Press Statement

15 July 2017 DRAFT

*Embargoed* until DARPA Announcement (sometime week of 17 July)

**Genetic Biocontrol of Invasive Rodents Program Secures Funds to Ensure Safe Research Outcomes**

*DARPA’s Safe Genes Program awards NCSU, partners, $6.5 for R&D of safety mechanisms for gene-drive mammal constructs for conservation.*

The Genetic Biocontrol of Invasive Rodents partnership (GBIRd) is cautiously investigating the suitability of gene-drive-based, self-limiting mice that have the potential to protect native island species and communities by eliminating introduced, damaging (invasive) rodents. DARPA has just announced a major investment in the program to ensure researchers and regulators could control the fate of the gene drive mouse construct if is someday released for testing in the wild.

**Background**

Our world’s island communities, plants, and wildlife are in crisis due primarily to invasive species, the leading cause of extinctions on islands. Most recorded extinctions have occurred on islands and 88% of IUCN RedList[[1]](#footnote-1) Critically Endangered and Endangered Species reliant on islands are threatened by invasive rodents. This is a disproportionately large percentage of our worlds Endangered species given that islands comprise a mere five percent of Earth’s land area. Invasive species also negatively impact island communities’ food security, livelihoods, and wellbeing. Human activities have introduced invasive rodents (rats and mice) to at least 80 percent of our world’s island groups and there are an estimated 400,000 islands across the globe (*UNEP-WCMC (2015))*.

But there is hope. About six hundred successful invasive rodent removal projects on islands demonstrate that eradication is one of the most impactful conservation interventions available to prevent island extinctions and benefit island communities, economies, and ecosystems.

Unfortunately, these interventions are insufficient to match the magnitude of this global crisis. Current methods to eradicate rodents from islands rely on toxicants, and such methods are costly, time-consuming, and reaching their limits as eradications become more complex. Indeed, only about 0.3 percent of our world’s islands have been treated to date, and on less than 15 percent of the world’s rodent-infested islands are these tools considered viable. New tools are required to prevent island-based extinctions caused by invasive rodents, and gene drives hold significant promise.

**Genetic Biocontrol of Invasive Rodents Partnership and Investigation**

The GBIRd partnership is evaluating the possibility and suitability of a self-limiting, transgenic mouse, with a gene-drive construct that biases single-sex inheritance selection up to 100 percent. The notion of introducing such a mouse to a remote oceanic island to affect an eradication-by-attrition, holds great potential to be part of the transformative solutions needed to match the magnitude of the island invasive species challenge and opportunity.

The Genetic Biocontrol of Invasive Rodents (GBIRd) program is a partnership of diverse experts from seven world-renowned universities, government, and not-for-profit organizations advancing gene drive research. Our not-for-profit conservation and humanitarian missions engage experts from governments, NGOs, and research universities including CSIRO, Island Conservation, Landcare Research, North Carolina State University, Texas A&M University, University of Adelaide, and USDA’s APHIS. Together we are cautiously investigating the feasibility of, and assessing the social, ethical, and biological risks of, gene-drive modified organisms for eradication of island invasive species. While the science and partnership have been underway for several years, GBIRd’s formalized coordination and strategy emerged in 2016.

We are investigating both the feasibility and suitability of this potential tool. Our step-wise, values-based, scientific, ecological, social, and ethical investigations and risk-assessments aim to answer these key questions in the coming decade:

* *Could* we create a self-limiting gene-drive modified mouse that biases future generations to be male (or female) only, thereby achieving eradication by attrition?
* If so, *should* we do it and, under what conditions?

The research goal is to use a naturally-occurring (t-complex) and/or a CRISPR “gene drive” in mice to facilitate a bias of subsequent rodent generations to all be a single sex. If successful, GBIRd’s proof of concept holds the potential to significantly expand conservationists’ toolbox to reverse the impacts that invasive rodents have on islands, their terrestrial and marine ecosystems, and human communities.

But even if it’s feasible that we could do it, we know that critical questions remain to be answered and careful assessments are necessary before we can determine if we *should* do it?

*Gene-drive modified organisms hold promise for addressing difficult-to-solve challenges, such as the eradication of insect borne infectious diseases and the conservation of threatened and endangered species. However, proof-of-concept in a few laboratory studies to date is not sufficient to support a decision to release gene-drive modified organisms into the environment. The potential for gene drives to cause irreversible effects on organisms and ecosystems calls for a robust method to assess risks. A phased approach to testing, engagement of stakeholders and publics, and clarified regulatory oversight can facilitate a precautionary, step-by-step approach to research on gene drives without hindering the development of new knowledge.* (National Academies of Sciences, Engineering, and Medicine (NASEM). 2016. )

We agree, and have aligned our own precautious, step-wise approach to our research with the guidelines outlined by the US NASEM (and Australia) issued for gene-drive research. GBIRd brings together world class geneticists, evolutionary biologists, ethicists, risk assessors, math modelers, regulatory experts, social scientists, and conservation professionals to engage in this suitability assessment.

**DARPA Safe Gene Program Award**

DARPA, the research and development branch of the US Government that brought us the internet, GPS, and self-driving cars, is investing in developing safety mechanisms to ensure that practitioners and governments can keep gene drive organisms in check and avoid any unintended consequences of their release. This week, DARPA announced an investment in GBIRd, that aligns well with the research guidance issued to date.

*An international, multi-institution and interdisciplinary team led by Dr. John Godwin of North Carolina State University aims to develop and test mammalian gene drive systems in rodents. The genetic technique targets population-specific alleles, ~~that work on "private alleles" in the target population~~- ~~that is, the a~~unique forms of a gene ~~that are specific to~~ found only in~~a~~ particular invasive populations. If successful, the work will expand the tools available to manage invasive species that threaten biodiversity and human food security, and that serve as potential reservoirs of infectious diseases affecting native animals and humans populations. The team plans to develop mathematical models of how drives would function in mice, and then perform highly-contained, biosecure live testing in~~biosecure and contained~~ simulated natural environments that mimic real-world conditions to gauge the robustness, spatial limitation, and reversibility of the drives. The team’s plans also include rigorous social engagement efforts and risk assessments to further assess the suitability of these potential tools.*

The principal investigator for the grant is Dr. John Godwin from the Genetic Engineering and Society (GES) Center at NCSU. Godwin said, “We are pleased to and humbled by receiving this award which further demonstrates our commitments to a highly bio-contained, step-wise investigation into this potentially powerful conservation tool. Together we can ensure that such technology is deployed safely and benevolently.” Funds will support several other investigations being conducted by other GBIRd partners.

**Timeframe and Biosafety**

GBIRd is years away from answering all the questions that need to be addressed before we can consider asking ourselves, communities, and their governments if we should consider a highly-contained field trial on a remote oceanic island. However, we have an obligation to undertake this research in a cautious, thorough, and step-wise way. We benchmark our assessments against the world’s leading gene drive research and public values alignment guidelines like these issued by the US National Academy of Sciences and others. The diversity of assessments will need to run their course before we can collectively ask: *Could we? Should we? Under what conditions?*

While GBIRd’s gene-drive research has been ongoing for a few years, it is still in its nascent stages. Developing a gene-drive modified mammal construct is a great challenge and may take years-more research to achieve proof-of-concept stages, even in the laboratory. “Safety is central to this investigation; All our gene-drive research partners are located at research universities or institutions in either Australia, the United States, or New Zealand.” Said Dr. Karl Campbell, Island Conservation Program Director. “In every case, the researchers are adhering (as minimum standards) to the mature national, provincial, and local biocontainment laws, regulations, and protocols for genetic research. Any potential risks are well contained and managed by these jurisdictions and the researchers. The Safe Genes award, provides more insurance for future safety mechanisms.”

**Guiding Values**

We are all in this for the interests of society and nature. Like you, we want to save lives, support livelihoods, and preserve our natural world for generations to come. Our guiding principles include:

* Early and sustained consistent engagement with stakeholders and communities
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* Proceeding cautiously, with deliberate step-wise methods
* Uncompromising commitment to biosafety, existing regulations, and protocols as minimum standards
* Using international best practices for multiple risk analyses
* Soliciting external ethics reviews and considering unsolicited ones
* Transparency of research, assessment, findings, and conclusions

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**Contacts:**

John Godwin, via [patti\_mulligan@ncsu.edu](mailto:patti_mulligan@ncsu.edu) M: +1.[919.559.2308](tel:(919)%559-2308)

Dr. Karl Campbell, via [sally.esposito@islandconservation.org](mailto:sally.esposito@islandconservation.org); M +1.831.359.4787

*Add other Steering Committee members & PIOs as they volunteer.*

The following is **NOT FOR CIRCULATION – INTERNAL GBIRd** **Communique** only.

**Recommended Strategy (from Heath)**

GBIRd Steering Committee & friends – I have just landed in Barcelona and will be on holiday for the next two weeks. As promised, I’ve drafted a starting point for a press statement regarding the DARPA Safe Genes announcement anticipated next week. [Sally.esposito@islanconservation.org](mailto:Sally.esposito@islanconservation.org) M +1.831.359.4787 will be serving you all in my stead…I am available for consultation and coaching if we find ourselves under attack in the Media by detractors concerned about the ‘color’ of the DARPA funding. I think that is unlikely, and propose this measured response to help ensure proper framing of the issue.

1. Post the press statement on www.geneticbiocontrol.org as soon as the DARPA announcement is released (Claudio and our team will set up a blog on the [www.geneticbiocontrol.org](http://www.geneticbiocontrol.org) on Monday, if at all humanly possible.)
   * Provide the URL to all inquiring reporters
   * Respond promptly with interviews at least from John and Karl, but offer anyone else who is interested in getting in this news cycle.
   * I do not recommend promoting this proactively unless your organization has professional capacity to do the media outreach; reporters will come to us, and we have limited capacity to do effective and strategic media outreach
   * Promote the [Audubon Story](http://www.audubon.org/magazine/summer-2017/how-genetically-modified-mice-could-one-day-save) to reporters for context…it is one of our best, most objective coverage to date; Megan Serr’s Scientific American blog is also an ideal story…I’m asking Claudio to set these up on the new blog as well and provide links to you all…
2. Add all willing Steering Committee Members as “Contacts” but include their PIOs so that they are buffered from being put on the spot and PIO’s can assist with interview prep.
   * [Sally.esposito@islandconservation.org](mailto:Sally.esposito@islandconservation.org) is available as a surrogate media engagement prep coach
3. If you all can shorten this statement to 2 pages or less, that’d be ideal…always harder to shorten things, but maybe you can move the background into a postscript position or something.
4. I recommend the following **key messages** for all interviewers:
   * This is a principled, step-wise investigation designed to evaluate the suitability of gene-drive modified mammals to control introduced, damaging (invasive) mammals…particularly on islands
   * We are cautiously optimistic, but recognize that the investigation could prove that this tool is not suitable.
   * Regardless we have an obligation to evaluate this tool’s feasibility, potential, and if it can be safely deployed for good.
   * We are delighted to have a new donor and research partner investing in the risk assessments, social engagement, and very importantly in the development of the safety mechanisms that may prove to be requisites for safe deployment.
   * Today’s research by GBIRd partners uses, as minimum standards, the biocontainment protocols, standards, and best practices to ensure current research is highly contained and safe; this partnership will help evaluate and if and help develop additional safety measures for future stages of this investigation.
   * This is a big step forward for GBIRd, but current budget estimates for the life of this investigation tell us we may need an additional ~$12M US.
   * Obviously, add any other specifics about your work as is warranted…
   * Whenever in doubt, you can answer questions with a value statement or a principled reponse like “Those are the excact types of questions we endeavor to answer in this investigation.”
5. I’d recommend the following responses to questions, if asked…but I wouldn’t volunteer/lead with these unless you know that the reporter will be reporting detractor points of view…

Qs: How can you possibly pursue this technology knowing that the US Dept. of Defense has obviously concluded that it will be used for nefarious (dual-use) purposes, maybe against our own people? How can you fund most your project with DOD funds?

As:

* We are all in this for the interests of society and nature. Like you, we want to save lives, support livelihoods, and preserve our natural world for generations to come.
* Our guiding principles help ensure that our work will not make any direct contributions to dual uses; which certainly wouldn’t be stopped if we shuttered our research.
* This project will determine if this is suitable, and under what conditions. Our faith in our own mission to do good, transparency, and willingness to share our findings with other benevolent causes, along with the potential of this tool to prevent extinctions without using toxicants, far outweighs any potential that we have to contribute to any dual uses.
* In fact, our open approach and deep investment in safety mechanisms might just deter or prevent dual uses (which certainly wouldn’t be developed in plain sight).
* Don’t forget that DARPA brought us the internet and GPS…both tools that are critical to our work today to prevent extinctions on islands by removing invasive speices.
  + Whenever in doubt, you can answer questions with a value statement or a principled reponse like “Those are the excact types of questions we endeavor to answer in this investigation.”

1. http://www.iucnredlist.org/ [↑](#footnote-ref-1)