:55 PM
To: Dean, Wesley - NIFA <Wesley.Dean@nifa.usda.gov>
Cc: awards <awards@nifa.usda.gov>
Subject: Award No. 2018-67023-27676

Dr. Wesley Dean,

I am sending you the attached communications and documents as requested during our phone call earlier today.

I coordinated with Jose Berna, who was very helpful, responsive and professional, to supply additional requested information as part of the administrative review process for the award. He and I talked about the delayed onset determination I had obtained from the IRB here (and included in the PDF). As Mr. Berna was uncertain as to whether that document would suffice as the IRB approval document requested, he was going to discuss it with his supervisor. I'm not sure what the outcome of that discussion was.

I am following up with you because Provision 1 of the Award Face Sheet we received after submitting the attached files, stipulates that all of the funds are being withheld pending provision of an IRB approval document. As we discussed, there will be multiple phases to this research project, which will result in multiple IRB protocols, and the protocols will be developed based on activities conducted as part of the funded project.

Thank you for checking into this matter and helping to find a way to move our project forward. Please let me know if any additional information is needed. We're very excited to begin our research and look forward to working with you.

Sincerely,

Carol L. Goldsmith, MPA
Senior Research Associate and Institute Manager
4350 TAMU, College Station, TX 77843-4350
clgoldsmith@tamu.edu / 979-845-6860 / Allen Building Rm. 1116

Institute for Science, Technology and Public Policy
Bush School of Government and Public Service
http://bush.tamu.edu/istpp/

From:	Elizabeth Heitman
To:	Ruth Vinciguerra
Subject:	FW: NIFA 2017-08610 and FP00012171 by Feb. 27th
Date:	Tuesday, February 27, 2018 3:31:00 PM
Attachments:	UTSW-USDA Budget Justification 2-27-18 final (EH reworded).docx RR_Budget_UTSW(Heitman)2-27-18 (EH reworded).pdf

USDA's numbers – as final as they get on this end....

Liz

Elizabeth Heitman, PhD
Program in Ethics in Science and Medicine
University of Texas Southwestern Medical Center
5323 Harry Hines Boulevard, NC5.832
Dallas, TX 75390-9070
(214)-648-5379
(214)-648-4967 fax
Email: Elizabeth.Heitman@UTSouthwestern.edu
www.utsouthwestern.edu/ethics

From: Goldsmith, Carol [mailto:clgoldsmith@tamu.edu]
Sent: Tuesday, February 27, 2018 3:29 PM
To: Elizabeth Heitman <Elizabeth.Heitman@UTSouthwestern.edu>
Cc: Johnston Vasquez, Elizabeth K <evasquez@tamu.edu>
Subject: RE: NIFA 2017-08610 and FP00012171 by Feb. 27th

Yes, other than the letter we have what we need.

Carol L. Goldsmith, MPA
Senior Research Associate and Institute Manager
Institute for Science, Technology and Public Policy

From: Elizabeth Heitman [mailto:Elizabeth.Heitman@UTSouthwestern.edu]
Sent: Tuesday, February 27, 2018 3:28 PM
To: Goldsmith, Carol <clgoldsmith@tamu.edu>
Cc: Johnston Vasquez, Elizabeth K <evasquez@tamu.edu>
Subject: RE: NIFA 2017-08610 and FP00012171 by Feb. 27th

Carol,

Do you have everything you need now other than UTSW's letter of commitment ?

I have to count on Yelonda and Latasha to send the truly official version of what Yelonda just said was the final version.

Liz

Elizabeth Heitman, PhD
Program in Ethics in Science and Medicine
University of Texas Southwestern Medical Center
5323 Harry Hines Boulevard, NC5.832
Dallas, TX 75390-9070
(214)-648-5379
(214)-648-4967 fax
Email: Elizabeth.Heitman@UTSouthwestern.edu
www.utsouthwestern.edu/ethics

From: Goldsmith, Carol [mailto:clgoldsmith@tamu.edu]
Sent: Tuesday, February 27, 2018 1:58 PM
To: Elizabeth Heitman <Elizabeth.Heitman@UTSouthwestern.edu>
Cc: Johnston Vasquez, Elizabeth K <evasquez@tamu.edu>
Subject: RE: NIFA 2017-08610 and FP00012171 by Feb. 27th

So Liz, do I have your final budget number correct - $74,236?

And you will be sending me a final RR budget form, final budget justification, and a revised letter?

Carol L. Goldsmith, MPA
Senior Research Associate and Institute Manager
Institute for Science, Technology and Public Policy

From: Johnston Vasquez, Elizabeth K
Sent: Tuesday, February 27, 2018 1:37 PM
To: Goldsmith, Carol <clgoldsmith@tamu.edu>; Elizabeth Heitman <Elizabeth.Heitman@UTSouthwestern.edu>
Subject: RE: NIFA 2017-08610 and FP00012171 by Feb. 27th

If you can round to whole dollars that would be great

Elizabeth Johnston Vasquez
ph: 979-458-8074 | evasquez@tamu.edu

From: Goldsmith, Carol
Sent: Tuesday, February 27, 2018 11:34 AM
To: Elizabeth Heitman <Elizabeth.Heitman@UTSouthwestern.edu>; Johnston Vasquez, Elizabeth K <evasquez@tamu.edu>
Subject: RE: NIFA 2017-08610 and FP00012171 by Feb. 27th

Liz, see item 8 re: transportation costs.

Elizabeth, I don't know the answer about the rounding.

Carol L. Goldsmith, MPA
Senior Research Associate and Institute Manager
Institute for Science, Technology and Public Policy

From: Elizabeth Heitman [mailto:Elizabeth.Heitman@UTSouthwestern.edu]
Sent: Tuesday, February 27, 2018 11:18 AM
To: Goldsmith, Carol <clgoldsmith@tamu.edu>
Subject: RE: NIFA 2017-08610 and FP00012171 by Feb. 27th

Do youthink we need to say anything about offsetting transportation costs?

On the two different budget totals, do you want it to be the rounded (down) .00 or the .25?

Liz

Elizabeth Heitman, PhD
Program in Ethics in Science and Medicine
University of Texas Southwestern Medical Center
5323 Harry Hines Boulevard, NC5.832
Dallas, TX 75390-9070
(214)-648-5379
(214)-648-4967 fax
Email: Elizabeth.Heitman@UTSouthwestern.edu

www.utsouthwestern.edu/ethics

From: Goldsmith, Carol [mailto:clgoldsmith@tamu.edu]
Sent: Tuesday, February 27, 2018 11:15 AM
To: Elizabeth Heitman <Elizabeth.Heitman@UTSouthwestern.edu>
Subject: RE: NIFA 2017-08610 and FP00012171 by Feb. 27th

How about this?

This item in the budget and the budget justification has been revised to remove the reference to gift cards. Instead, funds are being requested to provide an honorarium to compensate participants for their services. Their input is a vital part of our research into people's knowledge, perceptions, and values concerning gene drive.

Carol L. Goldsmith, MPA
Senior Research Associate and Institute Manager
Institute for Science, Technology and Public Policy

From: Elizabeth Heitman [mailto:Elizabeth.Heitman@UTSouthwestern.edu]
Sent: Tuesday, February 27, 2018 11:14 AM
To: Goldsmith, Carol <clgoldsmith@tamu.edu>; Johnston Vasquez, Elizabeth K <evasquez@tamu.edu>
Subject: RE: NIFA 2017-08610 and FP00012171 by Feb. 27th

Thanks, Carol. Honorarium it is! I may still use the term "de minimis" .

Back shortly with the new paperwork.

Liz

Elizabeth Heitman, PhD
Program in Ethics in Science and Medicine
University of Texas Southwestern Medical Center
5323 Harry Hines Boulevard, NC5.832
Dallas, TX 75390-9070
(214)-648-5379
(214)-648-4967 fax
Email: Elizabeth.Heitman@UTSouthwestern.edu

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From: Goldsmith, Carol [mailto:clgoldsmith@tamu.edu]
Sent: Tuesday, February 27, 2018 11:11 AM
To: Johnston Vasquez, Elizabeth K <evasquez@tamu.edu>; Elizabeth Heitman <Elizabeth.Heitman@UTSouthwestern.edu>
Subject: NIFA 2017-08610 and FP00012171 by Feb. 27th

Hi Elizabeth and Liz,

I just spoke with Jose. We are allowed to request rebudgeting!

We do need to submit a revised version of the RR budget and updated budget justifications.

We spoke about the gift cards. We're close on the rewording we used. He said to use 'honorarium' that will be given them to compensate for services that they provide.

Carol L. Goldsmith, MPA
Senior Research Associate and Institute Manager
4350 TAMU, College Station, TX 77843-4350
clgoldsmith@tamu.edu / 979-845-6860 / Allen Building Rm. 1116

Institute for Science, Technology and Public Policy
Bush School of Government and Public Service
http://bush.tamu.edu/istpp/

BUDGET JUSTIFICATION

Total Project Funds Requested: $74,235.60

A. SENIOR/KEY PERSON

1. Co-PI Elizabeth Heitman, PhD, as part of her effort on this project, will:
   - Travel to and participate in team meetings and training sessions at Texas A&M; travel to and participate in the PIs' Biotechnology Risk Assessment Grants Meeting in Riverdale, MD; participate in the development of a pre-test of baseline knowledge on gene drive technology for Texas IPM Extension Program Specialists and IPM Agents and develop materials and provide instruction on ethical issues in gene drive technology for their use; Assist in the development of survey instruments and develop interview guides/scripts in English and Spanish; Conduct up to ten (10) interviews in English and Spanish with key informants and five (5) focus groups with community organizations following education sessions by IPM Extension Agents; Oversee transcription, translate Spanish transcripts into English, and analyze transcripts for key themes; Assist in analysis of survey results; Develop, and write manuscripts for publication; and Communicate regularly with Co-PIs Portney and Adelman and the team at Texas A&M

   Her effort will be 10% for each of Years 1 and 2 and 2% for Year 3. (Requested funds – $ 44,663)

B. OTHER PERSONNEL

C. EQUIPMENT

D. TRAVEL

1. Over the course of the grant, co-PI Elizabeth Heitman, PhD, will conduct the following travel:
   - One overnight trip to Texas A&M University in College Station, Texas for an initial Project Team Meeting in Year 1, and one overnight trip to an interim Project Team Meeting at Texas A&M in Year 2, at a cost of $500 each ($1000)
   - One overnight trip in Year 2 to a location yet to be determined to report on the project's results to date, receive feedback, and discuss with Agents how this experience can improve upcoming IPM community education and engagement events. Trip is projected at a cost of $500
   - One overnight trip to Texas A&M University in College Station, Texas and one overnight trip to Lubbock, Texas, both in Year 1, to participate in IPM Research Dissemination Workshops on the project at a cost of $500 each ($1000)
   - Four (4) overnight trips to conduct focus groups following IPM agents' sessions with community groups, a cost of $500 each. Three such trips are planned for in Yr. 1 at a cost of 3 *$500 = $1500; and 1 such trip in Yr. 2, 1* $500= $500. ($2000)
   - One overnight trip in Year 1 to Riverdale, MD to attend the PIs' Biotechnology Risk Assessment Grants Meeting, at a cost of $950
   - Overnight travel costs are calculated to include either airfare plus rental car, OR long-distance mileage, together with hotel and meals.

   (Requested Funds - $5,450)

E. PARTICIPANT/TRAINEE SUPPORT COST

1. De minimis honorariums in compensation for participants' time and services in focus group sessions, at $10 for each of 40 focus group participants. Yr.1: 24 *$10 = $240 and Yr. 2 16 *$10= $160. (Requested Funds - $400)

F. OTHER DIRECT COSTS

1. Materials and supplies: $100 for each of Year 1 and Year 2 for office supplies to be used to develop guides/scripts and educational materials for interviews and focus groups. (Requested Funds - $200)

2. Publication costs

3. Other Costs
   i. UTSW Qualitative Research Core: Professional staff members from UTSW's Qualitative Research Core will provide support in developing the interview and focus group guides/scripts, analysis of transcripts using analytic software such as NVivo, and verification of translations between English and Spanish. This work will be internally billed at a rate of $50/hour. Support will be provided on a schedule that parallels Dr. Heitman's participation in the IPM's Community Outreach Meetings, anticipated at 100 hours over the first 2 years with approximately 60 hours in Year 1 ($3,000) and 40 hours in Year 2 ($2,000). (Requested Funds - $5,000)

   ii. Transcription – A professional research transcription service (such as The Data Café) will be contracted to provide transcription of audio recordings of four 90-minute focus groups at $2.00/audio minute ($720) and one 90-minute focus group in Spanish at $2.10/audio minute ($189), for a combined total of $909 for focus group transcription. They will provide additional transcription of five 20-30 minute interviews in Spanish with Mexican scientists and policymakers at $2.00/audio minute ($250), and transcription of five 20-30 minute interviews in English with agricultural officials in the Texas-Mexico border region at $1.85/audio minute ($231.25), for a combined total of $481.25 for transcription of interviews. Higher rates for focus groups reflect the increased difficulty of transcribing discussion among more than 2 individuals; higher rates for transcribing Spanish reflect the shortage of skilled Spanish-language transcriptionists. Yr. 1 10interview transcriptions, $481.25, plus (3) focus group transcriptions, 549, for a total cost of $1030.25 and Yr. 2 (2) focus group transcriptions: $360. (Requested Funds - $1,390.25)

4. Subrecipient costs

5. Graduate student tuition

G. DIRECT COSTS
   1. Total direct costs (Requested Funds $57,104)

H. INDIRECT COSTS
   1. UT Southwestern indirect cost is calculated at 30% of Total Project (30% of Total Direct Costs) per the USDA/NIFA institutional contract rate. The overall rate results in less indirect cost than the 30% Total Federal Award cap imposed by NIFA (Requested Funds - $17,131.60).

I. TOTAL DIRECT AND INDIRECT COSTS
   1. Total project costs include $36,870.60 in Year-1; $31,941 in Year-2; $5,424 in Year-3. (Requested Funds - $74,235.60)

From: Portney, Kent E
To: Elizabeth Heitman; Zach Adelman
Cc: Goldsmith, Carol
Subject: FW: NIFA 2017-08610
Date: Friday, February 23, 2018 9:49:57 AM
Attachments: image001.png

Elizabeth and Zach,

I think Carol mentioned this to you, but we received a request for more information in support of our grant. Carol is working on this, but I thought you might like to see the request. They have set a deadline of February 27 (next Tuesday) for our response.

Thanks.

- Kent

From the office of:

Kent E. Portney, Professor and Director, Institute for Science, Technology and Public Policy
The George H. W. Bush School of Government and Public Service
Allen 1113A
Texas A&M University
College Station, TX 77843-4155
Email: kportney@tamu.edu
Web page addresses:
http://bush.tamu.edu/faculty/kportney/
http://tiny.cc/portney
http://www.ourgreencities.com
Blog address:
http://ourgreencities.typepad.com
Office phone: 979-458-8031

The Bush School
OF GOVERNMENT & PUBLIC SERVICE
TEXAS A&M UNIVERSITY

From: Berna, Jose - NIFA [mailto:JBERNA@nifa.usda.gov]
Sent: Wednesday, February 21, 2018 4:30 PM
To: srs-awards@tamu.edu
Cc: Portney, Kent E <kportney@tamu.edu>; Berna, Jose - NIFA <JBERNA@nifa.usda.gov>
Subject: NIFA 2017-08610

Hello,

I'm currently conducting an administrative review for the referenced proposal,

entitled: "Gene Drive Applications to Agriculture in Texas: Knowledge, Perceptions, and Values". In order for me to continue this reviewing process, I need you to send me the following information:

1. The IRB for Human Subjects is still pending.

2. Under "Materials & Supplies" for $2,100 – What type of materials will you be requesting?

3. You have requested "Catering" services for a Project Team Meeting for $3,762. Unfortunately, 'catering' services are not allowed, such activity is considered to be an entertainment cost. You need to remove this line-item from your budget. Now, you may charge 'light meals' as long as this activity maintains the continuity of these meetings and to do otherwise will impose strenuous conditions on the meeting participants. Breakfast and/or dinners are generally not allowable either because no continuity of the meeting exists.

4. I noticed you have indicated "Contractors" for $62,265 (GFK Custom Research, LLC). I'm under the impression that these contractors should be treated as Subcontractors within your proposed budget and has to be in the same group as the other two sub-recipients (Univ. of Texas Southwestern Medical Center, and the Texas A&M AgriLife Extension). If you could please provide a broader explanation along with a signed Letter of Commitment, and Statement of Work. If they are indeed a sub-recipient, they must submit a 3-Year Budget, along with a budget justification, and reallocate this line-item under Subcontractors group in your budget and budget narrative.

5. Under UTSMC (Subrecipient): They have requested "Gift Cards" to compensate each patient ($400). Please have them remove these 'gift cards' as these are not allowable. Federal funds are not used to offer targeted program participants incentives (e.g., gift cards) to entice participation. This cost is prohibited under OMB Circulars. Have them remove this cost from their budget accordingly.

6. The Texas A&M AgriLife Extension's budget narrative was missing.

7. All Subrecipient's Letters of Commitment were missing. Make sure to have them send you these letters of collaboration and that these are signed by their Authorized Representatives.

If you could please coordinate the delivery of this information directly to my attention by February 27, 2018, so I'm able to continue this reviewing process.

Feel free to contact me via email if you have any questions or concerns.

Thank you so much!!

José A. Berna
Grants Management Specialist
Awards Management Division
Office of Grants and Financial Management
National Institute of Food and Agriculture
U. S. Department of Agriculture
Room 2130
800 9th Street., SW
Washington, D.C. 20024
Telephone: (202) 401-6509
E-mail: jberna@nifa.usda.gov

For faster service, inquiries regarding ASAP Payment Accounts should be directed to the Financial Management Division at asapcustomerservice@nifa.usda.gov.

Investing in Science, Securing Our Future

From: Goldsmith, Carol
To: Elizabeth Heitman
Subject: FW: TAMU IRB Links
Date: Monday, February 19, 2018 10:13:30 AM
Attachments: TEMPLATE - Protocol_Social-Behavioral_WITH_instructions.docx
TEMPLATE - Social - Behavioral Consent_revised.docx
TEMPLATE - Simple Survey Consent Script-1.docx
TEMPLATE - Translation Certificate.doc
TEMPLATE - General Site Authorization.doc

And here are the links and some templates (attached). I don't expect anything will be a surprise to you, but wanted to give you a sense of how the IRB and Human Research Protection Program staff approach things here. There's a lot to figure out, including our engagement question.

http://rcb.tamu.edu/humansubjects/investigator-resources-1 Resources for investigators

http://rcb.tamu.edu/humansubjects/forms/HRP096SOPManagementofMultisiteResearch.pdf Management of Multi-Site Research

Site Specific Authorizations are required when your research involves any organization or entity that is not part of Texas A&M University. This includes public schools or other educational settings, private clinics, hospitals, nursing homes, government agencies or any other outside business or field site. Written approval from the organization's authorized individual is required. In certain cases, contracts or other agreements may be required. Site Specific Authorization templates are available on the IRB website.

International Research protocols should include explanations of cultural norms or conditions, especially any customary consent practices that may warrant an alteration of the consent process or waiver of consent documentation. TAMU does not relax standards for the ethical conduct of research or for a meaningful consent process in foreign countries. Although, research conducted by TAMU investigators in foreign countries remains under the University's purview, the research must be approved by the local equivalent of an IRB before the TAMU IRB gives approval. Where there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. All international approvals must be in writing.

And, I forgot to mention during our phone call that I plan to submit a request for Delayed Onset Determination. I have the application prepared, just waiting for a project award number.

Carol L. Goldsmith, MPA
Senior Research Associate and Institute Manager
Institute for Science, Technology and Public Policy

From: Goldsmith, Carol
Sent: Monday, February 19, 2018 9:27 AM
To: 'Elizabeth Heitman' <Elizabeth.Heitman@UTSouthwestern.edu>
Subject: TAMU IRB Links

Hi Liz,

Thank you for sending the articles. I will read them soon. Here are the links to some of the information I referenced.

I'd like to set up a meeting with the HSPP folks to discuss our project. Please give me some options.

Also, our project executive committee should have at least a phone meeting soon, prior to getting the large team back together. So some options for that as well, please. Perhaps Friday afternoons?

Carol L. Goldsmith, MPA
Senior Research Associate and Institute Manager
4350 TAMU, College Station, TX 77843-4350
clgoldsmith@tamu.edu / 979-845-6860 / Allen Building Rm. 1116

Institute for Science, Technology and Public Policy
Bush School of Government and Public Service
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Site Authorization/Cooperation Letter Templates

SITE SPECIFIC AUTHORIZATION TO CONDUCT RESEARCH

[Note to investigator: Use this form to obtain authorization from site at which your research is conducted.]

Date:

Dear TAMU Institutional Review Board:

The purpose of this letter is to inform you that I give *[Name of Principal Investigator]* permission to conduct the research titled *[Title of Research Study]* at *[Name of Site]*. We have agreed to the following study procedures [insert procedures that site has agreed to] and/or [list any data or private information] for the research to be released for the research.

Sincerely,

[Name of Organization granting permission]
[Name of Signatory]
[Title of Signatory]

SITE SPECIFIC AUTHORIZATION TO CONDUCT RESEARCH

[Note to investigator: Use this form to obtain authorization from site at which your research is conducted.]

Date:

Dear TAMU Institutional Review Board:

The purpose of this letter is to inform you that I give *[Name of Principal Investigator]* permission to conduct the research titled *[Title of Research Study]* at *[Name of Site]*. We have agreed to the following study procedures [insert procedures that site has agreed to] and/or [list any data or private information] for the research to be released for the research.

I understand that *[Name of Principal Investigator]* will receive consent for all participants. *[Name of Principal Investigator]* has agreed to provide my office a copy of all Texas A&M University IRB-approved, stamped consent documents before he/she recruits participants on site. Any data collected by *[Name of Principal Investigator]* will be kept confidential and will be stored in a locked filing cabinet within his/her office. *[Name of Principal Investigator]* has agreed to provide to us a copy of the aggregate results from his/her study.

Sincerely,

[Name of Organization granting permission]
[Name of Signatory]
[Title of Signatory]

SOCIAL & BEHAVIORAL TEMPLATE WITH INSTRUCTIONS:

Use this template to prepare a document for SOCIAL AND BEHAVIORAL research with the information from the following sections.

Depending on the nature of what you are doing, some sections may not be applicable to your research. Mark N/A if it's not applicable.

When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.

Remove all instructions in red before submitting to the IRB or use the version without instructions and use this copy as a guide.

PROTOCOL TITLE:

Include the full protocol title.

VERSION DATE:
Also include version date in footer.

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

1.0 Purpose of the Study:

1. Describe the purpose, specific aims, or objectives. State the hypotheses to be tested or the research questions that will guide the study.

2.0 Background / Literature Review / Rationale for the study:

1. Briefly (500 words or fewer):
   a. Describe the relevant current context of the study and gaps in current knowledge.
   b. Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.
   c. Add relevant references at the end of the protocol (not at the end of this section).
   d. If you are uploading a funding proposal that has this information, indicate applicable pages.

3.0 Inclusion and exclusion criteria:

1. Briefly describe the total number of participants and the criteria (such as age, gender, language, etc.) that define who will be included or excluded in your study sample.

2. Indicate specifically whether you will include or exclude any special populations: (You may not include members of these populations as participants in your research unless you indicate this in your inclusion criteria.)
   a. Adults unable to consent
   b. Minors: infants, children, teenagers
   c. Pregnant women (where the activities of the research may affect the pregnancy or the fetus.)
   d. Prisoners

4.0 Procedures Involved:

1. Describe the setting of the study, including all locations where research procedures will be performed.
2. Describe the study design including the rationale.
3. Provide a description of all research procedures and activities.
4. Include when they are performed, and any procedures being used to monitor participants for safety or minimize risks.
5. Describe the study timelines including: the duration of an individual participant's participation in the study and the overall anticipated duration of the project.
6. Describe the actual source records or measures that will be used to collect data about participants. (All surveys, interview scripts, and data collection forms will be attached elsewhere in the application. Do not add other documents to the protocol.) Describe what data will be collected and how it will be collected at all measurement/data collection time-points.
7. If doing online research, include the URL where the data collection will occur.
8. If your research is conducted outside of Texas A&M University, please identify any site-specific regulations or customs affecting your project, including any local scientific and ethical review structure.
9. Describe any approvals that will be obtained prior to commencing the research. (e.g., school, external site. funding agency.)
10. If the research involves individuals who are vulnerable or susceptible to coercion or undue influence[1], describe additional safeguards included to protect their rights and welfare:
    a. If the research involves pregnant women where the research activities are expected to affect the pregnancy, review "CHECKLIST: Pregnant Women (HRP-412)" to ensure that you have provided sufficient information.

[1] Coercion occurs when an overt or implicit threat of harm is intentionally presented to obtain compliance. Undue influence, by contrast, often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance (http://www.hhs.gov/ohrp/policy/faq/informed-consent/what-does-coercion-or-undue-influence-mean.html). For example, the threat of the loss of reputation, good standing in class or of a bad grade if a student does not participate in a study would be an example of coercion. The offer of excessive money or special treatment or rewards for participation could be an example of undue influence.

b. If the research involves prisoners, review "CHECKLIST: Prisoners (HRP-415)" to ensure that you have provided sufficient information.

c. If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children"), review the "CHECKLIST: Children (HRP-416)" to ensure that you have provided sufficient information.

d. If the research involves cognitively impaired adults, review "CHECKLIST: Cognitively Impaired Adults (HRP-417)" to ensure that you have provided sufficient information.

5.0 Multiple sites:

1. If this research involves multiple sites, specify which is the lead site and describe the roles of each site in the study.
2. Indicate that all required approvals are already obtained or will be obtained at each site prior to project implementation. In addition:
   a. Describe the processes you have in place to ensure successful coordination of activities among sites. For example, do all sites have the most current version of the protocol, consent document, and HIPAA authorization? How will modifications be communicated to sites and approved prior to implementation? How will participating sites be kept abreast of any problems, interim results, or the eventual closure of the study?
   b. Describe the processes you have in place to ensure successful coordination of activities among sites. For example, do all sites have the most current version of the protocol, consent document, and HIPAA authorization? How will modifications be communicated to sites and approved prior to implementation? How will participating sites be kept abreast of any problems, interim results, or the eventual closure of the study?
   c. Describe the mechanisms you have in place to ensure that all local site investigators conduct the study appropriately and that engaged participating sites safeguard data as required by local information security policies. Please confirm that all non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

6.0 Incomplete Disclosure or Deception:

If the study will use incomplete disclosure or deception, please provide a rationale. Please also provide a description of the debriefing process that will be used to make participants aware of the deception and their right to withdraw any record of their participation. Include here if reconsent will occur (see the Deception Guidance on the IRB website).

7.0 Recruitment:

1. Describe when, where, and how potential participants will be recruited.
2. Describe the types of strategies and materials that will be used to recruit participants.

3. Upload all recruitment materials as separate documents in iRIS

8.0 Consent Process

1. If obtaining consent using a written consent document, describe:
   a. Where the consent process will take place.
   b. Any process to ensure ongoing consent if appropriate. This may include reconsent for longitudinal studies or if there are multiple stages to a project over time.
   c. The details of the consent process including:
      i. The role of the individuals listed in the application as being involved in the consent process.
      ii. The amount of time that will be devoted to the consent discussion.
      iii. Steps that will be taken to minimize the possibility of coercion or undue influence.
      iv. Steps that will be taken to ensure the participants' understanding.
2. If there are Non-English speaking participants who will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in the language with which they are most comfortable speaking or writing. Indicate the language that will be used by those obtaining consent. If you will be using a translator during recruitment, consent, data collection, or data analysis specify how you will identify an appropriate translator and what the provisions will be for protecting the confidentiality of participants.

3. Participants who are not yet adults (infants, children, teenagers):
   a. Describe whether parental permission will be obtained from:
      i. Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
      ii. One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
      iii. Individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's participation.
   b. Describe the process for assent of the children. Indicate whether:
      i. Assent will be required of all, some, or none of the children. If some, indicated, which children will be required to assent and which will not.
      ii. If assent will not be obtained from some or all children, an explanation of why not.
      iii. Describe whether assent of the children will be documented and the process to document assent.
   c. For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent procedures involved the research, under

the applicable law of the jurisdiction in which research will be conducted. See the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

4. Cognitively Impaired Adults:

   Describe the process to determine whether an individual is capable of consent. Indicate if you will be obtaining assent and documenting assent.

5. Adults Unable to Consent:

   a. List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)
      i. For research conducted in the state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "legally authorized representative."
      ii. For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective participant to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have the Office of General Counsel review your protocol.

9.0 Process to Document Consent:

1. Describe whether and how consent of the participant will be documented in writing.
2. If you will document consent in writing, you will attach a consent document. You must use [TEMPLATE – Social & Behavioral Consent]to create the consent document or script.]
3. If you will obtain consent, but not document consent in writing, you must attach a consent script. See the following sample [TEMPLATE – Simple Survey Consent Script]. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.
4. Waiver or Alteration of Consent Process (consent will not be obtained):

10.0 Risks to Participants:

1. List the reasonably foreseeable risks, discomforts, hazards, or inconveniences related the participants' participation in the research. Describe the probability, magnitude, duration, and reversibility of the risks.
2. Consider physical, psychological, social, legal, and economic risks as well as community or group harms.
3. If applicable, describe risks to others who are not participants.
4. Withdrawal of Participants:
   a. Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.
   b. Describe procedures that will be followed when participants withdraw from the research, including withdrawal from some but not procedures with continued data collection.

c. Describe the use of data after withdrawal.

11.0 Potential Benefits to Participants:

Note: participation in the research itself and compensation from participating in the research are not benefits.

1. Describe the potential benefits that individual participants may experience from taking part in the research. Describe also the probability, magnitude, and duration of the potential benefits.
2. Indicate if there is no direct benefit to participants. Do not include benefits to society or others.

12.0 Financial Compensation:

1. Describe any financial compensation that will be provided to participants. Include how much money or what gifts will be provided and for what activities.
2. Include whether compensation will be prorated if there are multiple research activities or if a participant withdraws from the study before finishing.
3. Describe any costs that participants may be responsible for because of participation in the research.

13.0 Provisions to Protect the Privacy Interests of Participants:

1. Describe the steps that will be taken to protect participants' privacy interests throughout the research activities.
2. Indicate who on the research team and how the research team is permitted to access any sources of information about the participants.

14.0 Confidentiality and Data Management:

1. Describe how data (and if applicable, biological specimens) will be handled study-wide including:
   a. What information will be included as data (or associated with the specimens)? "Data" includes all information collected in the conduct of the research, such as but not limited to: consents, surveys, interview notes, audio or video recordings, photographs, notes of observations, field notes, etc.
   b. Where and how will data (or specimens) be stored? How will data be transported from the point of collection to where they will be stored? Note: electronic storage of data in both domestic and international research must be secured using adequate protections.
   c. How long will the data or specimens be stored? (Note: IRB policy is 5 years after the completion of the study. However, there are circumstance when other time frames may apply (signed HIPAA Authorizations or Waivers require 6 years from end of research).
   d. Who will have access to the stored data or specimens?
   e. Who is responsible for receipt or transmission of the data or specimens?

2. Describe the steps that will be taken secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.
3. Describe any procedures that will be used for quality control of collected data. If conducting online research, specify if you will be using any attention check measures. If yes, you need to indicate what you will be doing and what happens if a participant fails the attention checks.
4. Describe the data analysis plan, including any statistical procedures is applicable.

15.0 Data Monitoring Plan to Ensure the Safety of Participants:

1. Describe the plan to periodically evaluate the information collected regarding risks or harms to determine whether participants remain safe. For example, if you are collecting depression or suicidality data, what is your plan for monitoring severity? Note: Greater than minimal risk studies require a plan; it might be necessary to establish a data monitoring committee and a plan for reporting the findings to the IRB and the sponsor. It also could include referral to an appropriate resource. Include the following:
    a. What information / data are reviewed, including safety data, untoward events, and efficacy data.
    b. How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
    c. The frequency of data collection, including when safety data collection starts.
    d. Who will review the data.
    e. The frequency or periodicity of review of cumulative data.
    f. The statistical tests for analyzing the safety data to determine whether harm is occurring.
    g. Describe any conditions where the research team may intervene and what the plan is for intervening. (For example, if a participant identifies harm to self or others.)
    h. Describe any conditions that might trigger an immediate suspension of the research.

16.0 Data and if applicable, Specimen Banking:

1. If data or specimens will be banked for future use, describe where the data or specimens will be stored, how long they will be stored, how the data or specimens will be accessed, and who will have access to the specimens.
2. If storing data electronically, include a plan for managing the long term storage of the data if appropriate.
3. If storing data in a data repository outside of Texas A&M University, include the agreement with the entity where the data will be stored.
4. List the data to be stored or, in the case of specimens what information will be associated with each specimen.
5. Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens. Note: a separate IRB protocol may be required to support a research repository.

17.0 Qualifications to Conduct Research and Resources Available:

1. For international research or research with vulnerable populations, describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to conduct the research. When applicable describe the knowledge of the local study sites, culture, and society. Provide enough information so the IRB knows that you have qualified staff for the proposed research.
2. Describe other resources available to conduct the research: For example, as appropriate:
    a. Describe your facilities or other physical resources needed for the conduct of the research.
    b. Describe the availability of social, emotional or psychological resources that participants might need as a result of an anticipated consequences of the human research.
    c. Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions

18.0 Community-Based Participatory Research

1. Describe involvement of the community in the design and conduct of the research.

NOTE: "Community-based Participatory Research" is a collaborative approach to research that involves the community partners in the research design and all aspects of the research process. Community-based Participatory Research begins with a research topic of importance to the community, and has a goal of improving health or other outcomes and eliminating disparities. Simply recruiting participants from the community is not CBPR. If your research does not involve the community in all aspects of the research process, mark N/A)

TEXAS A&M UNIVERSITY HUMAN RESEARCH PROTECTION PROGRAM

INFORMED CONSENT SCRIPT

This is a sample consent script for simple surveys and questionnaires. It is to be used only when the IRB is not likely to require written documentation of consent.

Remove all instructional text and red color-coding from this document before submitting to the IRB for approval.

Title of Research Study: [insert title of research study]

Investigator: [insert name of principal investigator]

Why am I being asked to take part in this research study?

You are invited to participate in this study because we are trying to learn more about: *state what is being studied.*

You were selected as a possible participant in this study because ... *state why and how the subject was selected.* You must be 18 years of age or older to participate.

Why is this research being done?

The (survey or test) is designed to ... *explain the purpose of survey or test.*

How long will the research last?

It will take about ... *length of time expected to complete survey or test.*

What happens if I say "Yes, I want to be in this research"?

If you decide to participate, please do the following: *Include any specific instructions for completing the survey or test.*

What happens if I do not want to be in this research?

Your participation in this study is voluntary. You can decide not to participate in this research and it will not be held against you. You can leave the study at any time.

Is there any way being in this study could harm me?

Choose one of the following sentences as applicable and delete the other sentence:

(1) There are no sensitive questions in this survey that should cause discomfort. However, you can skip any question you do not wish to answer, or exit the survey at any point.

OR

(2) There is a risk of discomfort, as some of the questions are sensitive. You can skip any question you do not wish to answer, or exit the survey at any point.

What happens to the information collected for the research?

If this is an online study, provide a link to the terms addressing confidentiality that is published by the survey company (Qualtrics, Survey Monkey, etc.), otherwise delete.

You may view the survey host's confidentiality policy at *: insert link.*

Choose one of the following sentences as applicable and delete the other sentence.

(1) No direct personal identifiers will be collected.

OR

(2) Your *(email address or other contact information)* will be stored separately from your survey data, and is only being collected for payment purposes. All information will be kept on a password protected computer and is only accessible by the research team.

The results of the research study may be published but know one will be able to identify you.

What else do I need to know?

Include this section if you are paying subjects, otherwise delete.

If you agree to take part in this research study, we will provide you with (gift card, or other form of payment) sent to the email address you provide at the end of the survey. This is optional if you do not want to provide your email address.

Who can I talk to?

Please feel free to ask questions regarding this study. You may contact me later if you have additional questions or concerns at *telephone number and e-mail address and first and last name of investigator conducting the study.*

You may also contact the Human Research Protection Program at Texas A&M University (which is a group of people who review the research to protect your rights) by phone at 1-979-458-4067, toll free at 1-855-795-8636, or by email at irb@tamu.edu for:

- additional help with any questions about the research
- voicing concerns or complaints about the research
- obtaining answers to questions about your rights as a research participant
- concerns in the event the research staff could not be reached

- the desire to talk to someone other than the research staff

Use the following for online surveys, otherwise delete:

If you want a copy of this consent for your records, you can print it from the screen.

- If you wish to participate, please click the **"I Agree"** button and you will be taken to the survey.
- If you do not wish to participate in this study, please select **"I Disagree"** or select **X** in the corner of your browser

TEXAS A&M UNIVERSITY HUMAN RESEARCH PROTECTION PROGRAM

INFORMED CONSENT DOCUMENT

Remove all instructional text and red color-coding from this document once complete.

Title of Research Study: [insert title of research study here]

Investigator: [insert name of principal investigator]

Funded/Supported By: [List all monetary and/or non-monetary support for this research. If none, state Texas A&M University or applicable agency.] This research is funded/supported by _____.

Financial Interest Disclosure:

[Include if there is a financial interest to disclose. Otherwise delete.] The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

Why are you being invited to take part in a research study?

You are being asked to participate because you... [Fill in the circumstance or condition why this subject is selected to be in the study.]

What should you know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert contact information for the research team. Include a telephone number and email address.]

This research has been reviewed and approved by the Texas A&M Institutional Review Board (IRB). You may talk to them at at 1-979-458-4067, toll free at 1-855-795-8636, or by email at

irb@tamu.edu., if

- You cannot reach the research team.
- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Why is this research being done?

[Tell the participant the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others.]

How long will the research last?

We expect that you will be in this research study for _____ [hours/days/months/weeks/years, until a certain event Include long-term follow-up if any].

How many people will be studied?

We expect to enroll about _____ people in this research study at this site. Approximately _____ people in the entire study nationally [or internationally] will be enrolled.

What happens if I say "Yes, I want to be in this research"?

[Tell the participant what to expect using lay language and simple terms. Whenever appropriate include the following items:]

- A description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits
- The length and duration of study visits, activities, and procedures
- With whom the participant will interact
- Where the research will be done
- When the research will be done
- List experimental procedures and therapies and identify them as such
- How often study activities and procedures will be performed