

# Genome Editing for Human Benefit: Ethics, Engagement and Governance

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## Guidance and policy paper: Policy on gene editing and gene drive research in the Caribbean

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### **Brief description of the context**

While many lower and middle-income countries require guidance on genome editing, none in the Caribbean have any governance structure that can sufficiently address the challenges posed by the technology.

Genome editing can be used to alter an individual's genome in order to address a specific health issue such as sickle cell disease, or used as an intervention to effect genetic changes to some vectors of disease (i.e. gene drives), such as mosquitoes, to provide much benefit to the general public.

In 2017, one government in the Caribbean was approached regarding the possible release of genetically modified mosquitoes on a small island within the state in response to zika-spreading mosquitoes. Another was invited by a private company from an upper income country to partner in a similar project within their Caribbean country. The high burden of vector-borne diseases coupled with the low resources existing in many Caribbean states render them very viable candidates for such projects sponsored from upper income countries.

### **Commentary**

Most Caribbean countries currently lack the capacity to ensure the ethical acceptability of gene editing or gene drive research that may be proposed within their jurisdictions. Nearly all Caribbean countries will therefore need governance legislation and regulations that specify the requirements to be met for genomic projects and research within their borders.

The latter can be achieved through model legislation similar to that mandated by the Council for Human and Social Development (COHSOD), which is the Council of Health Ministers from across the Caribbean community (CARICOM). While drafting is not yet completed, the model legislation aims to protect persons in CARICOM countries by regulating human subjects research along with regulations on model sanctions for non-compliance. Its drafting was prompted by a position paper from the Caribbean Public Health Agency, which informed that only 1 Caribbean country had any regulations regarding human subjects research, and so CARICOM countries needed legislated protection from harmful exploitative research activities. These recommendations however preceded the current era of genomic research.

Accordingly, the draft legislation could be expanded to include gene-editing research within the Caribbean, even if no reference is made to humans by the researchers or sponsors. Alternately, the COHSOD could be asked to mandate a committee to review all such developments internationally, and recommend a governance framework that would be appropriate for all CARICOM countries.

Such a framework could be developed by learning from the dilemmas posed by the proposed project in 2017 that would have involved the release of genetically modified mosquitoes on a small island of 4,400 people within one of the Caribbean states. In a review of the landscape at the time by the CARPHA Ethicist, the challenges included achieving community engagement and 'buy-in', how to limit the spread of the genetically modified mosquitoes to this island which has many boats

coming and going to nearby surrounding Caribbean islands, and the unknown impacts the modified mosquitoes might have on the environment.

Further, cultural and religious beliefs within the Caribbean about altering the 'make-up' of genes and 'playing God' pose additional challenges for such proposed work. In fact, societal concerns about genetic information and research in the Caribbean was brought to the forefront in an article by Roach et al (2016). In the relatively research-naive populations of the Caribbean, the study found that all project designs must take into account the cultural beliefs and practices of the host community, as well as the degree of exposure and education of the community regarding genetics in order for such projects to have the potential to yield benefits to persons within the country.

Further, the issue of public perception of the research and cultural nuances could impact public trust towards future genomic research studies. So while there is potential benefit through gene-editing for the eradication of the highly morbid sickle cell disease that is very prevalent among the African heritage populations of the Caribbean, persons with strong religious beliefs would more likely support gene editing used for somatic therapy rather than germline editing used to eradicate some diseases. Consequently, particularly in any gene-editing research, there must be a specific sensitization and community engagement strategy which must be addressed within the governance framework.

### **Conclusions**

The science and applications of gene editing transcends national boundaries, and so effective governance of the process will require governmental cooperation at the regional and international levels. Within such a governance structure for the Caribbean, issues that will have to be addressed include the health and well-being of individuals, respecting individual rights, careful attention to constantly emerging and evolving information from the process, guarding against unwanted societal effects, and equitable distribution of information, risks, and benefits.

As differences in social and legal culture will inevitably lead to different domestic policies governing specific applications of genome editing internationally, specific principles that are shared across national borders throughout the Caribbean region must be captured in providing a governance structure for gene-editing projects of a public health nature and research within the Caribbean region.

In such projects, these principles should include the promotion of well-being, transparency, due care, responsible science, respect for persons, fairness, and trans-national cooperation. Arising from these principles, cooperating countries within the region would have the responsibility to respect differing policies, coordinate regulatory standards and procedures wherever possible, and provide inter-country collaboration and data sharing between the various scientific communities and regulatory authorities.

Nevertheless, with the very limited resources existing in the small island states of the Caribbean, any and all gene-editing projects must be regarded as research to be conducted under strict supervision. Consequently, the gene drive project that was posed to Caribbean governments as a public health project was evaluated by the ethicist at the Caribbean Public Health Agency, with recommendations made that the project should only proceed if conducted under strict research conditions, with *a priori* submission to a research ethics committee.

### **Recommendations**

1. The Caribbean community should adapt the draft model legislation to incorporate guidance on gene-editing and gene drive research. Alternately, it could mandate a task force to develop a governance framework that is informed by local beliefs as well as international developments in gene-editing.
2. The regional research ethics committee which has a geneticist-ethicist and a social scientist should be used to evaluate proposed genomic research within the Caribbean in the short term.

3. Research ethics capacity strengthening in the supporting disciplines that underpin genome editing technologies should be carried out by all sponsors of research arising from upper income countries.
4. Research Ethics Committee members should commence 'self-education' augmented by structured workshops on the science and 'ethics' underlying gene-editing, with funding and technical support from stakeholders in research from high income countries and the pertinent international agencies.

## References

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