SOP 317 Obtaining Remote Consent from Competent Adults in Clinical Trials

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
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This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

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1. Contents

2. Definitions of Terms Used / Glossary

CI	Chief Investigator
NNUH	Norfolk and Norwich University Hospital
PI	Principal Investigator
R&D	Research and Development
SOP	Standard Operating Procedure
UEA	University of East Anglia

3. Objective

The aim of this SOP is to outline the process for seeking informed consent remotely, from a competent adult to potentially enter them into a clinical trial.

4. Scope

This SOP is applicable to NNUH and UEA sponsored studies, where the study participants are competent adults.

5. Purpose

The purpose of this SOP is to outline the steps to be taken to ensure that potential participant/s understand what they are undertaking when they remote consent to participate in a clinical trial, and that valid evidence of the consent process is obtained prior to the competent adult becoming a study participant.

6. Rules

Remote Informed Consent

- Justification for using remote consenting must be written into the study protocol.
- For NNUH sponsored studies where using a video link it must be via the Trust approved secure method **AttendAnywhere.** Refer to **Trust Docs ID 17312 Guidelines for Video Consultations**
- For NNUH sponsored studies only NHS.net to NHS.net emails or encrypted NHS.uk emails must be used when sending **identifiable** information. Refer to **Trust Docs ID 982 Cyber Code of Conduct Appendix 2**
- For UEA sponsored studies where using a video link it should be via **Microsoft Teams**, and emails must adhere to the **UEA Information Classification and Data Management policy**.
- The person taking consent must have consenting recorded as a responsibility on the study delegation log.
- Informed Consent is an on-going process; the individual's willingness to remain as a study participant should be checked and documented within the study Case Report Form (CRF) and medical notes.
- Any changes to the design or procedures performed because of an amendment must be advised to the participant to ensure the participant is fully informed.

7. Procedure

- The identity of the competent adult **must** be confirmed and documented prior to the consent process being undertaken. For example, check date of birth, address including post code and email address.
- The competent adult will be sent all necessary trial documentation either via email or by post (including patient information sheet and consent form) and given sufficient time to consider these before the discussion.

- The CI/PI (or delegate) taking the consent will conduct the interview and discussion with the competent adult by telephone or video link.

- Following the discussion, the competent adult will be given sufficient time in private to consider the trial and read the written information, before a scheduled follow-up phone call or video meeting is held.
- If trial entry is considered appropriate and the competent adult wishes to proceed the competent adult can evidence consent via one of the following methods:

  1. If the consent form was sent to the competent adult via email or post they can reply to that email or send a return letter and confirm consent. All correspondence must be retained, and copies filed in the participant's medical and study notes.

  2. Or during the follow up call or video meeting the competent adult can verbally consent. **A video or audio recording of the conversation must be made,** and the recording must be retained to evidence consent.

- In both cases the CI/PI (or delegate) must confirm that the competent adult has read and understood the research information and consent form sent to them.

- Evidence of the consent obtained from each participant, and what has been consented to must be retained.

- If applicable, written consent to participate must be obtained at the time of the first face-to-face meeting between CI/PI (or delegate) and the competent adult. Refer to **SOP 315 Obtaining Written Informed Consent from Competent Adults in Clinical Trials**

References and Related Documents

References	
Trust Docs ID 17312 Guidelines for Video Consultation	
Trust Docs ID 982 Cyber Code of Conduct	
UEA Information Classification and Data Management policy	
MHRA and HRA Joint Statement on Seeking Consent by Electronic Methods	
SOP No.	**SOP Title**
SOP 310	Development of Participant Information Sheet and Informed Consent Form
SOP 315	Obtaining Written Informed Consent from Competent Adults in Clinical Trials
SOP 316	Distance (remote) Consenting for Children and Neonates in Research Studies

Approval

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- **Reason for new version and Training Implication**

NA. This is a new SOP

Changes made	
Reason	• N/A
Training Implication	**Yes**
Actions required	• Additional training may be required • Matrix to be updated