**Participant information sheet – Interviews with Donors, Parents and Donor-Conceived Adults**

**Version number & date:** 1.4: 08/09/2021

**Research ethics application number:** 9861

**Title of the research project:**

ConnecteDNA: donor conception in the age of direct-to-consumer genetic testing.

**Name of researchers:**

* Lucy Frith: Reader in Bioethics, University of Manchester (Principal Investigator (PI))
* Marie Fox: Professor in Law, University of Liverpool
* Nicky Hudson, Professor of Medical Sociology, De Montfort University
* Petra Nordqvist, Senior Lecturer in Sociology, University of Manchester
* Jackson Kirkman-Brown, Reader in Human Reproductive Science, University of Birmingham
* Fiona MacCallum, Reader in Psychology, University of Warwick
* Caroline Redhead, Research Fellow, University of Manchester
* Leah Gilman, Research Fellow, University of Manchester

1. **Invitation**

You are being invited to take part in this research project. This leaflet explains why the research is being done and what taking part involves. If you have any questions or there is something you do not understand you can speak to Leah Gilman or Lucy Frith. Their contact details are at the end of the leaflet. You should feel free to talk about whether or not to take part with your colleagues, friends or relatives. You do not have to take part. You should only take part if you want to.

1. **Why are we doing this study?**

Genetic testing is increasingly accessible directly to consumers, via websites, such as 23andme.com or ancestry.com. The expansion and increased availability of these technologies may have implications for people involved in donor conception and for organisations which store, manage and regulate information about donor conception. Our research aims to understand this impact and to assess whether, and how, further support and regulations are needed in this area.

1. **Why am I being asked to take part?**

We wish to explore the experiences of three different groups who have used, or been impacted by, direct-to-consumer genetic testing (DTCGT). We understand that you are fall into one or more of those groups: sperm, egg or embryo donors; donor-conceived adults (aged 18 and over) and parents through donor conception.

1. **Do I have to take part?**

No. You do not have to take part. It is up to you decide whether or not you want to be involved in this study. You can change your mind and withdraw from the study at any point until your data is used in a publication(s) or research output.

1. **What does taking part involve?**

Taking part would involve a one-to-one interview with one of the research team (usually Leah Gilman) at a time to suit you. Interviews will be conducted either face-to-face, on the telephone or via a video conferencing platform (i.e. Zoom) and will be audio recorded with your permission. Interviews will be arranged at a time and place which is mutually convenient for you and the researcher.

Interviews will explore your experiences of both donor conception and direct-to-consumer genetic testing. We will ask about your family relationships and any connections or communications arising from both donor conception and the of use genetic testing. We are also interested in your views about how information about donor conception and direct-to-consumer genetic testing is managed and regulated. The interviewer will ask about these broad topics of interest and you will also have the opportunity to raise any related issues you consider important.

At the end of the interview you will be asked to complete a short (less than 5 minutes), anonymous questionnaire which will ask for demographic information about yourself (e.g. age, ethnicity, gender, education) and your circumstances (e.g. type of donor used or the type of clinic you donated in). You do not have to complete this questionnaire and you can omit any questionnaires.

Interviews are expected to take 60-120 minutes, dependent on what you have to say and how much time you have available.

1. **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings. If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our privacy notice for research participants: <http://documents.manchester.ac.uk/display.aspx?DocID=37095>

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after as explained in section 7.

**7. How will we use information about you?**

We will only use the information you have provided to the research team for the purposes of this research project.

* This information will include your name and contact details. The research team will use this information to carry out the research and (if you request it) to provide feedback on the project’s findings.
* People who do not need to know who you are will not be able to access your name or contact details. Your data will have a code number instead.
* We will keep all information about you safe and secure.
* When reporting findings from the study, we will remove your name and other identifying details (e.g. other names, places, significant dates)
* What are your choices about how your information is used?
  + You can stop being part of the study at any time, without giving a reason.
  + If you take part, you can additionally choose to share anonymised transcripts from your interviews with other researchers via the UK Data Service (UKDS) ReShare, in accordance with UK Research and Innovation (UKRI) requirements.
* Where can you find out more about how your information is used?
  + by asking one of the research team
  + by sending an email to lucy.frith@manchester.ac.uk or leah.gilmman@manchester.ac.uk
  + Contact The University of Manchester’s Information Governance Office on 0161 275 7789, [information.governance@manchester.ac.uk](file:///C:\Users\msasslg4\Dropbox%20(The%20University%20of%20Manchester)\DTCGT\ethics\manchester%20ethics\information.governance@manchester.ac.uk)

Further information on how your data will be used can be found in the table below.

|  |  |
| --- | --- |
| How will my data be collected? | One-to-one interview (online, telephone or face-to-face) |
| How will my data be stored? | All electronic and digital data will be stored on the password protected University server.  Audio recordings of interviews and anonymised interview transcripts will also be made accessible to members of the project team at other universities (only those listed above) via a secure, university-managed platform for file sharing (SharePoint).  Any hard copies of documents will be stored securely in a locked filing cabinet.  Audio recordings of consent for interview will be stored on the secure University of Manchester file store for research data. |
| How long will my data be stored for? | Audio interview files will be stored until the end of the project (expected February 2024).  Non-anonymised interview transcripts will be stored until the end of the project.  Anonymised interview transcripts will be stored for at least 10 years in a secure and password protected folder on the University of Manchester server.  Hard copies of consent forms and audio consent files will be destroyed 10 years after the end of the project.  Your contact details will be destroyed at the end of the project unless you have consented for us to retain them for the purposes of sending you feedback (in this case they will be destroyed after 10 years or earlier if you ask us to). |
| What measures are in place to protect the security and confidentiality of my data? | The audio files, paper questionnaires and transcripts from interviews will be stored securely in accordance with University data storage procedures.  Transcripts will be anonymised (by removing or changing any names or identifying details) for the purposes of analysis and any extracts of data shared beyond the research team (i.e. in publications) will always be fully anonymised.  The audio recordings of interviews may be transcribed by professional transcribers. If this happens, we will use a professional transcription service regularly used by the University, and audio and text files will be encrypted during transfer. The transcribers will sign a confidentiality agreement (approved by the university’s legal team) and agree to delete your data after the transcription process is complete. |
| Will my data be anonymised? | Yes. Your name and the name and any other identifying details will be removed or changed in the interview transcripts which we use for analysis and in any extracts used in publications. |
| How will my data be used? | We will use the data to make recommendations and produce resources which improve support and regulation for people involved in donor conception and/or users of DTCGT. We will produce guidelines, reports and academic journal articles. Wherever possible, outputs will be made open access and hosted on the project website. |
| Who will have access to my data? | Only members of the project team, based at the University of Manchester will have access to your name and contact details.  The full research team (listed above) will have access to audio recordings of your interview and your anonymised interview transcript.  Once the project is concluded, with your specific consent, anonymised transcripts will be deposited for sharing with other researchers via the UK Data Service (see below). Audio data will not be deposited as it is not possible to ensure confidentiality and anonymity. |
| Will my data be archived for use in other research projects in the future? | Yes, with your specific consent (see consent form), anonymised transcripts will be deposited for sharing with other researchers via the UK Data Service (UKDS) ReShare, in accordance with UK Research and Innovation (UKRI) requirements. |
| How will my data be destroyed? | At the end of the project (expected February 2024) we will permanently delete all audio recordings and non-anonymised interview transcripts. At this time, we will also delete any record of your name and contact details, unless you have specifically requested that we retain these for the purposes of sending you feedback about the research.  After 10 years, all non-anonymised electronic information/data about you will be permanently deleted from the University server, and hard copies of any documentation such as consent forms and paper-based material will be shredded. |

1. **Will I get paid for taking part?**

No, there is no payment for taking part.

1. **Are there any risks in taking part?**

There are no significant risks to taking part. However, we recognise that donor conception and genetic testing can be personal and sensitive topics and for some could be distressing. If any particular question or topic causes distress or discomfort you can decline to talk about them or you can end the interview at any point. In addition, all participants will be given contact details of organisations which can provide support with issues relating to donor conception, relationships and mental health more generally.

Depending on the timing of the interview, there may be some risk of inadvertently transmitting covid-19 during face-to-face interviews. This risk will be minimised by careful following of national and local restrictions and guidance relating to the covid-19 pandemic. Where face-to-face interviews are not possible (due to one or both parties being required to self-isolate or because of general restrictions), interviews will either be postponed or carried out via telephone or video conferencing software, according to your wishes.

1. **Are there any benefits in taking part?**

No. There are no direct benefits to you for taking part but we hope the research will support people in a similar position to you who may be impacted by the rise in direct-to-consumer genetic testing and to provide some evidence-based recommendations and resources. Some of the resources we produce as a result of the findings may be of direct support to you.

1. **What will happen to the results of the study?**

We will use findings from our study to improve support for people involved in donor conception and to assess whether and how laws, policies and practices in relation to direct-to-consumer genetic testing can be improved.

Outputs from the study will be produced for a wide range of stakeholders including users of DTCGT, regulators and policy-makers, families through donor conception and academics. These will include reports, support guides and policy recommendations, as well academic journal articles. Wherever possible, publications will be made available open-access and linked to our project website.

1. **What will happen if I want to stop taking part?**

That’s OK. You can decide to cancel or stop your interview at any time. You can also choose to withdraw your data from the study at any point up until it is used in a publication or research output.

1. **What if I am unhappy or if there is a problem?**

If you are unhappy, or if there is a problem, please tell us. We will do our best to help. Contact Lucy Frith, [lucy.frith@manchester.ac.uk](mailto:lucy.frith@manchester.ac.uk) .

If you are still unhappy, or want to make a formal complaint, you can contact the University of Manchester Research Ethics Manager: [research.complaints@manchester.ac.uk](mailto:research.complaints@manchester.ac.uk) or 0161 306 8089. Tell them the name of our project (it is called ‘ConnecteDNA: donor conception in the age of direct-to-consumer genetic testing’. Also give them the name of the lead researcher (Dr Lucy Frith).

If you wish to contact us about your data protection rights, please email [dataprotection@manchester.ac.uk](mailto:dataprotection@manchester.ac.uk) or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

The University strives to maintain the highest standards of rigour in the processing of your data. However, if you have any concerns about the way in which the University processes your personal data, it is important that you are aware of your right to lodge a complaint with the Information Commissioner's Office by calling 0303 123 1113.

1. **Who can I contact if I have further questions or would like to take part?**

Please contact Leah Gilman if you have any questions or would like to take part: [leah.gilman@manchester.ac.uk](mailto:leah.gilman@manchester.ac.uk)

If you prefer, you can contact the lead researcher for this study, Lucy Frith, who can be contacted via e-mail [lucy.frith@manchester.ac.uk](mailto:lucy.frith@manchester.ac.uk)

**Plain language summary for the ‘What will happen to my information section’**

In this research study we will use information you have provided to the research team. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

We will remove your name and any other identifying details when we share data from this research. The Participant Information Sheet tells you more about this.

The discussions will be audio recorded and the recordings typed up for us to analyse. We will either use the transcription software otter.ai to do this automatically or an external company. The external company that we use to do this typing has been carefully vetted by the University of Manchester to ensure that it complies with the law (General Data Protection Regulations). The transcription company will be a third party who will receive potentially identifiable data however they will hold a confidentiality agreement with the sponsor

Members of the research team will read the anonymised written record of the discussion (the transcript) which will have had all names or references to specific people, places, job titles (or anything else that we believe is identifying) removed.

We will analyse the transcripts and use them in our findings. We may quote some of the things you said in the discussion. If we do this, you will not be named and will take care to ensure that any details included are not identifying.

The audio recording of your interview and the anonymised interview transcript will be securely stored on password protected servers at the University of Manchester and also on a secure and encrypted platform so that members of the project team from other universities (listed above) can access them. The audio recordings will be deleted at the end of the project.

Paper copies of your consent form will be stored in a locked filing cabinet at the University. Any audio recording of your consent will be store on the University’s secure servers. They will normally only be accessed by researchers directly involved in this project. They may, however, also be seen by research auditors. These are people whose job it is to check our research processes. After 10 years all this information will be securely deleted and paper information will be shredded.

We also need to be able to contact you during the project, for example, to organise a good time for the interview. To do this we will need to store your contact details. These will be kept on secure University of Manchester servers. They will not be linked with your data from interviews. Your contact details will be destroyed when you have finished taking part or after 10 years, if you wish to be kept updated with outcomes from the research.