**Secondary/additional findings in 100,000 Genomes Project evaluation**

**(SAFE;** IRAS Project number: 297591)

**Privacy Notice 06/10/2021**

Participants in the 100,000 Genomes Project were offered genome sequencing to investigate the cause of a known health condition in themselves or their relative. Adult participants were also offered screening for other findings in certain genes, termed ‘additional findings’ (AFs): potentially disease-associated genomic variants that are additional to the reason the participant was recruited to the 100,000 Genomes Project. International professional guidance around looking for AFs differs, since information on the predictive value and wider clinical utility is not yet clear.

The SAFE study has four main aims:

1. To understand the extent to which additional findings (AFs) correlate with clinical and/or family history;
2. To understand the clinical outcomes of AF disclosure;
3. To quantify healthcare resource use and costs accrued in secondary care following AF disclosure;
4. To evaluate the psychosocial and behavioural consequences of AF disclosure.

To address aim 4, we will conduct interviews with a small number of participants who receive an AF, with study-specific consent. If you would like to take part in this part of the study, please contact us using details below.

To address aims 1-3, trained clinical researchers will collect data from the clinical records of people in the South Central Genomic Medicine Service Alliance (Wessex, Oxford and West Midlands) *who receive an AF*, for 12 months after the appointment in which they were told about the AF. The data researchers will collect will include: age, gender, ethnicity, AF gene and variant, personal and history relevant to the AF, specialist clinic referral, clinical test results, clinical outcomes information. **SAFE study researchers will not remove, copy or store any identifiable data from the NHS**.

We have permission to link, transfer, process and analyse this information without study-specific consent, from the Confidential Advisory Group. This permission is given under Section 251 of the National Health Service Act 2006 and its current regulations, the Health Service (Control of Patient Information Regulations 2002) (CAG reference: 21/CAG/0160).

This study has been reviewed and approved by the South Central - Berkshire B Research Ethics Committee, reference 21/SC/0254.

Research is a task that we perform in the public interest. The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible.

The data that we store and analyse will be identified by a study number only, and will not be identified by name, date of birth, NHS number or address. The information retrieved from NHS records will be stored on a database held securely by the University of Oxford and used solely for academic research purposes. Importantly, whilst the information retrieved is specific to each participant, no individual person will be identifiable in any publication arising from this work. Your personal data will not be shared with any third parties and will not be used for any automated decision making or profiling. If you would like to have this data withdrawn, please contact the study team using the details given below.

 **What to do next?**

If you decide you do not want your data to be linked in this way you can withdraw from this follow-up, without affecting your current medical care, by visiting [rdm.ox.ac.uk/safe-study](https://www.rdm.ox.ac.uk/about/our-divisions/division-of-cardiovascular-medicine/safe-study)

You will be asked to input your NHS number in order not to retrieve your data in the 12 months after finding out about an Additional Finding. You would remain a participant of 100,000 Genomes Project.

Data protection regulation provides you with control over your personal data and how it is used. Further information about your rights with respect to your personal data is available at <https://compliance.admin.ox.ac.uk/individual-rights> or by contacting the study team using the details below. The University’s data protection officer can be reached at data.protection@admin.ox.ac.uk.

If you have further questions or are not happy with the way your data has been handled, please contact the study team using the contact details below. Alternatively, you can contact the study sponsor on 01865 616480 or ctrg@admin.ox.ac.uk. You have the right to lodge a complaint with the Information Commissioner’s Office (0303 123 1113 or [www.ico.org.uk](http://www.ico.org.uk)).

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