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# SOP 315 Obtaining Written Informed Consent from Competent Adults in Clinical Trials

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| **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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# SOP 315 Obtaining Written Informed Consent from Competent Adults in Clinical Trials

## 1. Contents



## 2. Definitions of Terms Used / Glossary

| | |
|---|---|
| CI | Chief Investigator |
| CRF | Case Report Form |
| HRA | Health Research Authority |
| ICF | Informed Consent Form |
| ISF | Investigator Site File |
| PI | Principal Investigator |
| PIS | Participant Information Sheet |
| REC | Research Ethics Committee |
| R&D | Research and Development |
| SOP | Standard Operating Procedure |
| TMF | Trial Master File |

## 3. Objectives

This SOP describes the on-going process for obtaining written informed consent face to face.

## 4. Scope

Face to Face Consent. For Remote Informed Consent Refer to SOP 317 Obtaining Remote Consent from Competent Adults in Clinical Trials.

## 5. Purpose

It is necessary to ensure that potential participant/s understand what they are undertaking when they sign an Informed Consent Form (ICF) for research.

By signing the ICF there is documented evidence that valid informed consent was obtained prior to the individual becoming a study participant.

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) or/ and medical notes).

Any changes to the design or procedures performed as a result of an amendment must be advised to the participant to ensure the participant is fully informed.

## 6. Rules

**The definition of an adult varies between areas of the UK and governing legislation in different EU countries.**

- For all studies, written, signed and dated consent for participation in a trial must be in place for a competent person aged over 16.

**The Chief Investigator (CI) or Principal Investigator (PI) has responsibility to ensure that:**

- If the activity of consenting is delegated to a member of a research team this needs to be clearly documented in the delegation log.
- Members of staff taking consent should have a good understanding of the study, associated disease area and potential risks associated with any study-associated intervention. They should be qualified by experience in consenting and receive appropriate study specific training, documented in their training log.

**A legal representative (a person not connected with the conduct of the trial) may be appointed.**

- A Personal Legal Representative is someone who is suitable to act as the legal representative by virtue of their relationship with the participant and is available and willing to do so.
- A Professional Legal Representative may be approached if no suitable personal legal representative is available.
- A Professional Legal Representation is a doctor primarily responsible for the medical treatment of the participant; or a person nominated by the relevant health care provider (e.g. an acute NHS Trust or Health Board).

## 7. Procedure NNUH

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|  | All individuals asked to consider taking part in research should be given full information about the research in verbal and written form, which may include providing the trial information/PIS by email (where consent is given to communicate via email), presented in non-technical language and in a form that they can understand. |
|  | The Participant Information Sheet (PIS) will be provided for each individual who is considering taking part in research. This will provide participants with the information described below: |
|  | • Objectives, possible benefits, risks and inconveniences of the trial<br>• Participants may get no personal benefit from the research |
|  | • Evidence that a research ethics committee has approved the research<br>• Participation is voluntary, and that they are free to withdraw consent at any time without providing a reason and without prejudicing future medical care |
|  | • Participant understanding of the research and what is involved<br>• Understand that it is research and that it is not possible to predict with complete confidence the effect of, or reactions to, the interventions used in the trial |
|  | • Potential participants should be encouraged to ask questions about the research<br>• Questions should be answered to the best ability of the person obtaining consent |
|  | • Additional information should be provided prior to completion of the consent process<br>• Sufficient time to read the information about the research must be given |
|  | • The time required should be provided in the research approvals application form for review by the REC and the HRA<br>• Extra consideration time will be given where participants are still unsure |
|  | • Participants will be advised to speak to an independent person (such as a healthcare professional or GP who is not involved in the study; who must first have been provided with information about the research) |

**Informed Consent Form (ICF)**

- Further information on the content of the ICF, refer to SOP 310 Development of PIS and consent forms.
- Only the approved version of the ICF (as stated in the REC list of approved documents) will be used
- Only investigators, co-investigators and staff named on the Delegation of Responsibilities Log (SOP 325) are permitted to obtain informed consent from participants
- For interventional clinical trials, informed consent can only be obtained by a qualified clinician and/or the person who conducted the informed consent discussion/study talk

who must be fully informed and familiar with all of the information being given to potential participants.

- Staff professionally registered should ensure that their professional registration covers this activity. The REC should be made aware if any person taking consent is not medically qualified.
- Where appropriate, training for taking consent should be sought and evidence of this training held in the study Trial Master File (TMF) or Investigator Site File (ISF) and the individual's Training File (SOP 505)
- Potential participants should neither be coerced nor unduly influenced to participate or continue to participate in a trial
- The person obtaining informed consent must be confident that potential participant/s:
  - Have been informed about a condition or given a diagnosis of the condition(s) to be investigated by the study
  - Fully understands what they are agreeing to
  - Is aware that they may receive a control intervention rather than active treatment
  - Understands the implications of any decisions that may be made within the course of the research
- **If there is any doubt as to the potential participant's understanding, then this individual should not be recruited**

## Documentation Approval

- Participant's name, date of birth, title of the study and assurance that the participant has received all appropriate documentation (PIS and any other relevant study information) must be checked for correctness
- ICF must be signed and dated by the participant and person conducting the informed consent study discussion
- The participant and the person obtaining consent should print their names in block capitals under their signatures
- Date should be written in full date format (*dd-month-yyyy*)
- The consent form must be signed by the participant and the person obtaining consent in each other's physical presence
- After consent has been obtained:
  - **Original copy** - will be placed into the (ISF), or (TMF) for single centre studies
  - **Second copy** - The participant will be given a copy to keep
  - **Final copy** - Should be placed in the patient's hospital notes with a copy of the PIS in accordance with (SOP 345). A participant's ICF will be kept regardless of how far the participant proceeds in the study

**Other considerations:**

- ICFs must be stored securely to ensure participant identity is not linked with CRF or other study data
- Deviations from the approved informed consent process must immediately be reported in writing to the REC/HRA
- Amendments to the trial protocol, PIS or ICF required after ethics approval and study start, CI/PI must contact the REC and HRA to obtain approval.
- Implementation of an amendment may be required prior to REC approval in the event of a medical emergency where the participant's well-being is at risk. Justification and notification to REC must be as soon as possible (SOP 230 Urgent Safety Measures)
- The subject's willingness to continue should be reaffirmed on each visit; or if new study information becomes available. The participant should receive an updated PIS and be re-consented on a revised and approved ICF
- The CI/PI must also notify the sponsor and regulatory authorities to discuss the need and immediacy for re-consenting existing participants
- For guidance on obtaining informed consent for minors and adults lacking capacity to consent, the CI should consult the CT Toolkit and/or HRA website and/or the Sponsor.

## 8. Procedure UEA (if applicable)

Procedure will be as defined in the local working practice documentation.

## 9. Procedure for NCTU (if applicable)

Procedure will be as defined in the local working practice documentation.

## 10. References and Related Documents

**References**

ICH GCP E6 / SI 2004/1041

| SOP No. | SOP Title |
|---|---|
| SOP 230 | Urgent Safety Measures |
| SOP 310 | Development of Patient Information Sheet and Informed Consent form |
| SOP 325 | Study Start Up Activities for Clinical Trials |
| SOP 345 | Identifying Trial Patients on Hospital Admission |
| SOP 505 | Training Requirement and Creating and Maintaining Training Records |
| SOP 317 | Obtaining Remote Consent from Competent Adults in Clinical Trials |

## 11. Approval

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## 12. Reason for new version and Training Implication

This SOP replaces the previous version number 1.6

| Changes made | What changes have been made to the contents of the document |
|---|---|
| Reason | • New template<br>• Reference to use of email to provide PIS and remote consent – SOP 317 |
| Training Implication | **Yes** |
| Actions required | • None |