



**JOURNAL OF RESPONSIBLE INNOVATION SPECIAL ISSUE:
ROADMAP TO GENE DRIVES:
RESEARCH AND GOVERNANCE NEEDS IN SOCIAL,
POLITICAL, AND ECOLOGICAL CONTEXT**

EDITED BY: JASON DELBORNE, JENNIFER KUZMA, FRED GOULD,
EMMA FROW, CAROLINE LEITSCHUH, & JAYCE SUDWEEKS (2018)

The Genetic Engineering and Society Center at NC State University hosted a workshop in February of 2016, supported in part by the National Science Foundation, entitled:

ACCESS FULL PAPERS AT:
RESEARCH.NCSU.EDU/GES/JRI-GENE-DRIVES

A Roadmap to Gene Drives: A Deliberative Workshop to Develop Frameworks for Research and Governance

In order to examine core **governance issues** and **research needs** in an anticipatory way, this 3-day workshop brought together over **70 subject matter experts** from academia, business, government, and non-profit organizations from **10 different countries** in Europe, Australia, and North and South America.

Those experts were invited to submit papers for this special issue of the *Journal of Responsible Innovation*.

A GENE DRIVE is a powerful genome editing technique that can "drive" a genetic trait through a population based on rates of up to 100% inheritance.



Interactions among risk governance and ethics prompted by systemic thinking at the 2016 Gene Drive workshop

In total, **14 peer reviewed papers** are included in the special Gene Drive issue of the Journal ([see back for full list](#)).

The editorial team included three NC State faculty and two GES PhD students.



**AWARD #
1533990**

Genetic Engineering and Society Center | Shaping the futures of biotechnology by integrating scientific knowledge and public values

Mapping research and governance needs for gene drives

> Introduction / *Delborne, Kuzma, Gould, Frow, Leitschuh & Sudweeks*

A roadmap for gene drives: using institutional analysis and development to frame research needs and governance in a systems context

> The deployment of gene drives is emerging as an alternative for protecting endangered species, controlling agricultural pests, and reducing vector-borne diseases. This paper reports on a 2016 workshop exploring the complex intersection of political, economic, ethical, and ecological risk issues associated with gene drives. / *Kuzma, Gould, Brown, Collins, Delborne, Frow, Esvelt, Guston, Leitschuh, Oye & Stauffer*

Harnessing gene drive

> Determining whether, when, and how to develop gene drive interventions responsibly will be a defining challenge of our time. Here we describe capabilities, safeguards, applications, and opportunities relevant to gene drive technologies. / *Min, Smidler, Najjar, & Esvelt*

Gene drive to reduce malaria transmission in sub-Saharan Africa

> Despite impressive progress, malaria continues to impose a substantial burden of mortality and morbidity, particularly in sub-Saharan Africa. A wide array of synthetic gene drive systems have been proposed to control the mosquitoes that transmit malaria. / *Burt et al.*

Anticipating complexity in the deployment of gene drive insects in agriculture

> Drawing on lessons from the deployment of other pest control technologies, we consider how insects containing gene drives could intersect with some of the complexities characterizing agricultural systems. / *Baltzegar, Barnes, Elsensohn, Gutzmann, Jones, King & Sudweeks*

Agricultural production: assessment of the potential use of Cas9-mediated gene drive systems for agricultural pest control

> We provide examples of gene drives that target specific genes, including female-essential genes. Further, we discuss issues related to containment in the laboratory & eventual field testing of strains harboring a Cas9-mediated gene drive system. / *Scott, Gould, Lorenzen, et al.*

Developing gene drive technologies to eradicate invasive rodents from islands

> Gene drive methods of rodent eradication offer an alternative to killing that has the potential to be more species-specific, more humane, and more biologically safe for use around humans. Technologies in development aim to apply gene drives to influence offspring, eventually creating a population that is not reproductively viable. / *Leitschuh, Kanavy, Backus, Valdez, Serr, Pitts, Threadgill & Godwin*

Identifying and detecting potentially adverse ecological outcomes associated with the release of gene-drive modified organisms

> We outline methods to identify hazards and detect potentially adverse ecological outcomes at the individual, population, community and ecosystem level, when progressing Gene Drive Modified Organisms through a phased test and release pathway. / *Hayes et al.*

The roles of ethics in gene-drive research and governance

> Ethics research queries the norms and values that shape the goals and justification for gene drive projects, and that might lead to issue or opposition to such projects. A framework for organizing ethics research is offered. / *Thompson*

Economic issues to consider for gene drives

> We examine four economic issues regarding gene drive applications. The potentially substantial benefits, coupled with the technical, social, and economic uncertainties, suggest that a responsible course of action is to move forward while maintaining regulatory flexibility and conducting research to resolve key uncertainties. / *Mitchell, Brown & McRoberts*

Regulating animals with gene drive systems: Lessons from the regulatory assessment of a genetically engineered mosquito

> Given the profound impact that gene drives could have on species and ecosystems, their use is a highly contentious issue. In this paper, we consider the question of whether the United States Food and Drug Administration is prepared to effectively regulate insects and other animals with gene drives. / *Meghani & Kuzma*

Anomaly handling and the politics of gene drives

> Decisions about the development and use of gene drives are framing broader debates about the need for fundamental changes to biotechnology regulatory systems. We summarize this debate and describe how gene drives are being constructed as potential anomalies within the regulatory landscape. / *Evans & Palmer*

Gene drives and the management of agricultural pests

> Difficulties involved in the containment of gene drives may restrict their use and require international agreements before release of approved types. The present commentary provides some thoughts on some of the issues one should consider when contemplating using gene drives in the management of agricultural pests. / *Medina*

Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values

> Executive Summary of 2016 Study Report, National Academies of Sciences, Engineering, and Medicine (Included with permission)