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Author for correspondence:
Jason A. Delborne
e-mail: jadelbor@ncsu.edu

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Articulating 'free, prior and informed consent' (FPIC) for engineered gene drives

Dalton R. George[1,2], Todd Kuiken[1] and Jason A. Delborne[1,2]

[1]Genetic Engineering and Society Center, and [2]Department of Forestry and Environmental Resources, North Carolina State University, Raleigh, NC, USA

DRG, 0000-0003-2885-7412; TK, 0000-0001-7851-6232; JAD, 0000-0001-6436-782X

Recent statements by United Nations bodies point to free, prior and informed consent (FPIC) as a potential requirement in the development of engineered gene drive applications. As a concept developed in the context of protecting Indigenous rights to self-determination in land development scenarios, FPIC would need to be extended to apply to the context of ecological editing. Without an explicit framework of application, FPIC could be interpreted as a narrowly framed process of community consultation focused on the social implications of technology, and award little formal or advisory power in decision-making to Indigenous peoples and local communities. In this paper, we argue for an articulation of FPIC that attends to issues of transparency, iterative community-scale consent, and shared power through co-development among Indigenous peoples, local communities, researchers and technology developers. In realizing a comprehensive FPIC process, researchers and developers have an opportunity to incorporate enhanced participation and social guidance mechanisms into the design, development and implementation of engineered gene drive applications.

1. Introduction: exploring free, prior and informed consent for environmental releases of engineered gene drives

Proponents of the rapidly advancing field of engineered gene drives offer alternative solutions to complex challenges across multiple sectors. These include vector-borne diseases [1], biodiversity conservation [2], agricultural pest control [3], and security and defence [4]. Potential social and ecological implications of engineered gene drives are substantial across the interconnected realms of ecosystems, economies and cultures [5,6]. Perceptions of desirability held by different researchers, technology developers, governments and other stakeholders related to these implications are diverse and wide-ranging [7–11]. Many technical uncertainties remain unresolved, motivating continued laboratory experiments and modelling to understand the potential efficacy of these kinds of novel interventions prior to a field trial or environmental release [5].

Paired with scientific uncertainty, complex political uncertainties emerge regarding the desirability [7,12], ethical implications [13–15], ecological risks [16–18] and governance challenges [19,20] of engineered gene drives (also see [5,6]). Indeed, for many years, researchers, program funders, regulators, non-governmental organizations (NGOs) and technology developers have wrestled with the ethical, legal and social implications (ELSI) of emerging genomic technologies [21,22]. Less attention, however, has been given to incorporating the lived experience of potentially affected communities [23]. Under conventional ELSI paradigms, communities are still largely assumed as passive recipients of technology, whose role to play in scientific and technological development is a reactionary one, and in response to downstream effects [24]. This can be especially problematic if certain gene drive applications prove to be environmentally or socially harmful and communities lacked any direct opportunities to impact decision-making. Parts of the gene drive research community have begun to wrestle with this important move from *social implications to social guidance* [5,6], with several early developers of potential gene drive applications building their own frameworks and processes for pursuing shared visions of technological futures [25–28].

Concurrent with these early-stage participatory initiatives, the United Nations (UN) has begun to discuss the possibility that any release of an engineered gene drive will require the 'free, prior and informed consent' (FPIC) of affected Indigenous peoples and local communities. For example, in 2017 the Convention on Biological Diversity's *Ad Hoc* Technical Expert Group (AHTEG) on Synthetic Biology [29] noted that 'free, prior and informed consent of Indigenous peoples and local communities, *might be warranted* in the development and release of organisms containing engineered gene drives [emphasis ours]' (para. 25, p. 4–5). The AHTEG also stated that the development of synthetic biology technologies 'should be accompanied by the full and effective participation of Indigenous peoples and local communities' (para. 26, p. 5). Likewise, in 2018, the Conference of the Parties to the Convention on Biological Diversity (CBD) [30] called upon Parties and other Governments to ensure 'the full and effective participation of indigenous peoples and local communities and with their prior and informed consent or free, prior and informed consent or approval and involvement, <*as appropriate*>, and consistent with national legislation and circumstances [sic], and in accordance with international obligations [emphasis ours]' (Decision 14/14, p. 1; also see Decision 14/16, p. 2). In 2019, the AHTEG [31] stated that

> the state of knowledge on potential impacts of current and near future applications of synthetic biology should consider that, for Indigenous peoples and local communities, those applications that may impact their traditional knowledge, innovation, practices, livelihoods and use of land, resources and water should seek their free, prior and informed consent, and the assessment of those applications is usually undertaken in a participatory manner *involving the whole community* [emphasis ours] [31, p. 9].

As demonstrated above, the CBD has evolved its interpretation of FPIC in regards to gene drives, advancing from 'might be warranted' in 2017 to 'where appropriate' and 'where applicable' in 2018, and then further evolving to 'involving the whole community' in 2019. However, the CBD does not specifically suggest how one would go about implementing FPIC, which would require its incorporation into national laws to become enforceable.

While it remains unclear whether and how FPIC will guide the engagement of Indigenous peoples and local communities with respect to the potential deployment of engineered gene drives, the disconnect between UN-level pronouncements and practice on the ground creates an opportunity for mutual learning across the international policy and research communities. This paper thus explores how principles of FPIC can inform paradigms for participatory governance of engineered gene drive applications intended for environmental release. We argue for an extended articulation of FPIC that attends to greater degrees of research transparency, iterative community-scale consent, and shared power of decision-making in the design and potential deployment of engineered gene drives, while involving Indigenous peoples, local communities, researchers, and technology developers.

The paper begins with a modest review of the origins of FPIC as a legal and normative concept for operationalizing Indigenous participation in natural resource-related decision-making. Second, we discuss the potential expansion of FPIC into emerging biotechnology applications, suggesting the importance of reconfiguring notions of informed consent and transparency with productive attention to the principle of respect for communities. Lastly, we articulate a vision for FPIC that emphasizes the sharing of power in decision-making, structured through researcher-community partnerships and co-development of technology. We follow these conceptual discussions with three current examples that appear to pursue these articulations to some degree. These examples, while imperfect and ongoing, illustrate the potential benefit of linking policy discourse at the international level with the practical pursuit of Indigenous and local community participation in the research, development, and potential deployment of engineered gene drives.

2. Origins and interpretations of free, prior and informed consent

FPIC emerged conceptually in the context of conservation and land development decisions impacting Indigenous peoples [32]. The idea, which originally applied to decisions that threatened the removal of Indigenous communities from their lands, stems from the human rights principle of self-determination of Indigenous peoples, which has been articulated as a right held by all people, who 'by virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development' [33, p. 173]. Motivating its development was the continual subjugation of marginalized, Indigenous communities to the power of large corporations and national governments, and the desire to rectify these inequities [34]. The recognition that Indigenous communities lacked meaningful avenues of participation in resource and land governance was a first step towards countering infringements upon the rights and well-being of these communities [35].

International law and policy has advanced self-determination as a right since before the turn of the century. It is recognized in the Charter of the United Nations (Article 55) [36], the International Covenant on Civil and Political Rights (Article 1) [33], and the International Covenant on Economic, Social and Cultural Rights (Article 1) [37]. Two particular pieces of international human rights law, the UN Declaration on the Rights of Indigenous Peoples (UN-DRIP) and International Labour Organization (ILO) Convention 169, articulate the concept of FPIC as a procedural mechanism for realizing rights to self-determination. The ILO requires corporations and governments to 'respect the special importance for the cultures and spiritual values of the peoples concerned, of their relationship with the lands or territories, or both as applicable, which they occupy or otherwise use' [38, Article 13, p. 4]. ILO specifically situates FPIC in the context of 'relocation,' or the removal of Indigenous peoples from lands (Article 16). UN-DRIP extends FPIC to broader contexts: government or industrial interventions relating to the disposal of hazardous materials (Article 29), military activities (Article 30), the adoption or implementation of new legislative or administrative measures that may affect Indigenous Peoples (Article 19), and broader issues concerning land and resources (Article 32). These extensions signal FPIC as an evolving concept in international law, potentially applicable to a broader range of contexts where participation in decision-making can benefit Indigenous communities in the pursuit of economic development, social cohesion and cultural sustainability [39].

Clarifying the normative vision of FPIC, the UN Permanent Forum on Indigenous Issues' (UN-PFII) 2005 *Report of the International Workshop on Methodologies regarding Free, Prior, and Informed Consent and Indigenous Peoples* defines the elements of

FPIC [40]. *Free* implies a lack of coercion, intimidation, or manipulation on the part of external entities. *Prior* implies that Indigenous involvement in decision-making happens before the activity in question commences. *Informed* implies accessible dissemination of information that covers several categories, such as the intervention's purpose, procedures, duration, location, size, reversibility, and locality of the areas that will be affected. Specifying the domains of information required, the report calls for a 'preliminary assessment of the likely economic, social, cultural, and environmental impacts' of an intervention, and further assessment on the 'fair and equitable benefit-sharing' of all parties involved and affected by the intervention [40, p. 12]. Lastly, *consent* implies a community's approval of an action, underwritten by processes of consultation and equitable participation with affected communities, which are anchored in dialogues fostering mutual respect and understanding that lead to either community approval or endorsement [40, p. 12]. The UN-PFII also describes the range of activities or interventions on Indigenous lands and territories where FPIC should apply: treaties, agreements, and other arrangements between States and communities; extraction of resources; conservation measures; hydro-power development; tourism activities; and access to and use of natural resources and Indigenous knowledge [40, p. 11].

Given FPIC's status as an 'evolving principle' that is 'adaptable to different realities' [40, p. 11], other organizations within the UN have begun adapting it within their areas of intervention. For example, the Food and Agriculture Organization's (FAO) report, *Free, Prior and Informed Consent: an Indigenous peoples' right and a good practice for local communities* [41] echoes the best practices criteria laid out in the UN-PFII report and promotes specific methodologies for FAO activities [41]. One key extension beyond the original FPIC norms is the emphasis on FPIC as good practice to undertake with local communities, in addition to its historic focus on Indigenous peoples [41, p. 5].

Notwithstanding the FAO's report, there is much disagreement and uncertainty involved with how—and even whether—to interpret the principles of FPIC across diverse contexts of application [42–44]. Questions regarding what situations require FPIC, who gets to participate, how consultations should be structured, and how decision-making power should be shared continually shape debates about the meaning of FPIC and what it should look like in practice [45–47]. Critics express concern that 'good faith' consultation practices that seek to build community support for an intervention, but not award decision-making power, sometimes masquerade as FPIC [48]. In addition, while FPIC has been successfully developed as a theoretical concept in the context of international law, translating it into practice across national, state, or provincial contexts of land and resource governance has proved challenging [35,49].

Translating FPIC from areas of resource and development governance to engineered gene drives represents an additional challenge. The AHTEG and CBD statements about how FPIC 'might be warranted in the development and release of organisms containing engineered gene drives' [29, pp. 4–5] and that these interventions 'should be accompanied by the full and effective participation of Indigenous peoples and local communities' (Decision 14/14, p. 1) remain vague, but do embrace the FAO's extension of FPIC to include involvement of local communities. The draft International Union for Conservation of Nature (IUCN) Principles on Synthetic Biology and Biodiversity Conservation take a stronger stance, stating that 'the free, prior and informed consent of Indigenous peoples and local communities *must be obtained* [emphasis ours]', in relation to the introduction of gene drives [50, p. 4]. As a whole, these pronouncements imply that the realm of science and technology governance—with engineered gene drives as the exemplar—could benefit from a more participatory approach. This paper thus considers what it would mean for scientific researchers and technology developers to apply the principles of FPIC, regardless of formal requirements and enforcement of international laws and policies.

3. Free, prior and informed consent as an extension of ethical research principles

Research ethics offers one way to understand processes supporting the AHTEG language in the context of engineered gene drive applications, specifically in two key areas: informed consent and transparency. Below we describe the potential for extending these ethical principles to considerations of collective autonomy and rights to self-determination on the part of affected communities (Indigenous or local) in the face of interventions in the shared environment. We suggest that these extensions of enhanced participation help articulate the meanings of FPIC.

(a) Expanding informed consent from individuals to communities

Traditional research ethics has viewed the application of informed consent through an individualistic lens. As stated in the Belmont report [51], informed consent operates according to the principle of 'respect for persons,' where individuals are seen as autonomous decision-makers possessing rights to choose what happens to them. Failure to respect the autonomy of an individual is to withhold the freedom for that person to act upon their own judgment, or to withhold information that would affect those judgements. FPIC extends this principle beyond the lens of individual consent, which arose from concerns regarding human subjects in medical research [51], and instead requires the 'full and effective participation' of wider communities in the authorization of research [29]. FPIC shifts consent away from the individual to the community, which raises the challenge of how to organize communication and decision-making to achieve community-level consent.

As described above, multiple international bodies have weighed in on processes for how individuals and communities should go about consenting to engineered gene drives, and whether consent is possible or necessary. In the academic literature, some authors have attempted to re-situate the medical concept of informed consent within the gene drive context. Kolopack & Lavery [52], for example, suggest that individual informed consent emerges as a requirement for researchers pursuing field trials when projects involve (i) the collection of personal clinical data, (ii) participation in behavioural or social science human subjects research (e.g., surveys or interviews), or (iii) the collection of other personally identifiable information such as a person's address [52]. Others have challenged the prospect of achieving door-to-door individual consent across an entire community; instead, they argue that researchers should pursue 'community authorization,' which authorizes a gene drive intervention on the basis of community consensus around social acceptability [53]. Tied to FPIC principles, the pursuit of community authorization allows communities to exercise a level of autonomy akin to the principle of self-determination, where communities can determine their involvement in projects in accordance with their economic, social, and cultural development [40,41]. Through these processes, the ethical principle of 'respect for persons' expands to 'respect for communities.'

Academic literature concerning biomedical, environmental and public health research with community populations supports the processes of community authorization and the principle of respect for communities. These arguments have paid explicit attention to expanding ethical norms and protections beyond the level of the individual to the level of communities, and mirror the protections advocated for by FPIC principles [54–56]. For example, Weijer & Emanuel [56, p. 277] articulate the boundaries of a research protections framework for biomedical research that emphasizes respect for community culture, knowledge and political structures. They stress community involvement throughout every step of the process, ensuring that some form of community-level approval is earned in early-stage protocol development as well as late-stage implementation.

Specific to the use of engineered mosquitoes in the natural environment, the 2014 World Health Organization (WHO) report, *A Guidance Framework for Testing of Genetically Modified Mosquitoes*, promotes strategies of 'ethical engagement' when conducting research with genetically modified mosquitoes and explicitly mentions 'respect for communities' as an ethical goal [57]. This report extends ethical responsibilities beyond what is captured via compliance-related individual consent practices and encourages researchers to 'conduct public and community engagement activities that will involve ethical reflection, interaction with the host community and a wide range of other interested parties, and iterative integration of findings from these activities into the ongoing planning and conduct of research' [57, p. 71]. The WHO process also encourages researchers and technology developers to take extra steps in order to provide communities the means to self-determine their involvement in the research, specifically by 'undertaking procedures that would be expected to identify them (affected communities), advising them that they may have interests at stake, finding out what concerns they may have, responding to those concerns, and reaching some form of agreement about whether the trial should proceed' [57, p. xxiii].

(b) From transparency that informs, to transparency that involves

Common research transparency principles encourage the dissemination of methods, data, and the results of research, with researchers being accountable for the completeness and accuracy in their reporting [58,59]. In addition, principles of fairness and reciprocity push researchers to produce useful products that contribute to the collective pool of scientific knowledge [60]. Moving beyond the conduits of research practices, transparency principles can also bolster the usefulness of research beyond publication practices [61]. Striving for dissemination mechanisms that contribute to a 'social license' for research can build a norm for high professional standards and trust in the research process [60,62]. In the context of FPIC, this form of enhanced transparency is crucial not only to ensure that information is accessible and understandable, but also to promote consultations that take place 'in an atmosphere of mutual respect in good faith, and full and equitable participation'([40], p. 12–13).

For communities to be effectively involved in decision-making, researchers and developers of engineered gene drives must disseminate materials in a community-accessible format, which means adhering to the language norms of those communities and local styles of information dissemination [11,63,64]. In addition, the construction of these enhanced transparency practices should take place within the context of working with communities, and merits the invitation of representatives of partnered communities into the design of these practices [63,64].

Enhanced transparency practices for gene drive experiments require contextualizing uncertainties to the intervention being proposed, or in other words, the need for researchers to be as explicit and honest about the risks and uncertainties associated with their work as they are about the benefits [65]. Overpromising can inhibit the ability for Indigenous peoples and local communities to deliberate and make decisions effectively if they plan to receive benefits that are unrealistic. Harms that may result from field trials can be perceived as more severe if they were never communicated, promised not to happen [15], or not evaluated because of a lack of understanding of what a community views as harmful. This can erode trust if communities feel like they are being deceived or that their concerns are not being taken seriously. It is, therefore, extremely important that uncertainties, risks, and benefits are communicated directly and openly with communities in language that aligns with community priorities and values.

Transparency also necessitates that communities be informed about alternative approaches as a means to assess the primary approach in question [51]. Analogous to a patient considering a new treatment who needs to understand the risks and benefits of existing treatment options, transparency with a community must include discussion of these types of alternative interventions. Such discussion is a prerequisite to 'informed' in FPIC, as it enables deliberation and judgment about acceptable risks and paths forward. We note that consideration of alternative approaches should also include 'doing nothing,' or preserving the status quo, with corresponding benefits and risks [57].

Researchers and developers cannot provide answers to everything communities might want to know, but they can communicate transparently about what they do know, and what they are uncertain about. Enhanced transparency and shared power may result in the strengthening of confidence in the proposed approach, the pursuit of a different one, or a decision to delay decision-making. Such outcomes reflect the full range of respect for self-determination and FPIC at the community level.

4. Co-development through the lens of free, prior and informed consent

The notion of co-development is rooted in philosophies associated with community-based participatory research, whose practices push researchers to enroll the participation of public representatives in research activities, orient research goals towards the needs of a community, and share knowledge and resources [66]. Applying this paradigm of co-development to engineered gene drives, developers and researchers would partner with Indigenous peoples and local communities in problem identification, selection of research goals, design and pursuit of methodologies, development of technical capacity, collaborative data collection, and equitable sharing of risks and benefits [63,67]. This diversity of activities implies that researchers must implement strategies of sharing power before projects get too far along (ideally at the idea formulation stage), enabling Indigenous peoples and local communities to access legitimate opportunities to assess how the goals and methods of research align with their values, socio-cultural norms and risk perceptions.

Adhering to visions of co-development, Indigenous and local communities would have an opportunity to exercise a more active form of *advisory power* by working with researchers and developers of engineered gene drives to design research protocols, explore social and ecological implications, and manage outcomes. This implies that Indigenous and local communities participate in developing aspects of the interventions that they themselves will eventually formally authorize, instead of being asked to authorize an intervention that they had no part in constructing. We note that researchers and developers may fear sharing this kind of power; however, two advantages emerge. First, sudden or unexpected withdrawals of consent are less likely in co-development because anxieties or concerns are more likely to be expressed along the way. Second, the investment in co-development makes it more likely that local values will be built into the research design, making it more likely that whatever is developed will be acceptable to the community.

(a) Navigating local power dynamics

An articulation of FPIC should also recognize the complexity of landscapes of local and Indigenous power. When researchers and developers of engineered gene drives approach a community, they are most likely to interface with existing leaders. On the one hand, this represents the most respectful engagement as it honours the political and cultural traditions of a community, respecting the principle of self-determination. On the other hand, researchers should be cautious not to cement these actors as permanent gatekeepers to information and participation. Doing so could reduce opportunities for less powerful voices to make their way into decision-making spaces, despite possessing critical knowledge or widely shared perspectives [11,68,69]. The pursuit of diverse consultations with community members of potentially lower status can create a more complete picture of community needs and concerns, without disrespecting local cultural traditions, if done carefully [70,71].

At a more formal level, the role of host governments may differ depending on the governance context for proposed applications of engineered gene drives. Host governments may or may not already integrate the principles of FPIC into their practices. In some cases, governments may enforce compliance, ensuring that an external entity has been given proper consent by the community before authorizing a project. In other cases, governmental entities themselves might have a facilitative role in consultations with communities in organization and information sharing, or even be part of those consultations [35,72]. In still other cases, governments may demonstrate little commitment to FPIC or even oppose or undermine the engagement of local communities and Indigenous peoples [73]. Thus, researchers and developers of engineered gene drives will have to pay close attention to how governments could potentially play assistive, inhibitory, or absentee roles in structuring partnerships with communities that reflect FPIC principles.

5. Moving closer to free, prior and informed consent norms

Regulatory agencies may evaluate the risk of engineered gene drives according to standards of safety anchored in science-based decisions that rely on experimental data to reduce uncertainties in order for a product to be approved for usage [74]. However, the risk paradigm associated with gene drive interventions extends outside of these traditional boundaries of expert control because uncertainty cannot be quelled without controlled experiment, and controlled experiment may not be possible [6]. Paradoxically, in order to gather the data needed to assess environmental effects, some form of environmental release would be necessary. Consideration of such risk extends beyond the statute-driven governance paradigm and requires the integration of multiple forms of knowledge and values-based concerns, including local knowledge and the perspectives of communities where field trials and environmental releases are being proposed [74].

Despite being embedded within several international treaties and unions (e.g., CBD, FAO, IUCN), translating FPIC principles into practice has proven difficult. The FPIC process has a history of being misused and mischaracterized as a strategy for ‘inclusionary control’ in project development that produces superficial certification and decision-making models that disrespect communities [75,76]. Instead of treating communities as autonomous agents and awarding power in decision-making, in certain cases, FPIC has morphed into ‘good faith negotiation’ that make communities reliant on ‘developer charity’ [48]. FPIC has been criticized as a ‘bureaucratic trap’ used to ‘legitimize’ land acquisitions, create social divisions, and reinforce existing power dynamics [48,77]. Clearly, researchers and developers of engineered gene drives should strive to not reproduce such distortions of FPIC, and instead abide by the ethical norms and foundational principles centred on self-determination, transparency, and shared power.

There is some evidence showing that early gene drive projects are attempting to incorporate these FPIC principles into their work. We review three such projects—not because they are exemplary in terms of achieving perfection—but as examples of efforts that seem at least partially aligned with a thoughtful articulation of FPIC.

The Gates Foundation began funding the project consortium Target Malaria, with a goal of eliminating disease vector mosquitoes that transmit malaria in Western Africa. With an engineered gene drive mosquito under development, the consortium has worked to structure stakeholder engagement into project-based decision-making practices [67]. They emphasize ‘knowledge engagement’ as an important principle of practice for co-development in research [48]. Some have criticized their efforts for not informing the community adequately in order for deliberation and self-determination to occur [78]. Despite these critiques, Target Malaria does represent an early-stage attempt at incorporating FPIC principles into gene drive applications, and offers opportunities for future projects to build on their experiences.

The ‘Mice Against Ticks’ project endeavours to quell the spread of Lyme disease in areas close to Martha’s Vineyard, Massachusetts. Incorporating the local island communities into decision-making is reported to uncover potential ecological consequences of research applications unanticipated by the research team, and resulted in the current project applications selecting against the use of local gene drive, and opting for an alternative method [28]. Their approach to structuring the role of communities in research emphasized a 'civic governance' ethos on the basis that once applications are enacted there is not an opportunity for communities to opt-out of their effects. The practices of the Mice against Ticks team show how communities may play valuable roles in directing research, while jointly working with researchers to solve a problem. While this particular community's demographics, culture and economic standing align closer to the research community than other gene drive projects, this example showcases how FPIC principles can be expanded beyond what has been traditionally recognized as Indigenous and local communities.

The Genetic Biocontrol of Invasive Rodents (GBIRd) partnership [25] is exploring the potential for engineered gene drives to eradicate invasive mouse populations on islands where they threaten biodiversity. The partnership has brought together scientists from multiple universities and federal agencies with an NGO, Island Conservation (note: all three authors have participated in some GBIRd activities, and J.A.D. has led U.S. stakeholder engagement since 2016). GBIRd's steering committee has adopted a number of guiding principles that align with FPIC, posted on their website:

(i) early and sustained consistent engagement with stakeholders and communities;
(ii) proceed cautiously, with deliberate stepwise methods and measurable outcomes;
(iii) engage early and often with the research community, regulators, communities and other stakeholders;
(iv) maintain an uncompromising commitment to biosafety, existing regulations, and protocols as minimum standards (e.g., NASEM 2016 [5]; AAS 2017 [79]);
(v) use, and participate in developing best practices;
(vi) only operate in countries with appropriate regulatory capacity; and
(vii) be transparent with research, assessments, findings and conclusions [25].

As part of a Defense Advanced Research Projects Agency (DARPA) funded Safe Genes project, social scientists (including authors D.R.G. and J.A.D.) have produced a landscape analysis based on interviews of diverse stakeholders [26] and conducted a stakeholder workshop to create two-way communication between technology developers and a diverse group of stakeholders, however not with potentially affected communities where gene drive applications might be deployed [80]. While deficient in terms of an expanded notion of FPIC as presented in this paper, this was in part because the selection of possible islands for field trials has not yet proceeded beyond the development of inclusionary and exclusionary criteria.

6. Conclusion: articulating free, prior and informed consent for engineered gene drives and proceeding with humility

Within their internal deliberations and public-facing policy statements, international bodies such as the UN CBD and the IUCN have begun to extend the concept of FPIC to the responsible governance of engineered gene drives. This extension has two important components: first, expanding the scope of concern from land-use interventions (e.g., mining, flooding of land for hydropower development) to technological interventions designed to affect ecosystems (e.g., engineered gene drives); second, expanding the inclusivity of engagement from Indigenous populations to local communities. While these policy statements have not yet resulted in clear, specific, or enforceable guidelines, they advance conversations about the importance of engagement of communities, stakeholders, and publics in governing the potential release of engineered gene drives ([5], ch. 7).

Meanwhile, a number of teams of gene drive researchers and developers have begun to pursue strategies of engagement that resemble at least some of the principles of FPIC. Target Malaria has organized and funded a strategy of engagement to both educate and seek the approval of communities for experiments that may eventually lead to an engineered gene drive mosquito to combat the spread of malaria. The Mice against Ticks project has sought community consent prior to the development of a genetically engineered mouse to interrupt Lyme disease transmission, and community steering committees have been formed to guide the research. Also focused on mice, but with the goal of conserving biodiversity on islands, the GBIRd partnership has conducted a workshop to connect diverse stakeholders and the technical research team in the service of influencing both the development and testing of a gene drive mouse as well as the design of future community-level engagement. These efforts are incomplete, in relation to the expansive interpretation of FPIC that we articulate in this paper, but we see them as necessarily experimental and worthy of support. Just as the design, development and testing of engineered gene drives carry some ecological risk in order to acquire the knowledge to make future design and governance decisions, so too will experiments in stakeholder and community engagement. These will result in a mixture of successes and failures that can build capacity—in terms of knowledge, social infrastructure, and trust—to inform future efforts.

Our paper has outlined an articulation of FPIC that seeks to situate practices of stakeholder and community engagement within the principles of transparency; iterative, community-level, informed consent; and the sharing of power through the co-development of technology. We suggest that researchers and developers of engineered gene drives align their practices with these principles whether or not FPIC becomes a legally-enforceable standard. Responsible engagement enables mutual learning—which can inform the design and testing of engineered gene drives—and explicitly recognizes the rights of self-determination, which, in our view, is a moral obligation situated deeply in the responsible conduct of science. At their core, such practices must proceed according to the ethos of humility [81], which can engender forms of trust based in the honest intention of respecting others' knowledge, concerns, and goals.

Data accessibility. This article has no additional data.

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