

# Barriers and Best Practices for Trials Transparency at UK Universities and NHS Trusts

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Registration Template adapted from: <https://osf.io/b6xmd/>

## General information

### ***Background:***

The registration and 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 World Health Organisation (WHO) supports a network of primary registries that aim to ensure a permanent record of clinical trials is maintained around the globe.[1] The publication of results is an ethical imperative, recognised by organisations like the WHO and World Medical Association.[2,3] It is also increasingly a legal requirement. Both the US and EU have legal requirements to report results of certain clinical trials directly to clinical trial registries.[4,5] These registries are public, online databases that hold information about trials.

Issues with the registration and reporting of clinical trials is well-established.[6–8] In our prior research, we have examined trial reporting under these legal requirements in the US and EU and found that many trials remain unreported, even with a legal requirement in place.[4,9] Poor reporting to the EU trial register by UK sponsors was examined by the House of Commons Select Committee on Science and Technology and led to multiple hearings. In addition letters sent to every University and NHS Trust in the country reminding them of their responsibilities.[10] Following these letters, evidence to the committee showed marked increases in reporting to the EU registry.

It is a particularly interesting time in the UK trial landscape. As the UK prepares to leave the EU they are forging an independent regulatory for clinical trials. Previously, much of the UK clinical trial registration and reporting infrastructure was run through the European Medicine Agency. Now organisations like the Health Research Authority (HRA) will begin to play a bigger role in ensuring UK clinical research is transparent and available. The HRA Make It Public Strategy outlines a way forward for ensuring these transparency goals are met.[11]

This study aims to understand how UK public research institutions are managing their trials transparency responsibilities. Through interviews with various personnel related to clinical research integrity, governance and conduct, we will examine what policies and procedures exist at these institutions and how they are implemented in practice. We aim to understand how

personnel from various levels of these organisations are engaging with these processes and what changes have been implemented and are to come as the landscape evolves. Understanding the barriers and best practices across these institutions will allow for key insights that can be shared throughout the community to elevate practice and policy recommendations that can look to address some of the largest impediments to complete and timely registration and reporting of clinical trials.

**Research Question:** What are the barriers and best practices that impact the complete and timely registration and reporting of clinical trials at UK public research institutions?

**Project Start Date:** First enrollment expected November 2020

**Expected Recruitment End Date:** Spring 2021

**Expected Project End Date:** Summer/Autumn 2021

**Ethics Approval:** This study was approved by the University of Oxford Division of Medical Sciences Research Ethics Committee reference R67457/RE001 on 27 July 2020.

## Research design specifics

**Data Generation Process:** This study will collect data through semi-structured interviews with various personnel at UK public research institutions related to the conduct and governance of clinical research. The study-lead will conduct all interviews (NJD).

**Unit of Analysis:** The unit of analysis will be the individual participants although groupings based on role and potentially affiliations may be made in the final data.

**Is this project hypothesis-testing or hypothesis-generating (or both)?:** This study is descriptive and hypothesis-generating. The output from this study will inform strategies for how institutions may be able to manage and improve their trial registration reporting. These can potentially be used to form hypotheses that can be tested, either interventionally or observationally, in future research related to process improvement at these institutions.

### Interview Sample Description:

*Please describe the target population:* The target population for this study is staff at UK Universities and NHS Trusts who are engaged with clinical trials from a governance or management perspective. Primary investigators (PIs) and other purely academic staff are not enrollment targets for this study. We aim to recruit subjects who sit in positions related to broad research integrity issues, clinical trials research governance, and trials management. Leadership at specific trial conducting entities may also be considered for inclusion, even if they also serve as PIs, on a case by case basis.

*What is the targeted sample size?:* This study aims to recruit approximately 10-30 participants. Final enrollment will depend on data saturation and project resources.

*Please describe the sampling strategy?:* Our primary mode of recruitment will be through outreach via professional organisations (e.g. UK Trial Managers Network, UKCRC, etc.). We may also conduct proactive outreach to certain individuals using purposive sampling based on our knowledge of the UK clinical trial landscape. Additionally, we will snowball recruit through referral either from other stakeholders in the area or existing participants.

## Analysis

**Software:** NVivo 12 will be used for analysis alongside word processing and spreadsheet software as needed.

**Active Citation and Data Availability:** We do not plan to formally use active citation in this analysis, however we do plan for anonymised transcripts to be available via the UK Data Service ReShare program (<https://reshare.ukdataservice.ac.uk>) for parties interested in secondary analysis of the source material. We also plan to quote extensively from interviews in our final materials as appropriate.

**Analysis Strategy:** There is no pre-set codebook for the analysis although the interview guide is separated into categories that may deductively inform some, but not necessarily all, high level groupings. More detailed codes will be derived, inductively, throughout the analysis process. Given the focus on applied policy, the analysis strategy will be to apply Framework approach[12] to thematic analysis in order to allow for easy mapping of themes and concepts across and within subjects.

**Coding and Analysis Details:** The final coding strategy may vary based on time and resources of the study team as the project advances, however preliminary plans involve familiarisation of all interviews by the study lead (NJD) and development of the thematic framework and coding-index steps. This coding-index will then be applied to a sub-set of initial interviews by NJD and a collaborator where consistency and any adjustments to the indices will be made. Dual-indexing of transcripts may persist as needed, and based on available resources, with incremental updates to the coding-index throughout. Any remaining manuscripts, if dual-indexing is not possible, will be coded by NJD. The subsequent synthesis and analysis steps will be performed by NJD but with opportunities for reflection and discussion with colleagues throughout as necessary.

## Logistics

**Planned updates:** Prior to the first dual-coding step in the analysis, this protocol will be revisited in order to update any changes that arose during the interviews and provide any changes, further refinement, or detail related to the analysis plan.

**Funding:** This work was Funded by the Fetzer Franklin Fund of the John E. Fetzer Memorial Trust from grants arising from the MetaScience 2019 Symposium.

**Expected Results Dissemination:** This research will be used in NJD's doctoral thesis and will also aim to be published in a scholarly journal and/or presented at academic meetings. Additional outputs, such as more policy focused documents aimed at improving trials transparency practices within public sector research in the UK may also rise from this work based on discussions with relevant government bodies and other interested organisations.

## Certification

I hereby register my research project and supplementary materials. I confirm that I own the rights to release these materials into the public domain

## References

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- 10 Clinical trials transparency: follow-up inquiry. UK Parliament. 2019.<https://old.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/inquiries/parliament-2019/clinical-trials-transparency-follow-u>

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- 12 Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: *Analyzing Qualitative Data*. Routledge 1994. 173–94.