

General Practice Data Trust Pilot Project

Participant Information Sheet: Patients

You are being invited to complete a survey. Some participants may also agree to take part in an interview.

These are part of a research study to understand:

- why patients opted out of sharing their GP data through NHS Digital's General Practice Data for Planning and Research (GPDPR) programme; and
- whether a Data Trust model could provide a more acceptable method for sharing GP data for health research and planning purposes.

Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

➤ **Who will conduct the research?**

Our research team consists of Dr Sarah Devaney, Professor Søren Holm, Professor John Ainsworth, Dr James Cunningham, Ms Catherine Bowden, and Dr Nigel Burns who are researchers at the University of Manchester.

➤ **What is the purpose of the research?**

The aim of the General Practice Data Trust (GPDT) pilot study is to find out why people opted out of sharing their GP data, and to explore whether a GPDT would provide a method of sharing their GP data that would be more acceptable. In May 2021 NHS Digital announced that the GPDPR programme would collect primary care (GP) data to be used in a non-identifying form in research and planning activities. Over a million people opted out of the programme, prompting NHS Digital to

delay it to provide more time to speak with relevant stakeholders about their concerns. In this pilot project we aim to explore in-depth the challenges which would stand in the way of establishing the GPDT.

➤ **Am I suitable to take part?**

Thank you for expressing an interest in taking part in this project. We would love to hear your views if you:

- Are at least 18 years of age;
- Are happy to discuss your views on sharing medical data for research and healthcare planning purposes;
- Do not have a current declaration of incapacity and no one is currently acting under a power of attorney on your behalf.

➤ **Will the outcomes of the research be published?**

We aim to publish our results. The findings from this research will also be shared with the project funder, the Data Trust Initiative, to inform their wider work on the development of data trusts. If you wish to be informed of the results, please indicate this on the consent form and provide your preferred contact details for this purpose.

➤ **Who has reviewed the research project?**

This project has been reviewed by The University of Manchester Proportionate Research Ethics Committee.

➤ **Who is funding the research project?**

This project is funded by the Data Trusts Initiative (Reference: G109655_25120) and you can find out more about their wider work on data trusts here: <https://datatrusts.uk/>

What would my involvement be?

➤ What would I be asked to do if I took part?

We invite you to complete our online survey at [survey link]. Then, if you agree to do so, you may be invited to take part in a one-to-one interview with our researcher, Catherine Bowden, to talk through your views on sharing GP data and the design of a GP Data Trust. There are no right or wrong answers: we are simply interested in what you have to say and what you think. The interview would last no more than 1 hour, take place by telephone, Zoom, or in person (your choice) and will be arranged at a date and time that is convenient for you.

We will audio-record these discussions (voice only) so that we can fully consider and review all that is said. A University of Manchester approved supplier will type up the recordings before we analyse them in our research. Interviews conducted online (via Zoom) will be video recorded and will capture your voice, head and shoulders as you appear in the Zoom format (you can elect to turn your camera off if you do not wish to be videoed). The video file will be deleted and will not form part of the study. Where Zoom is used, a transcript will be automatically generated. All transcripts will be checked for accuracy by the research team.

By taking part you will be taking the opportunity to participate in research that aims to contribute to the design of a data sharing system that may personally benefit you in the future.

➤ Will I be compensated for taking part?

We will reimburse you for any reasonable travel expenses incurred and we are offering a £50 Love2shop voucher if you take part in an interview in recognition of your participation.

➤ What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part.

- If you wish to take part, please continue with the survey.
- If you are also interested in being interviewed, you will have the chance to let us know this at the end of the survey.

If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project

once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

All interviews will be audio recorded. If you are uncomfortable with the recording process at any time you are free to stop the recording and withdraw from the project.

Data Protection and Confidentiality

➤ What information will you collect about me?

In order to participate in this research project we will need to collect information that could identify you, called “personal identifiable information”. Specifically we will need to collect:

- Your name
- Your contact details (telephone number, address, or email address)
- Your age range
- Your gender
- Your ethnicity
- Your employment status
- Your level of education
- The region of England you live in
- A record of your consent

➤ 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”.

➤ What are my rights in relation to the information you will collect about me?

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](#).

➤ **Will my participation in the study be confidential and my personal identifiable information be protected?**

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 in the following way:

Only the study team at The University of Manchester will have access to your personal information, but they will anonymise it as soon as possible. Your name and any other identifying information will be removed and replaced with a random ID number. Only the research team at the University of Manchester will have access to the key that links this ID number to your personal information. Your consent form will be retained in a locked filing cabinet on University of Manchester premises for audit purposes for up to 5 years. With your consent, we will retain your contact details until the end of the study so that we can keep you informed about the findings of the study (if you have asked for them) and also to inform you about any future studies you have expressed an interest in being contacted about. If you consent to this, your details will be safely stored on University of Manchester servers in a digital folder only accessible to the study team and used only for the purposes described above.

At the end of the project anonymised data will be stored in the University of Manchester Research Data Storage service.

Potential disclosures:

Audio recordings will be held on a University of Manchester approved encrypted recording device that can only be accessed using a PIN number until they can be transferred to the secure digital storage. Audio recordings will be transferred from the recording device to secure University of Manchester Storage as soon as possible, checked and then deleted from the recording device. Zoom transcriptions will be automatically generated and checked for accuracy by our researcher, Catherine Bowden. Recordings will be transcribed (typed up) in a secure environment by a University of Manchester approved transcription service. Any information that could identify you or anyone else you mention will be removed from transcriptions. Audio recordings will be destroyed as soon as possible after transcripts have been checked for accuracy.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

If you choose to be interviewed using Zoom, your participation in this research will be recorded in Zoom and your personal data will be processed by Zoom. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection.

If you participate in an interview and wish to receive the Love2Shop voucher as a thank you for your time, your full name and email address will be shared with our Finance department who will send the voucher to you. Your full name and email address will be securely retained by Finance for a period of up to 7 years for audit purposes only and then destroyed. It will not be used by them for any other purpose.

Sharing data:

When you agree to take part in a research study and with your informed consent, the information about you may be provided to researchers running other studies here or at other organisations. With your consent your anonymised information will be shared in order to support additional research in accordance with [The University of Manchester's Research Privacy Notice](#).

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of developing insights into what the ideal system for sharing GP data would be, and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you.

What if I have a complaint?

➤ Contact details for complaints

If you have a complaint that you wish to direct to members of the research team, please contact:

Dr Sarah Devaney, E-MAIL: sarah.devaney@manchester.ac.uk TEL: 0161 275 3565

OR Professor Søren Holm, E-MAIL: soren.holm@manchester.ac.uk, TEL: 0161 275 3588

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email 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.

You also have a right to complain to the [Information Commissioner's Office about complaints relating to your personal identifiable information](#) Tel 0303 123 1113 (<https://ico.org.uk/make-a-complaint/>)

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher:

**Ms Catherine Bowden
Department of Law
School of Social Sciences
University of Manchester
Williamson Building
Oxford Road
Manchester
M13 9PL**

Email: catherine.bowden@manchester.ac.uk

Additional information in relation to COVID-19

Due to the current COVID-19 pandemic, we have made some adjustments to the way in which this research study will be conducted that ensures we are adhering to the latest government advice in relation to social distancing as well as taking all reasonable precautions in terms of limiting the spread of the virus. You should carefully consider all of the information provided below before deciding if you still want to take part in this research study. If you choose not to take part, you need to inform research team. If you have any additional queries about any of the information provided, please speak with a member of the research team.

Are there any additional considerations that I need to know about before deciding whether I should take part?

As with all in-person interactions, if you are taking part in a face-to-face interview there is a risk of possible infection with COVID-19. To reduce this risk you should not to take part in face-to-face interviews if you are in a vulnerable group or if you, or anyone you live with has any symptoms of COVID-19.

What additional steps will you take to keep me safe while I take part?

The researchers will not attend face-to-face interviews if they or anyone they live with has symptoms of COVID-19 and steps will be taken to disinfect any equipment used including recording devices. The researchers are happy to wear facemasks if you would be more comfortable with this.

Is there any additional information that I need to know?

If you are attending an in-person interview, please arrive on time (not early or late) to avoid too many participants gathering in the same area.

Additional data use

We will follow any Government guidance on tracking and tracing COVID-19 which may require us to provide contact details to NHS Track and Trace if it becomes necessary.

What if the Government Guidance changes?

If Government Guidance changes we will take steps to contact you and make suitable arrangements, such as conducting the interview by telephone.

What if I have additional queries?

If you have any queries about the study and the impact of COVID-19 then please contact the researcher:

**Ms Catherine Bowden
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School of Social Sciences
University of Manchester
Williamson Building
Oxford Road
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M13 9PL**

Email: catherine.bowden@manchester.ac.uk