Participant Information Sheet

Study Title: Ethical Preparedness in Genomic Medicine: Patient journeys through genomic medicine
Researcher:
ERGO number: 65256
REC Reference: 21/WA/0344

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others, but it is up to you to decide whether to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?
The research team comprises Prof Anneke Lucassen, Dr Kate Lyle, Dr Susie Weller and Dr Lisa Ballard. The Wellcome Trust, a charitable foundation supporting health research, have funded the study and the University of Southampton are the Sponsor (referred to as 'we' in the rest of this document). This research has been reviewed by an independent NHS Research Ethics Committee (Wales REC 7; REC Ref: 21/WA/0344).

The project forms part of a wider study called Ethical Preparedness in Genomic Medicine (EPPiGen) that is examining the challenges that arise for those delivering and receiving genomic medicine. The researchers are interested in exploring your journey through genomic testing and would like to talk to you about your experiences.

Why have I been asked to participate?
Your clinical genetic service is working with the University of Southampton to do this research study. You have been invited because you (or a relative) have given consent to a genomic a test with your NHS clinical genetics team (for example, as part of the 100,000 Genomes Project).

What will happen to me if I take part?
The researchers are interested in learning about your experiences of genetic and genomic testing, the care you (or a relative) have received and how the process and information received has affected your life. The interview would last for approximately an hour and would take place at a venue of your choice or online/by phone. With your permission, the interview will be recorded to aid in the data analysis. . The recording would then be transcribed.

Where interviews are taking place in person, you will be asked to sign a consent form. In instances where interviews are conducted via telephone or online video conferencing, you and the researcher will read through the consent form together at the start of the interview, and you will be asked to return a signed copy via email or post.

The researchers would also like to keep in touch with you and potentially speak to you again as your journey progresses. If you are willing to do so, they may like to speak with you on more than one occasion to learn about your experiences at different stages in the process. This could involve either a short catch-up discussion or longer conversation. The total number of interviews would depend on how much time you are happy to dedicate to the study, and how far through the process you are when you first speak. This would involve approximately 1 to 3 interviews over the next 12-18 months. At the end of the project, the researchers will send you a summary of the main findings.

Are there any benefits in my taking part?

There may be no direct benefit to your participation. However, the research findings will provide detailed insights into the experiences of patients and their families, which will be valuable in developing the genomics service. You may also find it helpful to talk about your experiences.

Are there any risks involved?
Talking about genetic testing and diagnoses in your family can be difficult or upsetting. If you find the interview challenging, the researcher can pause and resume at another time if you are happy to do so. Alternatively, you can withdraw from the study completely.
You can contact your clinical genetics team if you would like to talk to a healthcare professional about anything that comes up in the interview. If you feel you need further support, either during or after the interview, please let the researcher know.

What data will be collected?
Personal data - the researchers will collect some personal data provided by you, which includes your year of birth, gender, ethnicity, employment, social class and religion. This will be collected either via email correspondence or completion of an iSurvey (University of Southampton online survey system). We will keep all information about you safe and secure.

Your responses to the personal data survey will:

- help the researchers to analyse your interview data and explore similarities and differences between people's experiences.
- ensure that the researchers have spoken with as diverse a range of people as possible.

Interview data – The interviews will be recorded using solid state digital recorders or, for online interviews, the recording function on MS Teams, to capture good quality audio. Audio files (that will not be pseudonymised (see section below titled 'Will my participation be confidential?') may contain personal information.

Contact details - some of the research team will need to know your name and contact details so they can contact you about your interview, or to send you further information. Researchers must always make sure that as few people as possible can see this sort of information that can show who you are.

Will my participation be confidential?
In lots of research, most of the research team will not need to know your name. In these cases, someone will remove your name from the research data and replace it with a code number or name. This is called coded data, or the technical term is pseudonymised data. For example, your interview data might be labelled with your code number instead of your name. It can be matched up with the rest of the data relating to you by the code number. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

Do I have to take part?
No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.
If you would like to take part in this study, please email cels@soton.ac.uk or reply to the invitation email.

What happens if I change my mind?
You can stop being part of a research study at any time, without giving a reason. If you decide to withdraw from the project, the researchers will talk to you about which (if any) aspects of your interview you would be willing for them to use in the analysis. However, if you are taking part in several interviews some data may have already been published.

If you would like to withdraw from the study, please contact one of the research team: Kate Lyle (k.lyle@soton.ac.uk), Lisa Ballard (l.ballard@soton.ac.uk), or Susie Weller (s.m.weller@soton.ac.uk).

It is unlikely that a participant would lose capacity during the study. However, if that were to happen, the data obtained before they lost capacity will continue to be used in order to inform the analysis and no new data will be collected.

What will happen to the results of the research?
Researchers must make sure they write the reports about the study in a way that no-one can work out that you took part in the study.

Once they have finished the study, the research team will keep the research data for several years, in case they need to check it. You can ask about who will keep it, whether it includes your name, and how long they will keep it. The organisation running the research will usually only keep a coded copy of your research data, without your name included. This is kept so the results can be checked. Any information that could show who you are will be held safely with strict limits on who can access it.

If you are happy for them to do so, the researchers would like to retain a de-identified version of your interview transcript(s) for future use by their research group. This will enable them to use the material for further research and learning. The funder, The Wellcome Trust, support the "need to share and preserve research datasets in a way that maximises their long-term value".

In addition, and again with your permission, the researchers would like to offer a de-identified version of your interview transcript(s) to the UK Data Archive (https://www.data-archive.ac.uk/). The archive is a national repository housing the UK's largest collection of data sets from the social sciences and humanities. The archive encourages re-use of existing data to further advance knowledge. Your interview transcript(s) would be classified as 'safeguarded data', which means that it could only be accessed by registered users (e.g. researchers) who have completed an End User Agreement regarding the responsible use of the material (for further information please see https://www.ukdataservice.ac.uk/get-data/how-to-access/conditions/eul).

Storing the data will enable the team, and other researchers, to conduct further analysis that will advance their understanding about how patients and healthcare professionals might prepare for the ethical and social challenges they may face in what is a rapidly expanding area of medicine. If you do not want the researchers to retain your interview transcript for future reuse you can just let them know on the consent form.

Will the use of my data meet GDPR rules?
GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules.

Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

More information about this can be found in the notes section at the end of this document called **'Data Protection Privacy Notice'.**

Where can I get more information?
If you would like to discuss this information sheet further, please contact one of the research team who would be happy to answer your questions. The research team are: Kate

Lyle (k.lyle@soton.ac.uk), Lisa Ballard (l.ballard@soton.ac.uk), or Susie Weller (s.m.weller@soton.ac.uk).

What happens if there is a problem?
If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. The research team are: Kate Lyle (k.lyle@soton.ac.uk), Lisa Ballard (l.ballard@soton.ac.uk), or Susie Weller (s.m.weller@soton.ac.uk). If you have any other concerns or complaints about the study, you can contact the Patient Advice Liaison Service (PALS) for advice on 023 8120 8498.

Thank you.
Thank you for taking the time to read this study information and considering taking part in the research project. If you would like to take part in this study, please email cels@soton.ac.uk or reply to the invitation email.

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires the researchers to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).