

PARTICIPANT INFORMATION SHEET

Study Title: Governance of Health Data in Cyberspace

Ethics Approval Reference: Social Sciences and Humanities Interdivisional Research Ethics
Committee; REF: R63378/RE001

This information sheet provides some information to help you decide whether to take part in the above study. Please take time to read it carefully, and discuss it with friends or family if you wish, before deciding whether or not to take part. If there is anything that you do not understand, or if you would like more information, please ask us.

What is the purpose of the research?

Advancements in healthcare and medicine rely on learning from a lot of health and medical information. Often, this information, also called health-data, is re-used to understand different health issues. Sharing health-data aims to bring about benefits to society through supporting medical decision making, the development of new treatments, and improved health outcomes. The potential for health-data to be reused by different researchers or organisations requires it to be shared with them, which can only be done under certain ethical and regulatory circumstances.

Although strict rules are in place, health-data is increasingly required to be shared with different professions within and outside traditional healthcare contexts, and frequently in vast amounts. Coinciding with a demand to share and reuse health-data, healthcare and medical research have increasingly adopted digital means to support its collection and distribution, allowing for it to be replicated, shared, and analysed faster and more easily. There is also a growing potential for data collected in our everyday lives to yield information relevant to our health and wellbeing, and increasing demand for that data to be used to inform healthcare and research.

This project aims to identify what rules should apply to the use and distribution of health-related data. A major part of this is to engage with members of the public from whom health data may be captured and reused, and with users of the data, to understand what constitutes appropriate data sharing and reuse with regards to health-data, and how risks could be managed. We will explore when you consider the sharing of your health-relevant data to be appropriate, the factors that influence your judgement, and how you would value systems that enabled you to play a role in decision making about your data.

Why have I been invited?

You have been invited to take part in this research because you are at least 18 years of age, and understand and speak English fluently. We will be recruiting around 36-48 participants in total to participate in 3 to 4 focus groups, with potentially 7-12 people per group.

Do I have to take part?

No. It is up to you to decide if you want to take part in this study. If you do agree to take part, we will ask you to sign a consent form and will give you a copy for you to keep. However, you would be free to withdraw from the study at any time, without needing to give a reason. You can withdraw

by notifying a research team member through the contact details provided, or on the day. This would not affect your legal rights.

You would also be able to withdraw your consent, which would mean that any responses you have given will not be used during the data analysis or published. Your ability to withdraw your consent continues after the focus group, until the data is analysed, however, after that point aggregated (grouped) data will be published and in the form of anonymised quotes (meaning identifiers have been removed) which cannot be withdrawn.

What will happen if I do take part?

We will arrange a focus group involving 7-12 participants to discuss topics about the sharing and reuse of health data in different circumstances. The focus group will last approximately 2-3 hours. With your consent an audio recording will be made of the focus group. If you do not wish to be audio recorded, unfortunately you cannot participate in the focus group.

A researcher will run through some made-up situations about how data might be shared in modern society, and pose questions to the group about your views. All participants will be given a chance to provide answers to these, including personal opinions. There are no right or wrong answers, just your perspectives about the discussion topics. The focus groups will be audio recorded, transcribed and analysed.

When you arrive, before we start the focus group, we will ask you to complete a short, optional, paper survey asking you about your background. Towards the end of the focus group we may ask you to take part in a ranking exercise, which would involve a brief group discussion with other participants to reach consensus about a related topic.

Are there any risks in taking part in this study?

We do not anticipate any risks to your participation, but you will be sharing your time and information, and giving your opinions. The focus group also aims to generate discussion between participants and you may disagree with what others have to say, potentially because of differences in personal values and opinions. Please be respectful of this, and do not repeat what is said in the focus group to others, to maintain confidentiality. Remember that participation is voluntary and you do not need to give or expand on any information of you do not wish to do so.

Are there any benefits from taking part in this study?

As a participant, you may get more knowledge about what it means to share data digitally by having the opportunity reflect on the issue. Otherwise, there will not be any direct benefits to you. The research will guide the development of future laws, guidelines and decision making approaches, helping to ensure that they are responsive to the citizens they are designed to protect.

Will my time/travel costs be reimbursed?

Yes. As a token of our appreciation participants will be offered £20 for participating in the study. You would also be able to claim back your travel costs up to the value of £30.

Who has reviewed this study?

All research studies are checked by an ethics committee to ensure the research is conducted safely and to the best standards. This research has been reviewed by and received favourable opinion through the University of Oxford Central University Research Ethics Committee.

How will the information I provide be used?

The group discussions and ranking exercise will be recorded, audio recordings will be transcribed and transcripts analysed. The results will be presented at scientific meetings and published in scientific journals.

All research materials, including audio recordings, completed surveys and consent forms will be retained for a period of three years after the data is published in accordance with University of Oxford policies. When processing the data, your name will be replaced by a code so that you as an individual cannot be identified and audio transcripts will be reviewed for removal of any potentially identifying information.

De-identified study materials, where any personal identifiable information is removed, will be retained and may be submitted for archiving to the UK Research Data Service, or a similar database/repository, through which access will be limited only to approved researchers, and the Oxford University Research Archive (ORA). All personal data will be destroyed 36 months after completion of the project, unless it is still in use, in which case it will be destroyed as soon as it is no longer needed. The Project Manager, Dr Sarah Coy (sarah.coy@dph.ox.ac.uk) will be the data custodian and will be responsible for ensuring the secure storage and confidentiality of the data.

Who will know that I am taking part in this research?

Any information collected about you during this study will only be accessible to members of the research team and will not be shared with anyone else without your prior explicit written permission. This includes your name and contact information, which are used for purposes of study administration and will be kept separately from the survey data, focus group audio recording and transcripts. No identifiable data will be shared with third parties.

What if something goes wrong?

If a participant in University research is ever considered to have suffered harm through their participation, the University has arrangements in place to provide for compensation. If you have a concern about any aspect of this project, please speak to the researcher Nisha Shah (details below) or the Principal Investigator Professor Jane Kaye (Email: jane.kaye@law.ox.ac.uk) who will do their best to answer your query.

The researcher should acknowledge your concern within 10 working days and give you an indication of how they intend to deal with it. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Research Ethics Committee at the University of Oxford:

Chair, **Social Sciences & Humanities Interdivisional Research Ethics Committee**; Email: ethics@socsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD). The chair will seek to resolve the matter in a reasonably expeditious manner.

Data Protection

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study.

The University will process your personal data for the purpose of the research outlined above. Research is a task that we perform in the public interest.

Further information about your rights with respect to your personal data is available from: <http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/>

What if I have further questions?

Please contact **Nisha Shah on Tel. 01865 287 896 or Email Nisha.shah@dph.ox.ac.uk** who will happily answer any further questions you may have.

About us

This work is being led by researchers based at the University of Oxford in collaboration with colleagues at the University of Oslo, Uppsala University and the University of Iceland. It is supported by a research grant awarded by NordForsk [grant number 81105] and the Economic and Social Research Council (part of UK Research and Innovation).

Thank you for reading this sheet and considering whether you would be willing to participate.