



## Oral Consent Script – V1.0

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

**Ethics Reference:** R67457

Hello, my name is Nicholas DeVito and I am a DPhil student at the University of Oxford Nuffield Department of Primary Care Health Sciences. Thank you for agreeing to speak with me today about trials transparency at your organisation. Are you ok with me recording our conversation today? I am happy to answer any questions you may have about how these recordings will be used and stored by the study team.

**If Yes:**

Ok, with your permission I am going to start recording now.

**If No:**

*Researcher will make determination for next steps (i.e. withdraw participant from the study or make alternate arrangements for participation.)*

I've sent along an information sheet and a written consent form ahead of our call.

Have you had a moment to review those?

**If Yes:**

Great. Just to review, I am interested in how public research institutions in the UK operationalise trials transparency policies. If you agree to participate in this research, I'll ask you some questions on your experiences and your organisation's policies and procedures regarding the registering and reporting of clinical trials. Today we have agreed to speak for up to XX minutes **[the expectation for time will be agreed in advance, approximately between 30 and 90 minutes]**. Our recorded conversation will be used to inform an analysis I plan to include in my doctoral thesis and subsequent research publications.

Do you have any questions or concerns about the study or anything you read in the information sheet?

**If No read information script below:**

Ok then I'd like to first tell you a little bit about the study. I am interested in how public research institutions in the UK operationalise trials transparency policies. If you agree to participate in this research, I'll ask you some questions on your experiences and your organisation's policies and procedures regarding the registering and reporting of clinical trials. Today we have agreed to speak for up to XX minutes **[the expectation for time will be agreed in advance, between 30 and 90 minutes]**. Our recorded conversation will be used to

inform an analysis I plan to include in my doctoral thesis and subsequent research publications.

Any responses you give today will be de-identified before inclusion in any public facing materials. The research team, made up of my advisors, collaborators who will aid in the analysis of the data, and myself, along with a University approved transcription service, are the only ones who will have regular access to the non-anonymised recording and transcripts. Responsible, designated members of the University of Oxford may be given access to data for monitoring and/or audit of the research. The only exception to this would be if any information was revealed that presented an immediate, direct threat to patient safety. Should this occur, the researcher would be obliged to raise concerns with the appropriate parties.

The consent records will be stored on the University Server for at least 3 years after study completion. Any other identifying information, including the audio recordings, non-anonymised transcripts, and any other study documentation will be destroyed at the conclusion of the primary analysis. I plan to make the de-identified interview transcripts available through the UK Data Service ReShare repository for secondary analysis by interested parties, but with all identifiers removed or replaced with pseudonyms. I can provide more information about the UK Data Service ReShare repository at your request.

The content of this interview is considered low risk and any use of data from the study will be done anonymously. If any subjects are raised during the interview that cause you unexpected duress, please let me know and we can terminate the interview and debrief about any issues at a later date as necessary. As in all research, standard risks of data breaches of non-anonymised research data exist, however all best practices and guidelines will be followed in order to minimize this possibility.

If you have any complaints or concerns please feel free to contact me in the first instance, at [Nicholas.devito@phc.ox.ac.uk](mailto:Nicholas.devito@phc.ox.ac.uk). This research project has been reviewed and approved by an Oxford University ethics committee. If, after contacting me with any concern, you're still unhappy and wish to make a formal complaint, please contact the ethics committee. Their email address is [ethics@medsci.ox.ac.uk](mailto:ethics@medsci.ox.ac.uk). I am happy to provide you with any of this contact information in writing at your request. The University of Oxford is responsible overall for ensuring the safe and proper use of any personal information you provide, solely for research purposes. Further information about your rights to information you provide is available from the University's data protection web site which I would be happy to provide to you upon request.

Do you understand this?

Do you have any questions or concerns?

**Oral Consent (To be gained if consent not already provided via e-mail or returned signed consent form):**

To confirm, do you give your permission for me to interview you today and audio record our conversation?

Do you understand that your participation is voluntary, and this interview can be halted at any time for any reason without penalty?

Do you give me permission to quote you anonymously in any outputs resulting from this study including the sharing of anonymised transcripts?

Do you understand how to raise a concern or make a complaint?

Do you understand that any information you reveal that presents an immediate risk to patient safety will be reported accordingly?

Do you give me permission to re-contact you to clarify any information if necessary?

Would you like to be contacted, via your email on file, with any results of this study when they become available?

Are you happy to take part in the study?

Ok, thank you, let's start.