



AUSTRALIAN CITIZENS' JURY ON GENOME EDITING

GENOME EDITING: FORMULATING AN AUSTRALIAN COMMUNITY RESPONSE

REPORT TO DECISION MAKERS, STAKEHOLDERS AND MEMBERS OF THE PUBLIC

Dianne Nicol^a, Rebecca Paxton^{ab} and Simon Niemeyer^b

with

Nicole Curato^b, John Dryzek^b, Christopher Rudge^{ad}, Sonya
Pemberton^c and Francesco Veri^b

^aCentre for Law and Genetics, University of Tasmania

^bCentre for Deliberative Democracy and Global Governance, University of
Canberra

^cGenepool Productions, Melbourne

^dLaw Faculty, University of Sydney

Centre for Law and Genetics

University of Tasmania

Occasional Paper No 12



EXECUTIVE SUMMARY

Genome editing is a new development in science that allows very targeted modifications to be made to DNA, the genetic material that almost all living things possess. It can potentially be used in plants and animals for such things as modifying the way they adapt to changes in the climate. It can also be used in humans to prevent or treat certain diseases and disabilities. There are many other potential uses. There are benefits and risks associated with genome editing, which raise many ethical, legal, and social concerns. One of the applications of genome editing that is seen as being particularly ethically fraught is its use to make changes to human DNA that can be inherited by future generations.

Over the past few years, a number of reports have been published on genome editing by eminent scientific and policy groups. In general, these reports reveal a cautiously optimistic outlook for the contributions that genome editing might make both to human health and welfare and to the environment. However, they recognise the need for robust regulation of genome editing applications, reflecting ethical norms and community values. They adopt a particularly cautious approach when it comes to changes to human DNA that can be inherited. The reports uniformly call for community engagement on genome editing, but provide little guidance on how this might be undertaken and to what end.

This report provides background, methods, results and policy perspectives on a community engagement project undertaken in Australia in 2020-2022, focusing exclusively on the use of genome editing techniques in humans. The project was funded by the Genomics Health Futures Mission (GHFM) of the Medical Research Future Fund (MRFF). The MRFF is a long-term investment by the Australian Federal Government supporting Australian health and medical research. The MRFF aims to transform health and medical research and innovation to improve lives, build the economy and contribute to health system sustainability. Funds from the MRFF are invested in genomics research through the GHFM, with the aim of improving testing and diagnosis for many diseases, helping personalise treatment options to better target and improve health outcomes, and reducing unnecessary interventions and health costs. The GHFM Roadmap lists 'developing a better understanding of the ethical legal and social implications (ELSI) of genomics and facilitating public trust and public engagement' as one of the priority areas for investment. This project was one of nine ELSI-related projects selected for funding in the first tranche of GHFM funding. The team undertaking this project brings expertise in respect of the ELSI of genomics and related technology (Nicol and Rudge), deliberative democracy (Niemeyer, Dryzek, Curato and Veri), science and technology studies (Paxton) and science communication (Pemberton).

The centrepiece of the project was the Australian Citizens' Jury on Human Genome Editing. Although we recognise that a discrete event such as this is not a substitute for a wider process of public



engagement and debate, it can provide a valuable contribution. Deliberative events of this nature are particularly important for complex issues such as human genome editing which raise profound ELSI affecting the public interest. The citizens' jury thus has an important 'discursive' role, allowing us to learn what happens when the public interacts with the science under conditions that approach the deliberative ideal, where norms of respect, reflection, and informed reason-giving are in play. Even so, while the outcomes of these types of citizen deliberation are informative, providing important insights, they should not be seen as decisive. Forming a discursive (or considered) public view requires an extensive and ongoing approach. The outcomes of the Australian Citizens' Jury thus provide important material that can be harnessed to inform and engage the wider public.

The Australian Citizens' Jury on Human Genome Editing also has a 'decision-making' role, by identifying some of the most important policy questions that need to be addressed. These questions cannot easily be answered in this initial step, but their foregrounding as part of this project constitutes an important outcome. The citizens' jury, along with wider engagement with experts and other members of the community, has identified a range of matters that require policy consideration and further public discussion.

The Australian Citizens' Jury on Human Genome Editing was held at the Museum of Australian Democracy at Old Parliament House in Canberra, Australia from 17 to 21 June 2021. Participants heard from experts and engaged in a facilitated process to deliberate on the basic principles that should underpin policy responses to current and future developments in human genome editing technology. Participants were asked to deliberate on the following question: 'under what conditions (or circumstances) might the application of human genome editing technology be acceptable?'

Alongside the citizens' jury itself, a range of associated activities involving members of the public took place, which are summarised in Figure 1. Highlights included:

- A study to examine the range of salient positions on genome editing that currently exist among the public (discourse mapping), undertaken prior to the citizens' jury.
- Recruitment of two cohorts guided by the mapping study in order to reflect both demographics and the diversity of positions on genome editing in the community (discursive representation). The first cohort comprised the 23 individuals who participated in the citizens' jury (the participant group). The second cohort comprised 21 individuals who did not participate in the citizens' jury but participated in other aspects of the project (the control group).
- Post-citizens' jury interviews with the participant group.
- A follow-up online forum with some of the members of the participant group to finalise reported recommendations.
- A survey on genome editing, the aim of which was to assess the medium-term impact of the citizens' jury on participants' positions, and to compare their responses with the control group and a broader sample of participants from the Australian population (the population group).

Figure 1 also shows the range of additional research material collected in association with the event, the preliminary analysis of which informs this report.



Figure 1: Public engagement activities conducted over the course of the project, with associated data collection methods and sample sizes.

	Pre-process				Australian Citizens' Jury on Human Genome Editing								Post-Process			
					Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8				
	Scoping study	Discourse Mapping	Participant recruitment	Pre-deliberation interviews	Introductions	Group building	Information	Information	Deliberation	Deliberation	Close	Post-deliberation interviews	Online participant forum	Population, expert, and participant surveys	Expert workshops	
	Issue scoping and identification of experts	Mapping survey and online interviews with mapping study participants	Selection based on demographic and "discursive" representation	Mapping survey and online interviews (Citizens Jury and Control Group)	Ice-breaker Introduction to process Evening reception	Participants create group guidelines for participation	Expert witness presentations Breakout group deliberations to develop questions Q&A	Expert witness presentations Breakout group deliberations to develop questions Q&A	Development of preliminary considerations (in breakout groups)	Refinement of recommendations (in breakout groups) Synthesis of recommendations (in plenary)	Presentation of recommendations to decision makers Response from decision makers Final reflections and evaluation	Mapping survey (Citizens Jury and Control Group) Online interviews (Citizens' Jury)	Review of draft Recommendations Report with Citizens' Jury participants	Benchmark the Australian population, experts, and control group against the (pre- and post- deliberation) positions of Citizens' Jurors (Feb' 2022)	Two workshops discussing policy options for human genome editing with subject matter experts (Aug' 2022)	
Data collection		Mapping survey (n=31)	Screening survey (n=123)	Mapping survey (n=44)			Surveys					Mapping Survey (n=23)		Survey of population (n=1008), expert (n=30), control group (n=20), Citizens' Jurors (n=23)		
	Expert interviews (n=34)	Participant interviews (n=31)		Participant interviews (n=44)			Interviews					Participant interviews (n=23)				
							Workshops/forums						Online forum (n=10)		Expert workshops (n=36)	
Other	Expert witness briefings and development of presentations	Assess participants' knowledge and identify important gaps	Information Pack given to participants				Expert witnesses available to answer participants' technical questions as they arise					Participants given fact sheet on research involving human embryos				Participants given draft report

Throughout the project, experts representing a diversity of views and disciplinary expertise (see Appendix D) in the fields of genomics, healthcare delivery, bioethics, politics, social sciences and other disciplines were also consulted. In particular, prior to the discourse mapping study, open-ended interviews with 34 experts were used to identify the relevant dimensions of the issue. These and other experts were also invited to undertake a slightly modified version of the post-citizens' jury survey on genome editing to compare the responses of experts with the participant group, the control group and the wider population. Experts were also invited to attend online workshops to canvass the policy implications of the outcomes of the citizens' jury and assist in their translation into policy recommendations. Seven experts were invited to give presentations and answer questions at the citizens' jury, to assist participants in their deliberations.

The primary outcome of the citizens' jury and the subsequent interactions with the participant group was a set of recommendations, along with supporting reasons, both of which are provided in full in Section 5 of this report. Participant discussions at the citizens' jury and in the post-jury interviews, online forum and survey revealed wide diversity in underlying discourses. This same diversity was also detected in the population, control and expert groups. Some participants in each group expressed reservations about any forms of genome editing, particularly those involving use of human embryos. Others were much more enthusiastic about the promise of genome editing, and concerned that excessive regulatory requirements could hamper progress. The citizens' jury recommendations thus reflect primarily the views of the majority of participants, which could perhaps best be described as cautiously optimistic that genome editing could provide a valuable contribution to healthcare in the future, provided that it is properly regulated, well researched and delivered equitably. To a large extent, then, these views mirror those expressed in the reports of science and policy groups mentioned above.

The recommendations include both general principles and specific points relating to non-heritable and heritable forms of genome editing. In summary, the recommendations illustrate that, in the view of the majority of participants:

- Applications of human genome editing should be restricted to the alleviation of human suffering, improvement to quality of life, and reduction of childhood mortality.



- Genome editing should be properly regulated, with regular review including stakeholder and community input.
- Genome editing should be made available equitably to those most in need, and informed consent must be assured.
- Clinical development of genome editing should be informed by adequate research to identify and assess the potential risks and benefits, both to the individual and to society.

Participants were more cautious about heritable than non-heritable forms of genome editing, emphasising that the former should only be considered at some stage in the future, after more research to assure safety and efficacy, and more community engagement for guidance on how to proceed responsibly with the technology.

Participants also considered genome editing research involving human embryos. Given that questions associated with embryo research were not fully canvassed at the citizens' jury, they were revisited in post-jury interviews and an online forum. Many participants expressed particular discomfort with the creation and use of human embryos specifically for research. For some participants, creation of human embryos for research was and would continue to be untenable. However, a majority of participants expressed in principle support, recognising the need for this form of research if heritable genome editing is to become a reality, in the absence of other suitable alternatives.

Although not discussed in detail, the majority of participants also expressed cautious support for mitochondrial donation, a technique that has since become legal in Australia, subject to stringent regulation.

From the policy perspective, five key themes have emerged from the academic and policy literature, from the citizens' jury deliberations, from the other forms of community engagement and from engagement with experts during the course of this project. Each theme is underpinned by more specific points for consideration in policy development.



1. Embedding equity and other values and principles in human genome editing policy

- As clinical applications of genome editing become available, they should be made broadly accessible to those in need, with particular focus on those applications that alleviate human suffering, improve quality of life, and reduce childhood mortality. Methods will thus need to be developed to operationalise priorities, based both on the severity of the disorder or disability and the number of people affected, taking into account considerations broader than financial burdens and benefits.
- Intellectual property should be a tool both for facilitating development of clinical applications of genome editing and for facilitating open and legitimate genome editing research. This may require the development of policies and guidelines to ensure that research remains unfettered by intellectual property constraints.
- Distributive justice demands both that genome editing applications are made broadly available, and also that research and development into new genome editing applications is targeted to those most in need in Australian society (and the broader global community). This will require further priority setting by governments.

2. Ensuring that therapy, enhancement and other applications of genome editing to humans are appropriately regulated

- Genome editing tools may be used in a range of ways, many of which may not even be in contemplation at the current time. As such, it is important to assess whether the current regulatory framework relating to therapeutic goods is adequate in assessing and monitoring the safety, efficacy and utility of the various uses to which genome editing tools might be put.
- Evidence of misuse of genome editing tools internationally indicates that the Australian federal government should consider supporting the WHO recommendation for reporting misuse of human genome editing research and other activities. The Australian federal government and other funding agencies should consider whether to require that all clinical trials involving genome editing should be included on the WHO's Global Human Genome Editing Registry. Further, Australian governments should also consider whether explicit offences should be enacted for unapproved human genome editing, whether it used for clinical or non-clinical purposes.

3. Deciding what types of human genome editing research should be allowed and supported, recognising differing views on the status of the human embryo

- Noting that various non-heritable forms of human genome editing research are already well underway in Australia, Australian governments may wish to consider funding priorities to ensure that this country remains at the forefront of this research effort. The Genomics Health Futures Mission may be an appropriate forum for this work.
- Although there appear to be no current licences for the use of human embryos for genome editing research, it would be unfortunate if no further progress is made in increasing our understanding of the legitimacy of using embryos for genome editing research until such time that the first application is made for a licence. As such, it may be appropriate for the governments of Australia to consider questions associated with the use of human embryos for these purposes in the near future.
- More particularly, the creation of human embryos for research purposes remains contested. The experience with mitochondrial donation provides a model both for how to undertake public consultations on such matters, and how a strict and tightly prescribed legislative regime might be created for this purpose, should this be deemed appropriate.



4. Preparing for a future when heritable human genome editing may be shown to be safe and effective

- We are not yet at a point in time in Australia where the application of heritable human genome editing is imminent. Indeed, it appears that we are not yet at a point in time in this country when genome editing research involving human embryos is being planned. Despite this, it is suggested that it is timely to consider the approach that might be taken in Australia, should heritable human genome editing ever be seen as a realistic option for parents desiring to have healthy, genetically related children.

5. Building meaningful public participation in governance of human genome editing into the future

- Should the Australian governments decide to explore further any of the points we have outlined above, public participation will need to be built into the process. Moreover, any new regulatory and other policy directions emerging from this exploratory process will need to be accompanied by ongoing public participation.
- Public participation planning should include culturally respectful inclusion of Aboriginal and Torres Strait Islander communities.

There were some provisos in relation to this project. The topic is both complex and anticipatory (i.e., not yet subject to substantial public debate). Funding and time limitations, together with the breadth of the inquiry, posed particular challenges. This meant that the citizens' jury had to be carefully designed, in consultation with practitioners and experts, if we were to achieve the primary goal of generating an informed and reflective account of the public view that could then be shared with the wider community as well as relevant decision makers. The resulting limitations lead to three important provisos:

First, despite the care taken in designing the process, insufficient time was available at the citizens' jury for detailed deliberation on this complex area of scientific development and associated ELSI. The post-jury interviews and the online forum provided the opportunity for further reflection, but the shortage of time for group deliberation is duly acknowledged by the research team. Although the process succeeded in facilitating reflection across a wide range of issues (Appendix E), there were a group of concerns that were not fully worked through, and these concerns represent a particularly important perspective.

Secondly, almost half of the participants at the citizens' jury drew attention to the absence of advocates speaking in opposition to genome editing. This is despite the distribution of perspectives among the expert witnesses reflecting a diversity of views, including those reflecting the more sceptical views of participants and the community (see Appendix D, section D.3). Experts were chosen for their expertise in canvassing the wide ranging scientific, clinical, legal, social and ethical issues associated with genome editing, and for representing a wider range of views (see Section C.5). Nonetheless, many participants felt that the Australian Citizens' Jury would have benefited from inclusion of other viewpoints, in addition to expertise provided by the expert witnesses. It is noted, however, that, while this limitation, combined with limited time, impeded reflection on some potentially important issues, it did not have a regressive impact in a deliberative sense. Our analysis reveals that genuine deliberative reflection did occur, and that Australian Citizens' Jury participants did not simply adjust positions to reflect those of the participating experts (sections 6 and 7). In short, we achieved our objective of simulating a high quality deliberative public conversation, but there are important provisos, and lessons for decision making and further public engagement, including with important but potentially marginalised perspectives.



Thirdly, the absence of participants from Australia's Aboriginal and Torres Strait Islander communities represents a notable and significant gap in the perspectives canvassed at the Australian Citizens' Jury. We acknowledge that these perspectives would have been deeply valuable to the current project, as well as to future decision-making. However, we were unable to identify a model of participation that was consistent with the requirements for engagement with Aboriginal and Torres Strait Islander peoples that were articulated to us by two recognised experts in Indigenous genomics with extensive experience conducting indigenous engagement. We discuss the feedback from these experts in Section 2 and Appendix B of this report. Nor was there scope within this project to meet the definitions of inclusiveness that we surveyed from the emerging research literature on inclusive participatory democracy, and which could enable Indigenous participants to contribute in a way that shaped meaning within the broader deliberation. Given these considerations, it was determined that the detailed, respectful and sometimes sensitive task of achieving Indigenous engagement with respect to human genome editing would not be possible within the scope and remit of the Australian Citizens' Jury. On balance, then, we concluded that there were clear and compelling reasons for deferring or reserving questions relating specifically to Aboriginal and Torres Strait Islander people and genome editing to another project, where a representative and multidimensional engagement with the issues would be possible.

This project has parallels in other countries and has the potential to feed into a larger global citizens' deliberation. This report has been provided to relevant government and policy bodies and other stakeholders in Australia and internationally, and is being made publicly available. It is hoped that this report will assist relevant agencies in deciding such matters as: whether the regulation of human non-heritable genome editing is working optimally, or needs reform; and whether it would be appropriate, now or at some time in the future, to open the Australian regulatory regime for heritable human genome editing and embryo research to further scrutiny.

This report is divided into ten Sections, outlined below in the Table of Contents. Detailed material for some aspects of this report can be found in the corresponding appendices for Sections 1, 2, 3, 6 and 7.

The report also includes a detailed list of acknowledgements. In brief, we first wish to acknowledge that this project was undertaken on the lands of Aboriginal and Torres Strait Islander peoples, and we pay our respects to their elders, past, present and emerging. We gratefully acknowledge funding from the Medical Research Futures Fund Genomics Health Futures Mission. We thank the many experts globally and members of the Australian community who contributed to this project. We particularly thank the 23 exceptional Australians who participated in the Australian Citizens' Jury on Genome Editing. We thank the Museum of Australian Democracy, and particularly Daryl Karp, for hosting the citizens' jury. We also thank Genepool Productions, in association with December Media and By George Studios for filming jury deliberations, and SBS, Screen Australia and Film Victoria for providing funding for this aspect of the project. Dynata assisted with recruitment, and we would particularly like to thank Ariane Hayes. Nicole Hunter and Keith Greaves from MosaicLab facilitated our expert workshops. We thank the many members of our research, facilitation, and administrative teams who assisted us throughout the project, particularly Kath Fisher, who led the facilitation of the Australian Citizens' Jury and the table facilitators.

Our highly respected friend and colleague Professor Christine Critchley was a core member of the research team at the start of this project. Tragically Christine passed away in November 2020. We



have missed her friendship, collegiality and expertise throughout the course of this project. It would have been all the richer for her involvement.

This research was approved by the University of Tasmania Human Research Ethics Committee (project number H0021841) and the University of Canberra Human Research Ethics Committee (project number 9095).