

# UK citizens' jury on genome editing

A large, stylized graphic of a DNA double helix is positioned on the right side of the cover. It is composed of white outlines on a teal background. The helix is partially cut off at the top and bottom edges. The two strands are represented by thick white lines, and the base pairs are shown as diagonal white lines connecting the strands.

Handbook

13-16 September 2022  
Wellcome Genome Campus

## **Acknowledgments**

This handbook was prepared by Alessia Costa, Christine Patch and Anna Middleton from Wellcome Connecting Science, and Simon Burall from Involve. Part of the content is based on a similar document prepared for the Australia Citizens' Jury. This handbook was reviewed and approved by the UK Citizens' Jury Oversight Group.

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Designed by Laura Olivares Boldú. Printed in the United Kingdom.

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# Welcome

Welcome to the UK Citizens' Jury on Genome Editing. We are grateful that you have accepted our invitation to be part of this project.

To help you make the most of the event, we have put together this participant handbook. It contains an overview of what to expect from the Citizens' Jury and some of the questions we will be discussing.

**You DO NOT need to learn or memorise anything from this handbook. As a juror, you will have access to further information during the event itself. You will have the opportunity to discuss the questions with other participants, specialists in the science and politics, as well as people with personal experience of the issues. This handbook is to help you familiarise yourself, SHOULD YOU WANT TO, with some of the questions we will be discussing and make sure you have all the information you might need in one place.**

If you have any questions before or during the event, please do not hesitate to get in touch using the contact details at the end of this handbook.

We look forward to welcoming you when you arrive at the UK Citizens' Jury on Genome Editing.

# Why this, why now?

Scientists can now edit the human genome with relative ease and precision. However, the idea of changing the code of life (the genome) creates strong opinions. In the UK, as in most countries worldwide, it is illegal to perform genome editing on embryos that lead to a pregnancy. In fact, there is no clear proof that this has ever been done.

In 2018, a Chinese researcher, Jiankui He, announced the birth of the first babies whose genome he claimed to have edited. The news provoked immediate global condemnation. Jiankui He was later prosecuted and sentenced to prison in Chinese Court, and to this date there is no clarity about the outcome of the experiment. The global consensus is that, at present, it would be irresponsible to proceed with genome editing of human embryos for reproductive purposes. Safety aside, the technology raises profound social and ethical issues, and the public should be given the opportunity to debate these in order to decide whether or not genome editing should be allowed in the future.

## **So what is the matter with genome editing?**

The technology has been hailed as a game changer for potentially curing some hereditary genetic disorders. Using genome editing we can, in principle, alter the genes in a newly formed embryo, potentially stopping disease genes from being passed on to future generations. This could enable families with a known genetic disorder to have children who are unaffected by the family condition. What's more, by stopping the disease-causing genes from being passed on, the condition would not only be avoided in the individual child, but could be eliminated from all future children and grandchildren. Some believe these potential benefits outweigh ethical reservations against the technology.

Others consider that in light of existing alternatives, the ethical risks of genome editing are not justified. Families with a known genetic disorder already have the option to use genetic technologies to try and have children who are unaffected by the disease. These existing technologies (e.g. pre-natal testing with termination of pregnancy or pre-implantation genetic diagnosis with selection of unaffected embryos) can help families without going to the lengths of altering the genome of future generations.

Either for religious, cultural or personal reasons, some people strongly feel that the human genome is not ours to change. Genome editing also involves manipulating human embryos, which is opposed by certain sections of society. Further, some fear that the possibility of correcting disease-causing genes could lead society to be less accepting of disease and disability in general. Finally, there are concerns that, due to costs, the technology would be out of reach for many, meaning only wealthier countries/individuals could benefit from it.

As the technology continues to develop, the debate on genome editing is here to stay. A new case similar to the Jankui He's experiment, or pressure from interested groups, could mean that governments might soon have to make a decision on how the technology should be regulated. When this happens, it is important that the public has been given the opportunity to consider and deliberate these matters, so that their views can inform any government's decision.

This is why we are convening a UK Citizens' Jury on Genome Editing to feed into the national and global debate on these matters. Over the course of the Citizens' Jury, you will be invited to listen to and debate different arguments for and against genome editing. Together with other jurors, you will have the opportunity to reach your own conclusions and make your recommendations as to whether there are any conditions under which the UK government should consider changing the law to allow genome editing in the future.



# The project

## The UK Citizens' Jury on Genome Editing

The UK Citizens' Jury on Genome Editing is part of a series of national juries taking place around the world. These juries are designed to lead to the Global Citizens' Assembly on Genome Editing. This will be led by a group of researchers from the University of Tasmania and the University of Canberra, and is being planned for delivery in Athens in the next couple of years. The aim is to contribute to shaping the public conversation and decision-making about genome editing technologies around the world.

As a juror on the UK Citizens' Jury, you will join other patients, family and carers affected by genetic disorders to deliberate on the following question:

**Are there any circumstances under which a UK Government should consider changing the law to allow intentional genome editing of human embryos for serious genetic conditions?**

Sub-questions:


- In terms of 'serious genetic conditions' is germline editing a logical extension of somatic editing?
- Given pre-implantation genetic diagnosis (PGD) is already available, is there any added benefit to be gained from genome editing?
- If the law were changed, what should the role of the private in vitro fertilisation (IVF) sector be?
- What type of governance and accountability should be put in place if the law were changed?

Given the potential changes in technology and medicine, we will be looking at these questions within a **10 year time frame**.


Right now, we do not expect you to even try to answer these questions. We will unpack all of this together during the Jury itself. As a juror, you will have access to some of the leading experts on genome editing and the complex issues raised by this technology. You will be given time to reflect and engage in a series of large and small group deliberations with the help of trained facilitators.

Through the process, you will have the opportunity to collectively decide your recommendations on how genome editing technologies should be used. These will be shared with the Department of Health and Social Care as well as the wider genetics, policy and academic communities so that they can inform future decisions about the technology.

To find out more about the UK Citizens' Jury, please see the **Participant Information Sheet** or visit our website:

webpage		<h3>UK Citizens' Jury on Genome Editing</h3> <p>URL: <a href="https://bit.ly/uk-citizens-jury">bit.ly/uk-citizens-jury</a></p>
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You can also see what the Australian citizens' jury on genome editing looked like:

video	<h3>Australian Citizens' Jury on Genome Editing</h3> <p>URL: <a href="https://vimeo.com/679998383">vimeo.com/679998383</a> Credit: Genepool Productions</p>	
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To have an idea of what the Global Assembly is about you can watch the video here:

video		<h3>The Global Citizens' Assembly on Genome Editing</h3> <p>URL: <a href="https://vimeo.com/417090291">vimeo.com/417090291</a> Source: <a href="http://www.globalca.org">www.globalca.org</a></p>
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# What is a citizens' jury?

A citizens' jury is a way of engaging members of a community on questions of public importance. Citizens' juries have been used, for example, to make decisions on where to make cuts in public service spending, how to improve mental health services, and whether to allow a new technology to be used.

When we ask people to take part in an opinion poll, a survey, or other forms of public consultation, we ask them about issues that they may not have thought about. By contrast, a citizens' jury asks participants to weigh evidence from experts, listen, and exchange ideas with their fellow participants. Through this process, everyday citizens are given enough time and support to think carefully about the issue and come up with their considered collective judgement.

Typically, citizens' juries are asked to make recommendations on specific **policies**. Broadly, policy means the decisions that those in power take. These include:

- the laws which are passed by parliament
- the way money is spent by a government department
- rules and regulations
- long term strategy





Image credit: Involve

Citizens' juries are particularly helpful to make decisions when a specific policy is controversial. This might be because different individuals and communities will be affected differently by the decision, or because there are disagreements, or important ethical and social implications.

Citizens' juries can help those making decisions (the 'policy-makers') to learn more about the needs of a community and what different members think is important to take into account when making a decision, so that policy can be made in a way that reflects the values and interests of the community.

**The Citizens' Jury is a safe space. We don't expect anyone to have all the answers and there are no stupid questions. All perspectives and opinions are valid and it is OK to disagree. When doing so, please remember that you are challenging an opinion, not the person voicing it. If you need a break, you can leave the room at any point. Quiet places and dedicated support will be available throughout the event.**

To get an idea of what a citizens' jury looks like you can watch the video here:

video



### What is a Citizens' Jury?

URL: [youtu.be/fwScIUIDUD0](https://youtu.be/fwScIUIDUD0)

Credit: newDemocracy Foundation

Source: [www.newdemocracy.com.au/what-is-a-citizens-jury](http://www.newdemocracy.com.au/what-is-a-citizens-jury)

# The UK Citizens' Jury as a creative project

The UK Citizens' Jury on Genome Editing is also a creative project. We have commissioned Green Eyed Monster Films in collaboration with Lambda Films to film the entire Citizens' Jury and release a short documentary about the event.

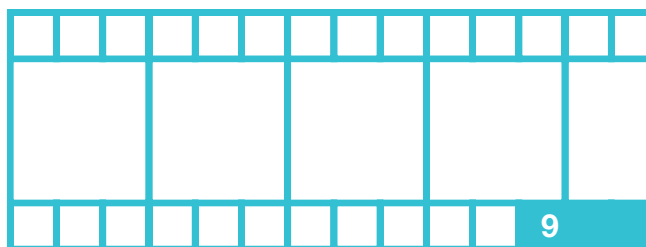
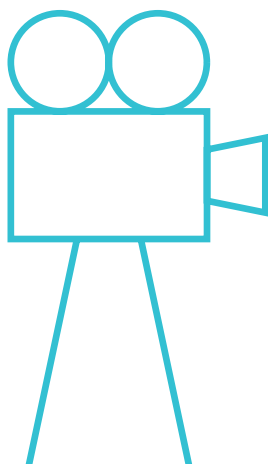
The film will be made publicly available on the project website and related social media channels (e.g. Youtube) and will also be presented at national and international film festivals.

In addition, we will also share the footage with a team of film-makers based in Australia (Genepool Productions) who are working on a series for worldwide distribution. The series will be mostly based on the Global Citizens' Assembly that is planned to take place in Athens, however footage from the UK Citizens' Jury might be featured in the production.

The creative part of the project is essential to make sure that the wider public can learn about the results of the jury. For this reason, we kindly ask your consent to be filmed during the event. Taking part in filming might be an unfamiliar experience, but there is nothing you need to prepare. We advise wearing comfortable clothes and acting naturally, without paying too much attention to the cameras. Some people may be asked to wear microphones and others won't.

In the **Participant Information Sheet** you can find more information about the filming process and your rights as a participant.

If you have any questions, please do not hesitate to get in touch with Prof Anna Middleton ([anna.middleton@wellcomeconnectingscience.org](mailto:anna.middleton@wellcomeconnectingscience.org)) who has commissioned the Citizens' Jury on behalf of Wellcome Connecting Science.

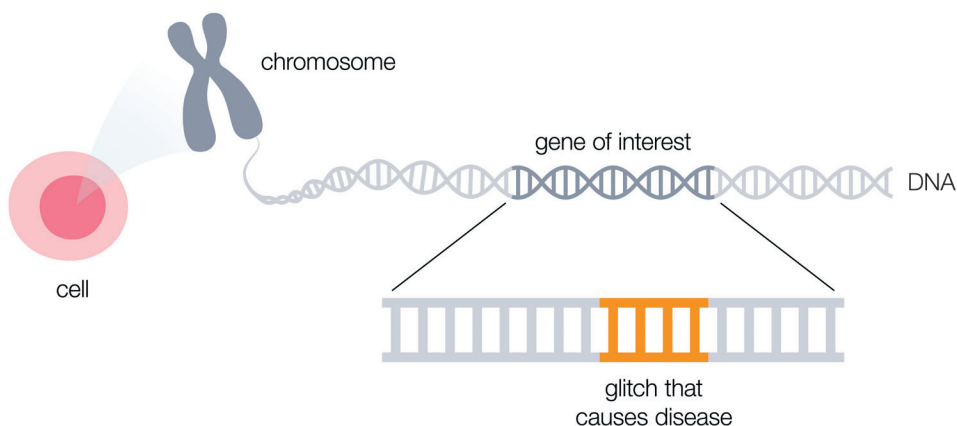


# The basics of genome editing

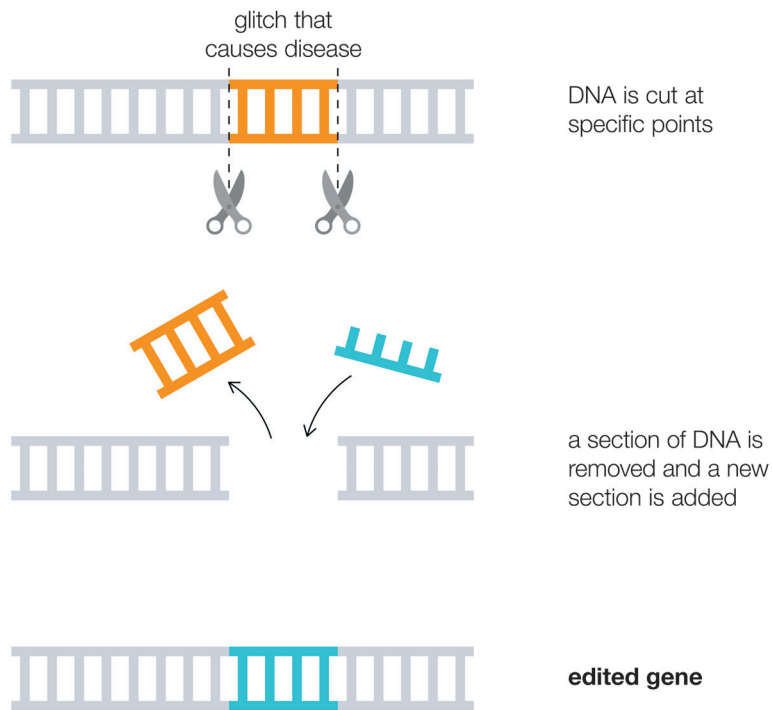
Below you can find some background information on genome editing in general, and on the specific type of genome editing we will be focusing on - heritable human genome editing for therapeutic purposes. This is for your personal reference only, so you don't need to learn or memorise any of this right now. As a juror, you will have the opportunity to hear directly from experts at the event itself.

## What is genome editing?

Genes are made of DNA. There is DNA inside each cell of every living thing, i.e. in insects, plants, animals and humans. DNA contains the instruction that gives us particular characteristics like our eye colour or height. DNA is inherited from our parents. We have a combination of genes from each of our biological parents. Sometimes genes contain changes, or glitches, which mean we are more likely to develop particular diseases. A 'genome' refers to the full collection of DNA that an organism has and in humans this includes the 20,000 or so genes, as well as the DNA between them.



Genome editing is a new development in genetic science. There are different technologies that have been developed. With these technologies, it is possible to alter parts of a person's DNA. In other words, genome editing can be used to add, remove or alter someone's genes, which may help to treat particular conditions that are caused by glitches in DNA. These could include some cancers or rare genetic disorders. This is at a very early stage of research and testing in humans. At the moment, when gene editing is done, there is a chance that it might be inaccurate, it is anticipated in time that this will improve and become highly accurate and stable.



You can find more information about genome editing here:

webpage



### What is genome editing?

URL: [www.yourgenome.org/facts/what-is-genome-editing](http://www.yourgenome.org/facts/what-is-genome-editing)

Source: Yourgenome



# Types of human genome editing


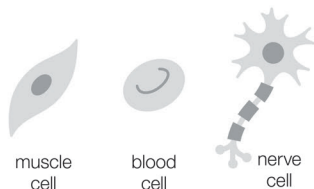


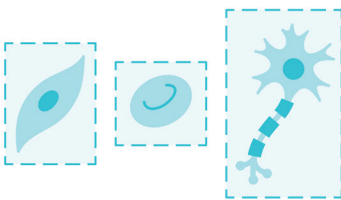

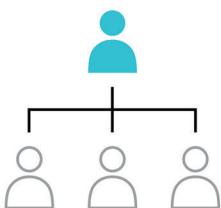
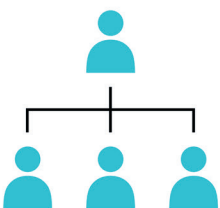
Genome editing can be done in cells from a person (e.g. in the eye, muscle cells in an adult person or even in a baby in utero). In this case, any changes made would only affect that person, but could not be passed on to future children the person might have, meaning the changes are **non-heritable**. This is called **somatic genome editing**.

Genome editing can also be done at a very early stage in a developing embryo. In this case, any changes would remain in any cell as the embryo develops, meaning they would then be present in all the cells of the baby born from that embryo. This would also include the eggs and sperm so the edited (non-disease) gene could be passed on to future children of that baby. This is called **germline genome editing**.

When germline gene editing is performed for reproductive purposes, meaning the edited embryo is implanted and leads to a pregnancy, we speak of **heritable genome editing**. In reality, if heritable genome editing was to be done, it would be delivered using IVF technologies, i.e. the mother would need to take hormones so that she can create multiple eggs. The eggs would be surgically collected and then fertilised outside of the body in a laboratory setting. If the eggs are successfully fertilised, then at a very early stage, before the cells start to divide, the genetic edit to the DNA would be done. If the early embryo survives this, in theory, all the cells that are then created within that embryo would contain the edited DNA.

The key difference between somatic genome editing and germline/heritable genome editing, is that in somatic genome editing the edited genes only affect the person being treated, and these changes cannot be passed on to future generations. For germline or heritable genome editing, the changes can be passed on to future generations.

There are potential benefits from both somatic genome editing and germline/heritable genome editing, such as treating, or even, eliminating life-shortening, heritable diseases. However, as heritable genome editing in particular would change the genes of future generations it is often seen as controversial. This is because it potentially raises spiritual, religious and deeply personal issues, as well as concerns about non-discrimination and fairness. Broadly speaking the clinical use of somatic genome editing is legal and germline or heritable genome editing is not.

	somatic genome editing	germline genome editing
edited cells	<p> modifications are made on specific types of cells</p>  <p>muscle cell      blood cell      nerve cell</p>	<p> modifications are made very early in development</p>  <p>egg cell      sperm cell      very early embryo</p>
cells that will have the edited gene	 <p>only the target cell type contains the edited gene</p>	 <p>every cell in the body contains the edited gene, including sperm and eggs</p>
heritability	 <p>the edited gene is not passed down to future generations</p>	 <p>the edited gene has the potential to be passed on to future generations</p>

# What is heritable human genome editing for therapeutic purposes?

This refers to changing DNA in embryos in order to treat the baby that is then born.

You may have heard concerns about so-called ‘designer babies’, where genome editing could be used to change embryos so that the baby born will have particular characteristics such as being good at sports or music or have their natural abilities ‘enhanced’. These characteristics are influenced by many genes together with the environment and it may never be possible for genome editing to affect these.

For now, genome editing is likely to work best for characteristics caused by a single genetic change. These include many rare genetic disorders such as muscular dystrophy, sickle cell disease and cystic fibrosis. Discussion about this is still at a very early stage, but it is one of the areas that is more likely to receive attention from policy-makers in the future. For this reason, it will be the main focus of our discussion.

## What are the current options?

### **Somatic (non-heritable) genome editing**

Trials have already started on somatic (non-heritable) genome editing, for example in sickle cell disease. There is much discussion about the promise of genome editing to treat genetic disorders that are not currently treatable and research is active and ongoing. To date, however, no gene therapy based on genome editing has been approved for routine medical care outside of research studies in the UK, or globally for that matter. This is because the technology is still very new and the safety and effectiveness of procedures are still being researched.



A significant challenge with somatic (non-heritable) genome editing is delivering the edited genes so that they can work in the right cells and tissue. For example in sickle cell disease the blood cells can be edited outside of the body but the patient would need a bone marrow transplant to get red blood cells at an early stage of development, edit them and then replace them into the bone marrow.

Editing genes in an embryo (heritable genome editing) might be one way of getting around this issue as all the cells would have the altered gene. However, editing genes in an embryo is only allowed in a research setting, not for reproductive purposes (see more below). This means that, at the moment, embryos that have been edited are not yet able to be implanted and lead to the birth of a baby. Therefore we have no way of knowing what the potential benefits or added risks of heritable vs non-heritable editing might be.

There are still many unanswered questions about the safety and effectiveness of the process of genome editing, both heritable and non-heritable. One of the major concerns is that the change introduced into the DNA may not be restricted only to the target gene. The technology itself may introduce other unanticipated changes in the DNA - 'off target effects'. In heritable genome editing this is even more relevant since the changes could persist from generation to generation. Or the changes may become introduced into the embryo too late and thus only affect some cells but not all.

## **Treatment for genetic disorders**

For many of the most serious rare genetic diseases, apart from treating the effects of the disorder, there are no existing treatments or cures.

Advances in treatments have included:

- Enzyme replacement therapy, replacing the enzyme that the variant gene doesn't produce.
- Repurposing of existing drugs or development of novel drugs that work in the same pathway that is altered by a dysfunctional gene.
- Gene therapy, introducing a 'working' copy of the gene, for example by using a vector such as a virus.

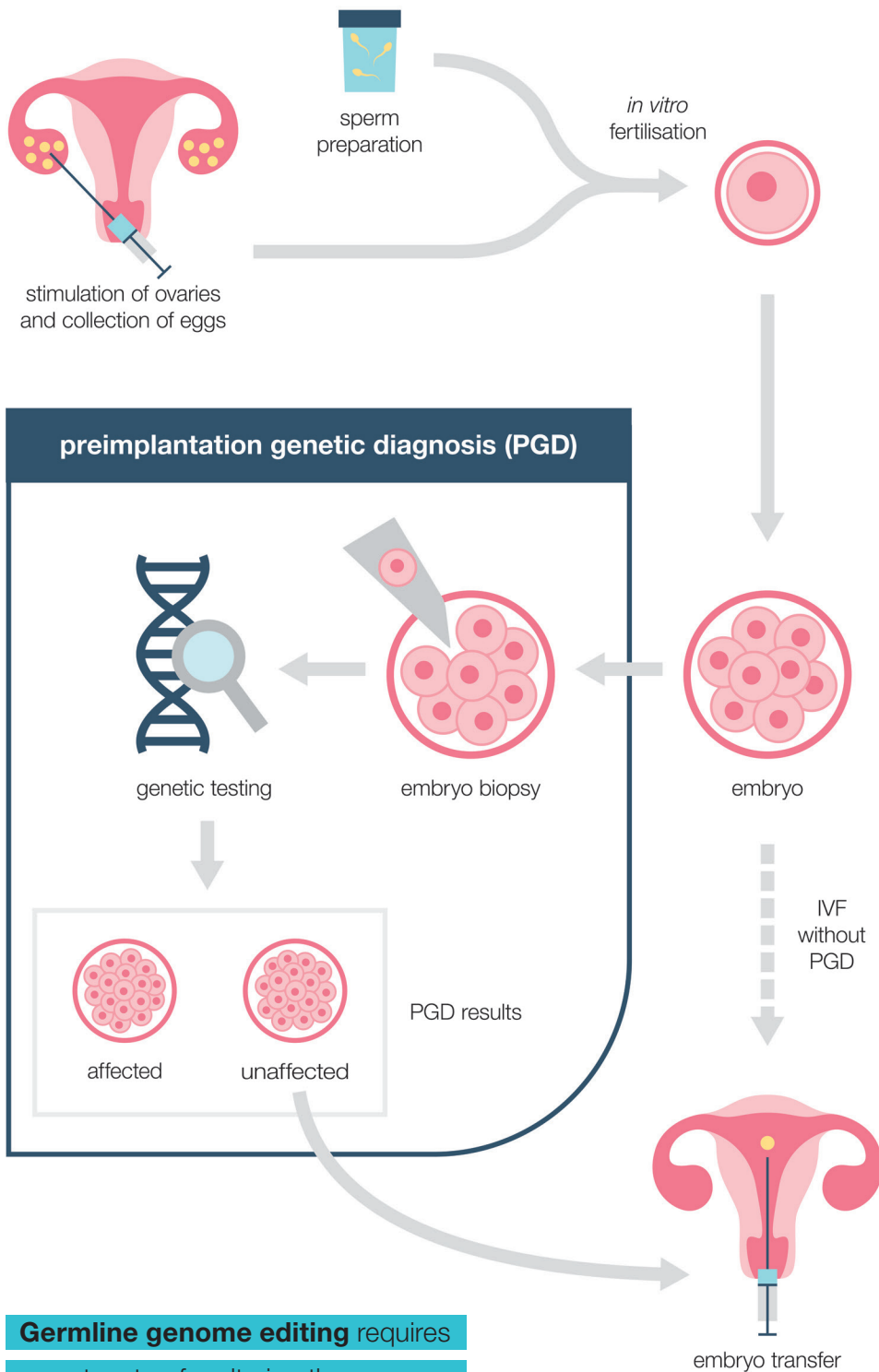
## **Other options: genetic testing and preimplantation genetic diagnosis (PGD)**

Individuals and couples who have a known inherited genetic disorder, and who want to have genetically related children unaffected by that disorder, in many cases can have testing during pregnancy and choose to end the pregnancy if the baby has the disorder.

Another alternative is preimplantation genetic diagnosis (PGD). With PGD, embryos are created using in vitro fertilisation (IVF). These are tested and only embryos without the disorder are implanted back into the womb. The conditions where this is allowable are regulated by the Human Fertilisation and Embryology Authority (HFEA) and are based on an assessment which includes a criteria of 'seriousness' of the condition.

The process is similar to heritable genome editing, without the extra step of altering the genome. The chance of having a baby with IVF is estimated at about 1 in 3 per treatment cycle, so with both PGD and genome editing more than one cycle of treatment might be needed for a successful pregnancy and birth.

Depending on the way the condition is inherited in the family, with PGD, the child may still pass on the genetic condition to future children. There are also some very rare circumstances where there is no possibility for a couple to have an unaffected child. In these situations, genome editing in the embryo may be the only way for a couple to have a genetically related child without the condition they are worried about.



**Germline genome editing** requires an extra step for altering the genome.

## What is the legal situation?

Non-heritable or somatic genome editing for treatment of disease is permitted and legal. Indeed it is being explored in research projects. This research is regulated in the same way as any other therapy or treatment. The decision to approve and fund non-heritable genome editing as a treatment in the NHS would also be assessed in the same way as other new treatments (see FAQs section).

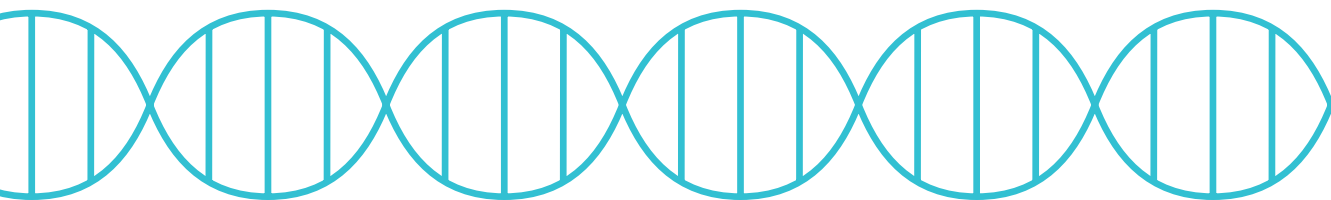
Heritable or germline editing is prohibited in the UK and in most countries.

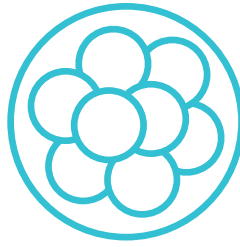
### In the UK

In the UK, the Human Fertilisation and Embryology Act Section 3(2) prohibits the implantation into a woman of an embryo that has had its DNA altered, meaning human heritable genome editing could not be performed.

The editing of human embryos is allowed for research purposes but is heavily regulated. Here, editing of human embryos is allowed in a laboratory but only until the embryos (not babies) are two weeks (14 days) old. After this age, they must be destroyed.

It is against the law at the moment in the UK to implant an embryo that has had its DNA edited, into a woman.



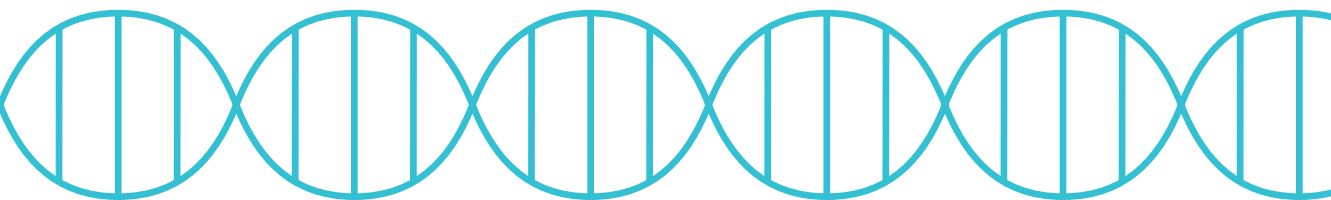


## In other countries

There are international agreements that prohibit heritable genome editing (in both a clinical and research setting) and some of these are legally binding if countries have adopted them into domestic law.

In other countries (like the UK), the editing of human embryos is allowed under strict research conditions that can never lead to a pregnancy or birth of a baby.

There are some countries that do not have any laws or other regulations prohibiting the editing of embryos for reproductive purposes. And there is always a possibility that heritable genome editing could be performed in places in the world where it is not clearly prohibited.



# What are some of the ethical issues with human heritable genome editing?

Here are some different perspectives about some of these issues.

## Should anyone be allowed to edit the human genome?

We might instinctively feel suspicious of editing the genome. It feels 'unnatural' and like 'playing God'. But as humans, we have always been modifying what God and nature give us. From IVF to other forms of gene therapy, we find ways to change 'nature' in order to alleviate suffering and improve health, and there is nothing wrong with that.

There are good reasons why we feel instinctively suspicious of editing the genome. Unlike other medical technologies, any change we make would be passed on to future generations, altering the gene pool of humanity as a whole. The code of human life (the genome) is not ours to tinker with.

## Is genome editing really needed?

It could stop the disease being passed on to future generations.

It could allow people who have no possibility of having a genetically related child unaffected by the specific genetic condition to have a genetically related child. For example, a couple who both have cystic fibrosis.

There are already effective alternatives for couples who want a genetically related, unaffected child.

As a society we should invest in other options, for example, improving the care and treatment of individuals with genetic disorders.

## Will it lead to discrimination?

It will not be radically different from other reproductive options (including termination of pregnancy and PGD) that allow the selection of embryos based on genetic testing.

It could make society less accepting of disease, disability and difference and have negative implications for the more vulnerable.

### **Will it lead to more inequalities?**

All technologies can be used unfairly. This is not unique to genome editing and should not be used as a reason to stop or prohibit the development of this technology.

The technology will be very expensive and will not be available in areas of the world where health care resources are more limited, thus leading to more inequalities.

### **Will it be accessible to all?**

Many treatments (including PGD) are not equally accessible to all. The solution is to ensure a better distribution of resources, not to prohibit a specific technology.

Because of the cost, it will be a struggle for the NHS to ensure everyone can access it on an equal footing. Realistically, it will be out of reach for many.

### **Does it consider the rights to self-determination?**

No unborn child is able to choose their DNA, whether they are born with or without genome editing.

Children who have their DNA altered through genome editing cannot give consent for the changes being made.

### **Is it acceptable to manipulate embryos?**

In the UK, it is already possible to manipulate embryos for research purposes until they are 14 days old. Genome editing will lead to concrete benefits for patients.

The current restrictions are intended to protect the moral status of the embryo as a future person and should not be removed.

# FAQs and glossary

## FAQs about genome editing

### **Has genome editing of embryos already been done?**

A lot of people may have heard anecdotes about animal genome editing but the actual number of cases is limited. In the UK the use of genome editing to edit human embryos in a research setting is highly regulated and only possible with tight controls and a licence from the Human Fertilisation and Embryology Authority. It is also illegal to grow these embryos beyond 14 days old and it is illegal to implant them into a woman. There are only a very limited number of scientists in the UK who have been given a licence to do any research on human embryos.

As mentioned, in 2018, it was announced that a Chinese scientist, Jiankui He, had performed heritable human genome editing on a small number of human embryos. This was not to treat a disease in the embryo but attempted to introduce a gene that increases resistance to infection by HIV. From media reports, it appears that three children may have been born as a result. The case sparked worldwide controversy and, according to media reports, led to the imprisonment of the scientist. The facts of the case however remain unclear.

### **Could heritable (germline) human genome editing be legally performed today?**

The simple answer in the UK is no. In the UK the Human Fertilisation and Embryology Act Section 3(2) prohibits the implantation into a woman of an embryo that has had its DNA altered. However, as we have seen, there is the possibility that it could be performed in countries where it is not clearly prohibited or it could be done illegally.



## **Have there been clinical trials for heritable human genome editing?**

No, not as far as we know. Because heritable human genome editing is not allowed in countries that have clinicians with the technical capacity and expertise to perform it, it has never been approved for clinical trials. As far as we know it has not been done illegally, but then again, would we actually know?

## **What risks are involved in heritable human genome editing?**

We don't yet know enough about what the risks of heritable human genome editing are or might be. Genome editing is still in the research phase, and until there have been more non-heritable human genome editing clinical trials on adults, we can't really say what the risks might be.

## **Can genome editing be used to change any disease or trait?**

Genome editing works best when there is a single gene with a change in the DNA that causes the condition. This means that, for now, genome editing is likely to work only for diseases that are caused by small genetic changes, which includes conditions like cystic fibrosis, sickle cell disease, some early onset cancers and other diseases. The idea that genome editing may be used to treat complex diseases like heart disease, diabetes and neurological disease, or to modify traits like intelligence, eye colour or height, is a long way from being realised and would be unlikely to have a significant (or perhaps any) effect on these conditions or traits.

## **Why don't we just use existing medical treatments?**

For many of the most serious, and often life limiting, rare genetic diseases there are no existing treatments or cures.

## **Who monitors human genome editing research?**

In the UK, in addition to ethical approval via the Health Research Authority (HRA), any research involving embryos has to have approval from the Human Fertilisation and Embryology Authority (HFEA). Research institutes undertaking research on embryos are licensed by the HFEA. Any research that is classified as gene therapy has to have approval from the Health Research Authority. All research on patients has to be reviewed by a research ethics committee who review and approve research involving humans and monitor progress of the research, guided by the HRA.

## **How is the safety of non-heritable (somatic) human genome editing assessed?**

The safety of non-heritable (somatic) genome editing is currently assessed through clinical trials. A number of clinical trials are underway, but they will take several years to complete. We have seen that in some circumstances, the safety of a particular treatment can be assessed quite quickly (for example, the Covid-19 vaccines have been assessed very quickly). Usually, the process is much slower and can take many years. The average time for assessment of a new drug, for example, is usually around 10 to 12 years. Examples of the types of diseases for which somatic genome editing clinical trials are currently underway include sickle cell anaemia and other blood-borne diseases, cancers, and eye diseases.

## **Who decides if human genome editing should be approved for medical care in the UK?**

In most countries, if a drug or a therapy is administered to a patient, it first has to be approved by a regulatory agency which has the authority to approve. In the UK this is the Medicines Health and Regulatory Authority (MHRA). The National Institute for Health and Care Excellence (NICE) would have to approve funding by the NHS. No treatment using somatic gene therapy has been approved as yet as part of routine clinical care. This is because they have to be safe, effective and beneficial before they can be approved, and evidence about these requirements is only just starting

to be collected in clinical trials (i.e. research). Other countries have similar agencies. Research on all gene therapies has to have ethical approval from the Health Research Authority.

If heritable or germline genome editing of embryos was ever considered suitable for medical care, a change in the law would be sought that was approved by Parliament.

### **Will genome editing technologies be ‘owned’ by pharmaceutical companies like other drugs?**

As with all other innovations in healthcare, genome editing has a commercial element. Patents exist for many aspects of genome editing technology. And even though the early discoveries were made in universities and other research institutes, the final stages in development of the technology from the lab to the clinic are generally undertaken by private companies. Research organisations are generally not well equipped to deal with clinical trials, particularly the final phase clinical trials, which involve a large number of participants and are very expensive.

### **Do political parties have a position on these debates?**

Political parties have not yet taken a position on debates around genome editing in embryos. In the UK, the government did make an amendment to the Human Fertilisation and Embryology Act to allow the modification of embryos to avoid mitochondrial disease, which includes serious genetic conditions. This was after a long period of debate and consultation. It was a free vote for individual members of both the House of Commons and the House of Lords and the outcome was that a change to the Act was supported. Families who want to avoid passing on inherited mitochondrial disease are now legally able to use the technology in the NHS.

# Glossary of technical terms

Below are definitions of some technical terms that may come up during your conversations. Because of the experiences you may have had, many of them will be familiar to you. If they are not, don't worry, you won't need to memorise these, but having this document to refer to during your discussions could be helpful.

**Cells:** The bodies of all living things are made up of building blocks called cells. In humans for example, there are a number of different types of cells—muscle, nerve, skin, kidney, liver and so on. One of the main ways of dividing up the types of cells is to separate out the cells that get passed on to future generations (germline cells) from all of the other cells (somatic cells). Inside all cells are our DNA; DNA offers the programming that tells the cell what to do.

**Germline cells:** These are the cells in a living thing (whether a human, a plant or an animal) that get passed on to future generations. Sperm cells and egg cells are examples of germline cells. 'Germline editing' can refer to the editing of egg, sperm or fertilised egg (that then becomes an embryo).

**Somatic cells:** These are the cells that do not get passed on to future generations. Liver cells, nerve cells, muscle cells and skin cells are all types of somatic cells.

**Embryos:** An embryo is created when an egg cell is fertilised by a sperm cell. Over time, the embryo goes through a series of cell divisions. The cells start to develop their own distinct functions (e.g. muscle, nerve, etc.). One of the things

that happens early in the development of the embryo is that the germline cells separate off from the somatic cells.

**Genetic code:** In most living things, almost all cells carry the same set of genetic information. This information provides the necessary instructions to tell the cell what to do. These instructions are generally referred to as the genetic code. There are four different types of components within the code, identified by the letters A, C, G and T.

**DNA:** DNA is a long chain-like chemical molecule that carries the genetic code (the 'code' consists of four chemicals called 'A', 'T', 'G', 'C'). One of the key features of DNA is that it generally exists as two closely intertwined mirror image strands. These two strands twist around one another to form the so-called 'double helix'.

**Chromosomes:** Almost all of the DNA in cells is organised into separate units, called chromosomes. In human somatic cells there are 46 chromosomes, organised in pairs (23 x 2). The egg and sperm cells only have one member of each pair (23 chromosomes). When the egg and sperm fuse to create an embryo, the number of chromosomes goes up to 46 again (23 from the egg and 23 from the sperm).

**Nucleus and mitochondria:** Cells themselves are made up of various small specialised microscopic structures, including two called the nucleus and the mitochondria. Cells generally have a single nucleus but many mitochondria. These two parts of the cell are particularly important because each carries DNA. The chromosomes are located in the nucleus, but the mitochondria have their own set of DNA. Mitochondria are important because they produce the cell's energy. Defects in mitochondrial DNA can lead to mitochondrial disease, some of which can be fatal.

**Genome:** The genome is the sum total of all the DNA in a cell, including both nuclear and mitochondrial DNA.

**Genes:** DNA within a cell is divided up into various components, some of which are called genes. Genes provide individual packets of information that instruct the cell what to do to carry out its particular functions. Offspring inherit their genes from both of their parents.

**Variants:** Changes, differences or errors in the genetic code carried in a

cell are called variants. These may be small, for example a missing letter in the genetic code, or a misplaced letter (for example, an A instead of a C), or they may be quite large. Depending on where the change is located, it may have a very large effect on the function of the cell, or no effect at all. For diseases like cystic fibrosis, for example, a number of known variants within a single gene can cause the disease. Although each change is small, the effect on the health of the person with the disease is significant.

**CRISPR and the rest:** Recently, various new techniques have emerged with names like CRISPR, TALENS, Zinc Fingers, Prime and Base Editing. These new technologies offer significant advances over earlier gene therapy techniques. The technique known as CRISPR makes very precise cuts in both strands of DNA, which are then either allowed to heal naturally (unguided) or are guided in the healing process. Where the DNA heals naturally, some of the code will be lost, which may result in a defective gene losing its function (often called being 'silenced'). Where the healing is guided, defects may be corrected or new functions introduced.

You can find more information on these and other relevant terms on:

website



**Yourgenome**

URL: [www.yourgenome.org](http://www.yourgenome.org)

# About the event

## The venue

The UK Citizens' Jury will take place on 13-16 September at the **Hinxton Hall Conference Centre** in the Wellcome Genome Campus in Hinxton, near Cambridge.

Set within the 100-acre estate, Hinxton Hall Conference Centre is located alongside research institutions that are at the forefront of genomic research. The venue combines stunning contemporary architecture with state-of-the-art facilities, alongside a Grade II\* listed country house, which was built in 1748. When Wellcome bought the estate in 1992, it meticulously restored the Georgian Hall and transformed the old stable block and kitchen garden into a purpose-built conference centre. Today the venue comprises a large auditorium surrounded by a beautiful glass-roofed event space, eight meeting rooms, dining room, bar and comfortable accommodation.

You will have already heard from us to arrange your travel and accommodation. If you have any questions, or if anything has changed on your part please contact Ben Tomlin [ben.tomlin@wellcomeconnectingscience.org](mailto:ben.tomlin@wellcomeconnectingscience.org).







Milton

**Cambridge**

Fulbourn

Six Mile Bottom

Great Shelford

Sawston

Duxford

Linton



**Wellcome Genome Campus**

Great Chesterford

Saffron Walden

M11

# During your stay

## Meals

We will serve breakfast, lunch and tea/coffee everyday at the venue. Evening meals will also be provided, either at the venue or in Cambridge depending on the planned activity.

## Entertainment

We will provide a series of **optional** entertainment options in the evening so you can unwind after a long day of deliberations and get to know other participants in a more relaxed environment **should you want to**.

# Your wellbeing

If you encounter a distressing incident during the event or have any questions or concerns about the way the jury is run, please do not hesitate to get in touch with Anna Middleton [anna.middleton@wellcomeconnectingscience.org](mailto:anna.middleton@wellcomeconnectingscience.org).

Anna is a trained and experienced genetic counsellor and will be available to discuss any issues you may have. She will also be present for the whole jury event.

In the Participant Information Sheet, you can find more information about what you can do if you need additional support or you remain unsatisfied about an issue you have raised.



## Covid-19 safety

**If you are in a higher-risk group for developing serious illness from Covid-19 please consult a medical professional prior to travel.**

Please refrain from attending the event and notify Anna Middleton [anna.middleton@wellcomeconnectingscience.org](mailto:anna.middleton@wellcomeconnectingscience.org) if you:

- Have tested positive for Covid-19
- Display symptoms of Covid-19, including high temperature or shiverings, a new and continuous cough, a loss or changes to your sense of taste or smell.

If you feel unwell during the jury, please do not attend the event or leave your room.

Please contact Ben Tomlin [ben.tomlin@wellcomeconnectingscience.org](mailto:ben.tomlin@wellcomeconnectingscience.org) / 07495 871786. We will arrange for you to take a Covid-19 test.

During the event, measures will be in place to ensure participants' safety. We encourage you to regularly wash your hands and use hand sanitisers, which will be available during the event. We will also provide disposable face masks, which we may ask you to use if necessary. Please be considerate and keep social distance from those who do not wish to come in close contact with others.

For more information, please visit the NHS website: [www.nhs.uk/conditions/coronavirus-covid-19/](https://www.nhs.uk/conditions/coronavirus-covid-19/)

# The team

## Project leaders

Anna and Simon are the project leaders, with support from Sophie. They are responsible for setting-up and running the project.



**Anna Middleton**

Wellcome Connecting Science



**Simon Burall**

Involve



**Sophie Peet**

Genetic Alliance UK

## Project support

Ben, Marion and Emma have been taking care of organising the logistics of the event. They will be your first point of contact for any questions you may have.



**Ben Tomlin**

Wellcome Connecting Science



**Marion Mitchell**

Wellcome Connecting Science



**Emma Garlick**

Wellcome Connecting Science

# The facilitators

## Lead Facilitators

Simon and Kaela are the lead facilitators. They are responsible for designing the Jury. They will make sure that it achieves what it is setting out to do and ensure that everyone's views are heard and fairly represented in the report the Jury produces.



**Simon Burall**

Involve



**Kaela Scot**

Involve

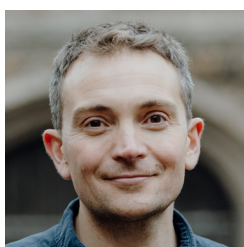
## Table Facilitators

During the Jury we will work both together as a whole jury, and break into smaller groups. Damian, Richard and Alessia will support the smaller group discussions to ensure everyone gets an equal opportunity to share their views on the topic.



**Damian Hebron**

Wellcome Connecting Science



**Richard Milne**

Wellcome Connecting Science



**Alessia Costa**

Wellcome Connecting Science

# The experts

## Expert Leads

Sasha and Felicity will support the jury by providing balanced, unbiased information about the issues the jury is discussing. They will be present for the four days of the Jury to answer your questions and provide information or support as you need it.



### **Sasha Henriques**

Wellcome Connecting Science

Sasha Henriques is a Principal Genetic Counsellor from Guy's and St Thomas's NHS Foundation Trust. Sasha has specialised in both cardiac genetics and focussing on meeting the needs of all cultural groups through policy, research, and clinical care in genomics.

She has also previously been a genetic counsellor in South Africa. This experience led to the development of a package of cross-cultural teaching for genetic counsellors which is now a component of the Genetic Counselling MSc at Cardiff University and the Scientist Training Programme in England. She is an advocate for sharing knowledge with communities and for inclusivity within genomics.



### **Felicity Boardman**

University of Warwick

Professor Felicity Boardman is a social scientist based at Warwick Medical School specialising in the social and ethical aspects of genomics, particularly as these relate to reproduction. Her work focuses on the perspectives and insights offered by people living with genetic conditions and her current research explores the use of genetic technologies within existing newborn screening programmes. Felicity sits on the Foetal, Maternal and Child Health Reference Group of the UK National Screening Committee, and was also recently involved as an expert witness in the Public Dialogue on Whole Genome Sequencing for Newborn Screening (Genomics England).

## Experts Witnesses

Between them, the expert witnesses will provide information and evidence about the issues the Jury will cover. Some of them will explain the science while others will provide their views on the moral and social issues raised by heritable genome editing. Each speaker will give a short presentation and jurors will also have a chance to ask questions



### **Sarah Bowdin**

Sarah Bowdin is the Medical Director of the East Genomic Laboratory Hub. She trained in paediatrics and specialised in Clinical Genetics, after witnessing the impact of genetic diagnoses on the care of preterm and sick babies on a neonatal intensive care unit.

Sarah has a special interest in facilitating the widespread clinical adoption of large scale genomic sequencing technologies, both in rare disease and cancer. As Medical Director, she draws on her previous experience of setting up and running a whole genome sequencing clinic for undiagnosed paediatric and cardiac disorders, at the Hospital for Sick Children, Toronto.



### **Mark Sheehan**

Mark Sheehan is an Associate Professor and Oxford Biomedical Research Centre (BRC) Ethics Fellow at the Ethox Centre in the Nuffield Department of Population Health. He is a National Research Ethics Advisor for the National Research Ethics Service and a member of numerous advisory boards and ethics committees, including the NICE's Highly Specialised Technology Evaluation Committee.

His research projects include: (i) the nature and role of research ethics governance, (ii) consent and governance in population level research, (iii) trust and trustworthiness, (iv) patient and public involvement in healthcare research and policy, and (v) the ethics of public health policy interventions.



## **Jackie Leach Scully**

Jackie Leach Scully is Professor of Bioethics and Director of the Disability Innovation Institute, University of New South Wales, Australia. After some years working in molecular biology, she switched to focus on the ethical issues of biomedical technologies. She has worked in Switzerland, Germany and the UK, and since 2019 has been based in Sydney. Her research examines how biomedical developments affect disabled people, and how to increase public engagement in bioethical debate. Jackie has been deaf since childhood and a disability activist for nearly 40 years. She holds several academic honours including Fellowships of the Academy of Social Sciences and of the Royal Society of New South Wales.



## **Sarah Norcross**

Sarah Norcross is Director of Progress Educational Trust (PET) and Commissioning Editor of its flagship publication BioNews. PET is an independent charity which aims to improve choices for people affected by infertility and/or genetic conditions. Sarah is a trustee at the British Fertility Society (BFS), chair of the BFS Special Interest Group on Law, Policy and Ethics, and an external adviser to the University of Cambridge's Reproduction Strategic Research Initiative. Sarah serves on the European Society of Human Reproduction and Embryology's Working Group on Add-Ons, and on the Human Fertilisation and Embryology Authority's Patient Organisation Stakeholder Group.



## **Sara Levene**

Sara Levene is a Consultant Genetic Counsellor at the Centre for Reproductive & Genetic Health, leading the Pre-implantation Genetic Diagnosis (PGD) service since 2017. Sara started her career in cancer genetics and general Genetic Counselling at Guy's and St Thomas's NHS Foundation Trust in 1998, before becoming part of the PGD team there in 2008. Sara has a strong interest in population screening. She previously ran the Tay Sachs screening service at Guy's hospital for the Jewish population, and now offers expanded pan-ethnic carrier screening at CRGH. Sara is Chair of the Association of Genetic Nurses & Counsellors and sits on the medical advisory panel of two charities.



## **Esther Fox**

Esther Fox is a programme director, artist and researcher, interested in exploring the synapses between medicine, art, museums and ethics. Esther is Head of Accentuate, creating opportunities for D/deaf, disabled and neurodivergent people to participate and lead in the cultural sector and is currently taking the strategic lead on Curating for Change, working with over 20 museums across England to deliver a programme for disabled people wanting to pursue a career in museums. She is a trustee for Hastings Contemporary and co-chairs the Community Panel at the Sanger Institute. Esther also has the genetic condition Spinal Muscular Atrophy.

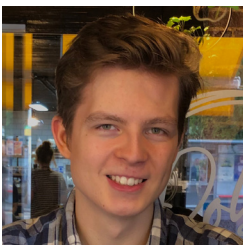


## **Trevor Stammers**

Trevor Stammers was a GP for 30 years before becoming Associate Professor of Bioethics and Medical Law and Director of the Centre for Bioethics and Emerging Technologies (CBET) at St Mary's University, Twickenham until 2021.

He is Editor of *The New Bioethics* and his latest book, co-edited with Calum MacKellar, 'The Ethics of Engendering Posthumans' was published in 2022. His book on the ethics of organ donation is due out in 2023.

Trevor's research interests are the ethics of transplantation and genomic editing. He has also written on conscience in medicine and the limits of autonomy in healthcare.



## **Oliver Bower**

Oliver is a PhD student in the Human Embryo and Stem Cell Laboratory at the Francis Crick Institute in London. His research focuses on using CRISPR/Cas9 gene editing to understand the function of genes crucial for early development. By using CRISPR/Cas9, genes of interest can be disrupted and the effect of their loss on development can be studied.

Before joining the Crick, Oliver worked as a research assistant at the University of Sheffield Centre for Stem Cell Biology. Oliver obtained his BSc in Biomedical Sciences at the University of Sheffield, with a final year dissertation on the suitability of using CRISPR/Cas9 for treating muscular dystrophies.





## Mark Bale

Over the past 30 years, Mark Bale has led and shaped Government policy at the intersection between research, healthcare, ethics, and legislation. He has experience with multilateral international bodies, including the EU, OECD, WHO, and UNESCO.

Until March 2022, Mark was policy advisor and Programme Director for the 100,000 Genomes (seconded to Genomics England) together with regenerative medicine and gene therapy, genome editing, precision medicine and rare disease policy. He represented the UK at the Council of Europe Steering Committee on Human Rights and Biomedicine, and was Chair of the predecessor Committee on Bioethics at the Council of Europe from 2014-2016.

## The evaluators

The evaluators will assist the project team reviewing and assessing your feedback on the event. This will help us to understand participants' experience and improve the process for future events.



**Nicole Curato**  
University of Canberra



**Lucy J. Parry**  
University of Canberra



**Lisa van Dijk**  
KU Leuven



## The genetic counsellor

Some of the topic areas might sometimes feel challenging, and raise strong and difficult emotions. Anna is a trained genetic counsellor. She will be present throughout the Jury to provide independent and confidential support to any juror who requires it. We will provide a private and quiet room for this purpose.

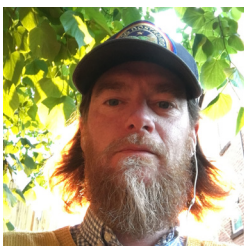


**Anna Middleton**

Wellcome Connecting Science

## The film-makers

We will be producing a film of the Jury process in order to document what happened. The film will provide a visual way of telling the story of how the Jury reached its conclusions. We will make the film widely available.



**Mark Downes**

Green Eyed Monster Films

# Project partners



LAMBDA FILMS

G<sub>PR</sub>E<sub>o</sub>N<sub>E</sub><sub>uct</sub>(P<sub>io</sub>N<sub>OL</sub>)<sub>s</sub>

# Key contacts

## Queries related to the project

Ben Tomlin:

[ben.tomlin@wellcomeconnectingscience.org](mailto:ben.tomlin@wellcomeconnectingscience.org)

Anna Middleton:

[anna.middleton@wellcomeconnectingscience.org](mailto:anna.middleton@wellcomeconnectingscience.org)

## Venue

Hinxton Hall Conference Centre  
Wellcome Genome Campus  
Hinxton, CB10 1RQ

Conference Centre reception:

01223 495000

[conference.reception@hinxtonhall.org](mailto:conference.reception@hinxtonhall.org)

Campus security:

01223 496815

