



Preventing Extinctions



LANDCARE RESEARCH
MANAAKI WHENUA



MEMORANDUM OF UNDERSTANDING

among

Commonwealth Scientific and Industrial Research Organisation,

Island Conservation,

Landcare Research New Zealand Limited,

North Carolina State University,

Texas A & M University,

University of Adelaide,

and

**United States Department of Agriculture Animal and Plant Health Inspection Service,
Wildlife Services, National Wildlife Research Center**

Expiration Date: December 31, 2020

This memorandum of understanding (MOU) is among the Commonwealth Scientific and Industrial Research Organisation (CSIRO); Island Conservation (IC); Landcare Research New Zealand Limited (LRNZ); North Carolina State University (NCSU); Texas A&M University (TAMU); University of Adelaide (UA); and United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), Wildlife Services (WS), and National Wildlife Research Center (NWRC) (collectively "the Participants") for the purpose of creating and assessing genetic technology that could be used to reduce or eradicate closed populations of pest species by altering fertility or viability.

The Genetic Biocontrol of Invasive Rodents (GBIRd) Program Participants have a common interest in the development of efficient, effective, safe, and humane methods of invasive rodent control and eradication that are available for non-profit and governmental use. The Participants seek to assess the potential of this technology for advances in agriculture, food security, and human health. The Participants desire to jointly promote an integrated and coordinated approach to creating, assessing, and communicating potential use of genetic biocontrol in preventing extinctions and other potential societal benefits including agriculture and human health.

The Participants' objective under this MOU is by 2020, to develop a shared, and open-sourced knowledge base that has enabled a thorough and cautious assessment of the biological, ecological, technical, social, ethical, and regulatory suitability of using genetic biology to eradicate invasive mammals from a closed, isolated, oceanic island system. This includes experiments with closed captive populations of mice under laboratory conditions in biosecured, contained facilities. Consistent with the U.S. National Academy of Sciences's 2016 gene-drive research recommendations¹, this objective is in service to the Participants' goal of being able to determine whether, or not, to pursue an application for a highly-contained field trial of this self-limiting mouse as a conservation tool.

I. AUTHORITIES:

USDA/APHIS/WS/NWRC

Under the Animal Damage Control Act of March 2, 1931, as amended (7 USC 426), and the Act of December 22, 1987 (7 USC 426c), the Secretary of Agriculture may conduct a program of wildlife services with respect to injurious animal species and take any action the Secretary considers necessary in conducting the program. Additionally, the Secretary of Agriculture, except for urban rodent control, is authorized to conduct activities to control nuisance mammals and birds and those mammal and bird species that are reservoirs for zoonotic diseases. In carrying out a program of wildlife services involving injurious and/or nuisance animal species or involving mammal and bird species that are reservoirs for zoonotic diseases, the Secretary is authorized to cooperate with States, local jurisdictions, individuals, public and private agencies, organizations, and institutions. Wildlife Services Directive 2.115 sets forth the responsibilities and duties of the NWRC as the research and scientific arm of the wildlife services program.

Under the Animal Health Protection Act (AHPA), as amended, (7 U.S.C. §§ 8301 et. seq.), the Secretary of Agriculture is authorized to issue regulations and orders and to carry out operations and measures to prevent, detect, control, and eradicate diseases and pests of livestock and to cooperate with other Federal agencies, States or political subdivisions of States, national governments of foreign countries, local governments of foreign countries, domestic or international organizations, domestic or international associations, Indian tribes and other persons to carry out the purposes of the AHPA. The NWRC of APHIS-WS enter into this Agreement pursuant to the authority of the AHPA.

II. PARTICIPANTS' RESPECTIVE MISSIONS:

CSIRO - At CSIRO, we do the extraordinary every day. We innovate for tomorrow and help improve today – for our customers, all Australians and the world. With more than 5,000 experts based in 55 centres, extensive local and international networks, and a burning desire to get things done, we are Australia's catalyst for innovation and a global force in transforming imagination into reality.

¹ <http://nas-sites.org/gene-drives/>

IC - Prevents extinctions by removing invasive species from islands.

LRNZ - Landcare Research is New Zealand's leading provider of science and solutions for land environments. Our purpose is to drive innovation in the management of terrestrial biodiversity and land resources in order to protect and enhance the terrestrial environment and grow prosperity.

NCSU - As a research-extensive land-grant university, North Carolina State University is dedicated to excellent teaching, the creation and application of knowledge, and engagement with public and private partners. By uniting our strength in science and technology with a commitment to excellence in a comprehensive range of disciplines, NC State promotes an integrated approach to problem solving that transforms lives and provides leadership for social, economic, and technological development across North Carolina and around the world.

TAMU College of Veterinary Medicine & Biomedical Sciences - We, the faculty and staff of the College of Veterinary Medicine & Biomedical Sciences, are a community of scholars committed to: Caring about animals and people; curing and preventing animal disease; creating new knowledge, new therapies, and new learning opportunities; and communicating with students, veterinarians, scientists, and the public.

UA - The University of Adelaide is an international institution that distinctively embraces the ideal of the research university, where the excitement, vitality and passion of the search for new knowledge is one in which all students participate; as an enlightened and tolerant community where able students can find support, whatever their background or circumstances; and as a place where the Kaurna people, original custodians of the land on which the campuses now rest, are acknowledged and their culture respected.

USDA/APHIS/WS/NWRC - The mission of USDA APHIS Wildlife Services (WS) is to provide Federal leadership and expertise to resolve wildlife conflicts to allow people and wildlife to coexist. WS conducts program delivery, research, and other activities through its Regional and State Offices, the National Wildlife Research Center (NWRC) and its Field Stations, as well as through its National Programs.

III. THE PARTICIPANTS INTEND AS FOLLOWS:

Subject to annual evaluations of resources and funding availability by each Participant, CSIRO, IC, LRNZ, NCSU, NWRC, TAMU, and UA may continue to work cooperatively to create genetic technologies with the intent to protect, maintain, restore, and enhance native species and ecosystems on islands and elsewhere when appropriate, and promote effective management and conservation research by sharing costs, expenses, and responsibilities associated with technology development as described herein for the term of this MOU. This MOU involves no exchange of funds between the Participants. Funding is expected to be addressed on a case-by-case basis during grant and/or other funding applications. Nothing in this MOU is intended to create legal obligations or embody a commitment by any Participant to expend funds not appropriated and administratively allocated for such purposes. This MOU is not intended to be an international agreement governed by international law.

CSIRO intends to:

1. Conduct risk assessment(s), including but not limited to ecological and health.
2. Develop and implement an Australian Stakeholder/Community/Public Engagement Plan to evaluate the potential for social acceptance of this technology.
3. Provide biosecure mouse facilities of various sizes to contain evaluations of the ecological risks of this technology and the proliferation of the genes necessary to enable the extirpation a closed population of mice.
4. Provide mathematical modeling necessary to assess this technology.
5. Assist and coordinate with US Participants during regulatory engagements and applications in Australia.
6. Host various in-person meetings as necessary.

Island Conservation intends to:

1. Provide a program coordinator for the GBIRD program, who will minimally:
 - a. Convene monthly partnership coordination meetings.
 - b. Coordinate grant/funding applications.
 - c. Convene an annual in-person meeting.
 - d. Coordinate development of a strategic plan.
2. Coordinate and develop the Partnership's external 'Communications and Outreach Plan' in which the Partners agree to coordinated media relations and effective messaging and messenger best practice.
3. Support the partnership's programmatic regulatory engagements and compliance efforts to help the world's leading government environmental regulators prepare for the potential of applications for the field trialing of this new technology.

Landcare Research intends to:

1. Coordinate a 'NZ incorporated' engagement with, and support for, GBIRD.
2. Explore social and cultural considerations with regards to the use of gene drives for vertebrate pest control.
3. Support the Partnership's 'Communications and Outreach Plan' and programmatic regulatory engagements and compliance efforts to help the world's leading government environmental regulators prepare for the potential of applications for the field trialing of this new technology.
4. Use mathematical modelling to explore the potential utility of alternate gene drive mechanism / genetic component driven / phenotypic effect to cause pest population regulation and eradication.
5. Explore the utility of alternate genes for application to mouse 'suppression drives.'

University of Adelaide intends to:

1. Modify mouse genomes to create a synthetic gene drive element using CRISPR/CAS9 genome editing technology, the heritable trait of the sex ratio determination being skewed to favor the male sex that approaches 100% by placing the phenotype-altering genes within a CRISPR/Cas9 complex.
2. Perform the initial experiments under appropriate laboratory conditions to analyze the transmission efficacy of the genetic modification and its propensity to skew the sex ratio or fertility of progeny through addition of additional transgenes or insertion into specific loci.

North Carolina State University intends to:

1. Analyze breeding fitness between different populations of mice including island populations that may be potential targets for field trials.
2. Host the GBIRD Program Coordinator.
3. Host in-person program meetings as necessary, including Ethics Committee, Steering Committee, Science Committee, and GBIRD Program meetings.
4. Develop and implement Stakeholder/Community/Public Engagement Plan specific to the United States.
5. Coordinate and support Stakeholder/Community/Public Engagement between countries.

Texas A&M University intends to:

1. Modify mouse genomes to create the heritable trait of the sex ratio determination being skewed to favor the male sex that approaches 100 % by placing the *Sry* gene within the T-complex.
2. In small cages, initially analyze the efficacy of modified mice to pass on the expected trait in a heritable manner.
3. Genetically characterize mouse populations, including potential target islands for field trials.

USDA/APHIS/WS/NWRC intends to:

1. When appropriate and through subsequent agreements, assess the efficacy, characteristics and risks of genetic constructs (mice) in biosecure USDA/APHIS/WS/NWRC facilities.
2. Assist the partnership with keeping this developed technology non-exclusive and appropriately controlled for environmental purposes.
3. Assist and coordinate, along with Island Conservation, regulatory engagements and applications in the United States.

All Participants intend to:

1. Collaborate in the development of a strategic plan to guide implementation of this MOU, and to envision subsequent phases of the Partnership's investigation pending the assessment and outcomes of this MOU.
2. Share data and information openly and regularly.
3. Identify opportunities for and coordinate applications to public and private funders to further shared objectives.
4. Attend and contribute to electronic and in-person partnership meetings, including sending an organizational representative if necessary for mutually agreed upon annual or more frequent meetings.
5. Coordinate the partnership's public communications and media engagements among all Participants spokespersons and public information officers.
6. Follow standard scientific publication principles. Investigators are not obligated to include other Participants in publications related to their research in this area.

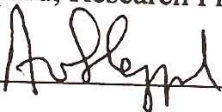
IV. GENERAL TERMS

1. This MOU is neither a fiscal nor funds obligation document. Any endeavor involving reimbursement or contribution of funds between the Participants to the MOU is intended to be handled in accordance with applicable laws, regulations, and procedures outlined in a separate written arrangement by the Participants' representatives and be independently authorized by appropriate statutory authority.
2. Notwithstanding anything contained in this MOU, each Participant retains its autonomy to conduct research independently of this MOU.
3. Each Participant's rights, title and interest in its intellectual property and confidential information remains unaffected by the existence of this MOU. For the avoidance of doubt, no Participant should be obliged to disclose any confidential or commercially sensitive information to another Participant or Participants, and any such disclosure or exchange of confidential information is expected to be covered by an appropriate confidentiality agreement.
4. Any dispute, controversy or difference as to the interpretation of this MOU is expected to be settled amicably by mutual consent between the Participants.
5. This MOU may commence on the date of last signature and continue until December 31, 2020.
6. Modifications to this MOU, including adding new participants, may be proposed by any Participant and become effective upon written concurrence of all Participants.
7. Participants wishing to discontinue participation the MOU should endeavor to provide sixty (60) days written notification to the other Participants.

V. SIGNATURES

For Commonwealth Scientific and Industrial Research Organisation:

Dr. Andy Sheppard, Research Program Director, Managing Invasive Species and Disease

Signature  Date 5/5/2017

For Island Conservation:

Karen Poiani, Chief Executive Officer

Signature  Date 4/21/17

For Landcare Research New Zealand Limited:

~~Richard Gordon, Chief Executive~~

Dr Fiona Carswell

Chief Scientist, Landcare Research

Signature  Date 4/7/17

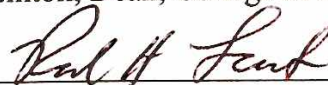
For North Carolina State University:

William Ditto, Dean, College of Sciences

Signature  Date 6/2/17

AND

Richard H. Linton, Dean, College of Agriculture and Life Sciences

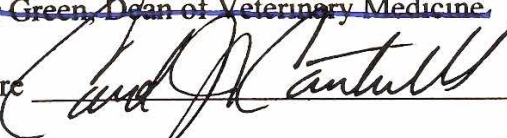
Signature  Date 5/30/17

For Texas A&M University:

~~Eleanor Green, Dean of Veterinary Medicine~~

Carol Cantrell

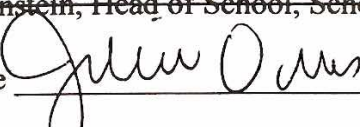
Sr. Associate Vice President for Research

Signature  Date 5/17/17

For University of Adelaide:

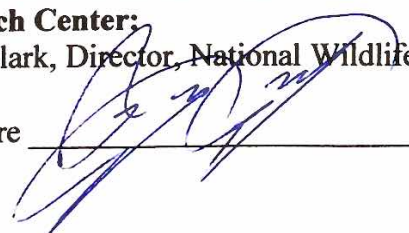
~~Phil Weinstein, Head of School, School of Biological Sciences~~

Professor Julie Owens
Acting Deputy Vice-Chancellor
& Vice-President (Research)

Signature  Date 27/6/17

For USDA Animal and Plant Health Inspection Service, Wildlife Services, National Wildlife Research Center:

Larry Clark, Director, National Wildlife Research Center

Signature  Date 4-21-17