**Patient notification document – SAFE**

**What is this leaflet about?**

Thank you for participating in the Genomics England 100,000 Genomes Project. You are receiving this leaflet because Genomics England has found an “additional finding” in your sample. We understand that it might be far from easy to receive this type of news.

It is the first time that the NHS has used genetic information in this way. We are a small team of researchers who are studying what happens next for people who receive an additional finding, and how the NHS handles this information. We have set up a study called SAFE (Secondary/Additional Findings Evaluation). With your help, the SAFE study can start to better understand this new area of medicine.

This leaflet explains more about the SAFE study, how you can discuss any concerns and opt out if you wish.

**What are additional findings?**

Additional findings are changes or glitches in a particular gene that may increase the chance of having certain health conditions. They are called “additional” as they are separate from a family's original reason for joining the 100,000 Genomes Project. Genomics England carefully selected a list of genes in which to look for additional findings. Glitches in these genes can either cause, or increase a person's likelihood of having, a particular health condition.

These glitches are “actionable” because actions can be taken if the person and their healthcare team know about them.

**What is the study about?**

The SAFE study will use information from the medical records of people who receive an additional finding, and interview some of them, to start to understand:

* the link between additional findings (genetics) and health conditions (signs and symptoms)
* how the NHS manages additional findings
* how additional findings impact upon patients

Understanding what happens after people are told about additional findings will contribute to national discussions on how best to use this type of genetic findings to deliver patient-centred care in the future. By doing so, we can help ensure that other families receiving this type of news in the future are receiving the highest quality care based on evidence.

Information from your medical record, relating to the additional finding, would be incredibly helpful to answer some of these questions. For example, any appointments or tests that your care team might arrange in the next twelve months (the length of the study). To collect this information from people who receive an additional finding, we would like to access your medical records at the hospital.

**Who is the study team, and how will you look after my information?**

We are a small team of experienced researchers. Some of our team also have clinical experience working in the NHS, talking to patients and their families about genetics in medicine. The SAFE study has Research Ethics Committee approval.

Information security is paramount to us. We will not store or copy any information that could be used to identify you. The three researchers who will access your medical records have been vetted by the NHS, and they will do so only to ensure they relate to the right person; the researchers will store only de-identified information on secure NHS servers.

A Privacy Notice can be found at [rdm.ox.ac.uk/safe-study](https://www.rdm.ox.ac.uk/about/our-divisions/division-of-cardiovascular-medicine/safe-study)

**Why do you need to ask about this? Isn’t it covered by the 100,000 Genomes Project consent?**

As part of your participation in the 100,000 Genomes Project, Genomics England can collect some information from your medical record and put it in a patient data library (sometimes called the “research environment”). This information does not identify people individually. However, the information needed for this study may not all be collected in the patient data library, and it may take a significant amount of time to be collected and available. For these reasons, we would like to access your medical records to ensure we are collecting the right medical information and doing so in a time frame that allows this research to be used to contribute to improving future patient care.

**What do I need to do now?**

If you are happy for us to look at your medical record relating only to your additional finding, and to analyse that information together with the information of other people who receive an additional finding, you do not need to do anything.

However, if you do not wish for us to access the information in your medical record for this research, you can opt out at any time.If you opt out of your information being used for the SAFE study, this will not impact the clinical care you receive, and you would stay in the 100,000 Genomes Project. To opt out of your information being accessed for SAFE, please visit this website [rdm.ox.ac.uk/safe-study](https://www.rdm.ox.ac.uk/about/our-divisions/division-of-cardiovascular-medicine/safe-study) – and fill in [this form](https://forms.office.com/r/4TrQm3fxN6) (clicking this link takes you to a secure form supported by Oxford University Hospitals NHS Foundation Trust). We ask that you input your NHS number (this is a 10-digit number which can be found on hospital letters) and tick the opt-out box.

Alternatively, you can opt out by calling 01865 226 017. We will only ask you to provide your NHS number. You do not have to provide a reason for your decision to opt out.

If you have any questions, we will be happy to discuss further on 01865 226 017.

Thanks to patients and families like you, knowledge of genetic medicine is improving at a rapid pace. We are very grateful to all participants for their invaluable role in our work. Together, we can contribute to our ever-expanding knowledge of the interplay between genetics and health and how the NHS can best support individuals receiving this type of genetic information.