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Study Title: Barriers and Best Practices for Trials Transparency at UK Universities and NHS Trusts

Ethics Reference: R67457

PARTICIPANT INFORMATION SHEET – v1.0

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

1. *What is the purpose of this research?*

The reporting of clinical trials is essential to realising the value of research, honouring researcher's commitments to patients, and removing bias from the clinical literature. The publication of results is an ethical imperative, recognised by organisations like the World Health Organisation. It is also increasingly a legal requirement. Both the US and EU have requirements to report results of certain clinical trials directly to clinical trial registries. These registries are public, online databases that hold information about trials.

The UK policy on trials transparency, once the UK fully leaves the EU, is currently in active discussions. The House of Commons Select Committee on Science and Technology has recently examined the issue of trials transparency and made clear to Universities and NHS Trusts that results of all their clinical trials should be reported in accordance with both legal guidelines and ethical standards. In the wake of this attention, UK public research institutions have shown substantial increases in clinical trial reporting to the EU Clinical Trials Register.

In these interviews, we will be trying to answer the following questions:

1) What trials transparency policies and processes are in place at your institution?
2) What works well for promoting and ensuring best practice in trials transparency at your institution, and what barriers remain?

2. *Why have I been invited to take part?*

You have been invited to participate because you either work directly in areas related to trials transparency or are impacted by these policies at your institution. We are looking to interview 15-30 stakeholders for this study.

To be eligible to take part, you must be:

- willing and able to give informed consent for participation in the study.
- Aged 18 years or above.
- In a position related to clinical trials and their reporting or overall matters of research integrity at the institution (e.g. creating policies, overseeing research, conducting research, administering research).

You will not be eligible to take part if:

- Your institution does not conduct clinical trials, or has not in recent years.

3. Do I have to take part?

No. You can ask questions about the research before deciding whether or not to participate. If you do agree to participate, you may withdraw yourself from the study at any time, without giving a reason, by advising the researchers of this decision. There will be no negative consequences to you if you decide not to take part.

4. What will happen to me if I take part in the research?

If you are happy to take part in the research, you will be asked to schedule a time to meet the researcher. This can either be in person or online. If there are extenuating circumstances, you may be able to answer some questions over email however please note that there are greater risks to your data when participating via email. Therefore, you should only use this method to take part in the study if no alternatives exist and you are prepared for your responses to be made public in the unlikely event of a breach. Shorter follow-up questions to your interview may be conducted over e-mail with your consent. The research write-up will not link any responses to individuals or institutions no matter your method of participation.

Given the ongoing COVID-19 pandemic, in person interviews will only be offered as an option if they can be conducted in accordance with government guidelines on social distancing (and any other relevant guidance related to the pandemic).

Your participation in this research involves taking part in an interview. Before the interview starts, you'll have the chance to ask any questions about the research and if you are still happy to take part, you will then be asked to sign a consent form or provide oral consent to the researcher.

The interview will last from 30-90 minutes. The length can be agreed upon, based on your availability, during scheduling. We ask you to put aside the agreed upon amount of time, though it may end up taking less time depending on how much you wish to say. We will be discussing trials transparency at your institution and your personal experiences regarding the role you play in the registration and reporting of clinical trials.

The interviews will be audio-recorded and then professionally transcribed. The transcribed text will be de-identified using redaction and pseudonyms, so that any identifiers for you or your institution are removed. If you are not comfortable being recorded, please let the researcher know and next steps on your potential participation through other means, if possible, can be further discussed. The research team plans to make this anonymised study information available via the UK Data Service ReShare repository for use in potential secondary analyses. Anonymised direct quotes from the interviews will be used in research outputs.

5. Are there any potential risks in taking part?

The following risks are involved in taking part:
A data breach of identifiable data could occur. Please note that all identifiable data from the study will be stored on secure University of Oxford servers and only shared with approved study personnel. We will take all necessary precautions to ensure that your data remains safe, and that any materials shared are fully de-identified with appropriate redactions or pseudonyms. Any information that could identify either you, your institution, or any relevant identifiable affiliations will be removed before any data is made public in any form.

The interview is confidential, but in accordance with Good Clinical Practice, if you were to reveal any information which shows an immediate risk to the safety of patients or study participants, the researcher would be obliged to raise concerns with the appropriate person or organisation.

6. Are there any benefits in taking part?

There will be no direct benefit to you from taking part in this study. We hope that you will find this an interesting discussion which may involve useful reflection on clinical trials transparency at your institution. In addition, the outputs of this work will be shared with key stakeholders throughout the UK clinical trials and research ethics community in an effort to share knowledge on barriers and best practice to improving trial reporting.

7. Expenses and payments

There is no compensation for participation in this study.

8. What happens to the data provided?

The information you provide as part of the study is the **research data**. Any research data from which you can be identified (e.g. your name, email address, audio recording), is known as **personal data**.

We will minimise our use of personal data in the study as much as possible.
Personal data will be stored confidentially on University of Oxford servers in password protected Microsoft Excel and Word formats or in an NVivo project file.

The **research data** collected for this project will include your consent form, audio recordings, transcripts of those recordings, notes taken by the researcher, and any additional study information provided via e-mail (if applicable).

The audio-recordings will be stored on University servers and transcribed and de-identified into text by professional transcribers and members of the study team. They will be deleted from any recording devices as soon as possible following our interview. They will be destroyed at the completion of the primary analysis. The transcribed data will only be analysed following the removal of your **personal data** and any original transcripts that contain identifiable information will be securely stored for reference and destroyed at the completion of primary analysis. The de-identified transcript data will be held in a securely stored electronic document and given an alpha-numeric code which will then be used to label the **research data being** analysed. The transcripts will then be read, analysed and summarised using computer programs like Microsoft Excel, Microsoft Word, and NVivo qualitative analysis software. Consent forms are required to be held for 3 years following any publication of the project. Any additional identifiable **research data** will be maintained on University servers until the completion of the analysis and then destroyed. The content of

what you say in the interview will not be published alongside any **personal data** in order to preserve your confidentiality.

The researcher, members of the study team including doctoral supervisors, and professional transcribers will have access to **personal data** and **research data**. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the research.

We would like your permission to use anonymous direct quotes in research outputs and to share the full anonymous transcripts of these interviews. If you say anything during the interview which you would prefer to not be directly quoted, then you are free to say so and we will ensure these are not quoted directly in any public outputs and are redacted from the shared transcripts.

All anonymous **research data** will be stored indefinitely on the UK Data Service ReShare database, following initial publications resulting from this work, for use in potential secondary data analysis by interested researchers. Only fully de-identified transcripts will be shared in this manner. We will retain and store your **personal data** only as long as it is needed for the purposes of the study, after which time it will be deleted. Hard copies of your signed consent forms will be stored in a secure location for 3 years after the interview, or until the study is published, whichever is longer.

9. Will the research be published?

The research may be published in peer-reviewed journal, presented at scientific conferences, and potentially used in future education, training, and policy materials.

We would like to be able to use anonymous quotes in research outputs, e.g. conference presentations or journal articles, and share the full de-identified transcripts via the UK Data Service ReShare repository. You can read about the UK Data Service ReShare program here: https://reshare.ukdataservice.ac.uk and their standards for data anonymity and security here: https://www.data-archive.ac.uk

The University of Oxford is committed to the dissemination of its research for the benefit of society and the economy and, in support of this commitment, has established an online archive of research materials. This archive includes digital copies of student theses successfully submitted as part of a University of Oxford postgraduate degree programme. Holding the archive online gives easy access for researchers to the full text of freely available theses, thereby increasing the likely impact and use of that research.

The research will be written up as a thesis. On successful submission of the thesis, it will be deposited both in print and online in the University archives, to facilitate its use in future research. The thesis will be openly accessible. The thesis will not contain any **personal data**.

10. Who is organising and funding the research?

The research is funded by the Fetzer Franklin Fund (Project code BZR02760).

It is hosted and organised by the Nuffield Department of Primary Health Care Sciences, University of Oxford under the supervision of Dr. Ben Goldacre and Professor Carl Heneghan.

11. Who has reviewed this study?

This study has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee (Reference number: R67457).

12. *Who do I contact if I have a concern about the study or I wish to complain?*

If you have a concern about any aspect of this study, please speak to the researcher, Nicholas DeVito [nicholas.devito@phc.ox.ac.uk] or his supervisor, Dr. Ben Goldacre [ben.goldacre@phc.ox.ac.uk] and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the relevant chair of the Medical Sciences Interdivisional Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD

13. *Data Protection*

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

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

You can find out more about how we use your information by contacting Nicholas DeVito (details below)

14. *Further Information and Contact Details*

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

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