

SOP-QA-9 V6

Title: Receiving informed consent

Effective Date: 01-05-23 | Review Date: 01-05-26

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GRAMPIAN CLINICAL RESEARCH OFFICE



Document History

Version	Description of update	Date Effective
5	Change of author and reference to emergency situations at 1.2 Reference to electronic consent/information at 1.1, 2, 3.4, 3.11, 3.17 Reference to qualitative sub-studies at 3.11	30-11-21
6	Updated scope at 1 and responsibilities at 2, Clarification of reporting deviations at 3.3 Removal of requirement for EudraCT number at 3.9 Clarification re Informed Consent discussion at 3.12 Updated E-consent process 3.19 – 3.22 Appendix 1 and 2 updated	01-05-23

1. Scope

- 1.1 This SOP applies to all staff and other collaborators involved in receiving informed consent (including electronic consent) for Clinical Trials of Investigational Medicinal Product (CTIMPs), Medical Device Clinical Investigations (MDCIs) and Interventional studies sponsored or co-sponsored by University of Aberdeen (UoA) and/or NHS Grampian (NHSG).
- 1.2 This SOP does not apply to receiving consent from adults with incapacity, children or in emergency situations; which should be written as study specific documents.
- 1.3 For all other studies please contact Research Governance Office at researchgovernance@abdn.ac.uk for advice.

2. Responsibilities

Principal Investigator (PI) Ensure all information (written or electronic) provided to participants has been approved by the research ethics committee (REC) prior to the study commencing.

Ensure informed consent is received prior to any research procedures, test or data collection from participant(s).

Ensure all staff receiving informed consent are adequately trained and listed on the Delegation Log.

Research Team

ICH GCP guidelines state that: 'The investigator, or a person designated by the investigator, should fully inform the subject...' and that: 'the written informed consent form should be signed by the person who conducted the informed consent discussion.'

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Research staff receiving consent shall be adequately trained to do so, prepared to take this responsibility and feel confident to receive consent.

3. Procedure

- 3.1  Informed consent is defined in ICH Good Clinical Practice guidelines as 'A process by which a subject voluntarily confirms their willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.'
- 3.2  Informed consent protects the research subject's rights and well-being, their autonomy and should be an on-going process of information exchange.
- 3.3  RECs review the informed consent process as described in the ethics application. This is an important factor in informing their decision to give a favourable opinion. Therefore, any deviations from the approved informed consent process must be reported to the Sponsor.

Providing Information to Potential Participants

- 3.4  All individuals asked to consider taking part in a study shall be given the fullest possible information about the study, presented in terms and in a form that they can understand. This must include (but is not limited to) the Participant Information Sheet (PIS) approved by a REC.
- 3.5  Information about the study may be in writing or electronic. However, special attention shall be paid to the information needs of specific populations and of individual participants.
- 3.6  A potential participant shall be invited and encouraged to ask questions about the study, which should be answered to the best ability of the person receiving consent. If additional information is needed, then this shall be obtained prior to completion of the consent process.
- 3.7  Participants shall be given enough time to read the information about the study. This is defined in the ethically approved protocol.
- 3.8  If a potential participant is unsure about participation, they shall be allowed extra time for consideration and offered the option of speaking to another member of the research team, or advised to speak to an independent person (eg a relative or their GP).

The Informed Consent Form (ICF) - this may be either electronic or on paper.

- 3.9  The ICF shall have an appropriate header, with the approved version number and date. The ICF must state the study title and IRAS number (see TMP-QA-5 - Informed Consent Form template).
- 3.10  Only currently approved version of the ICF may be used for receiving informed consent.

Receiving Informed Consent

- 3.11 Only investigators, co-investigators and staff named on the study delegation log are permitted to receive informed consent from participants.  Investigators, co-investigators and staff named on the study delegation log cannot be consented into the main study, although there may be situations where they may be consented into specific qualitative sub-studies.
- 3.12  The Informed Consent discussion must involve two-way communication between the participant and the study team and permit confirmation of the participant's identity (name and date of birth) and that the participant has received all appropriate documentation (PIS

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and any other relevant information) for the study. The discussion may occur using telephone, video conferencing, internet telephony or email if previously agreed by REC.

- 3.13  Pressure shall **not** be put on an individual to take part in a study.
- 3.14 The person receiving informed consent must assess the potential participant's understanding of the study and their involvement in it. This includes, but is not limited to, awareness that they have the condition under study, know that they may receive a control intervention (if applicable), and fully understand the implications of decisions that may be made within the course of the study. Any questions they may have, should be answered.  If there is any doubt as to the potential participant's understanding, they must **not** be recruited at that time.
- 3.15  The person receiving informed consent must inform the participant that they are under no obligation to participate, that they can withdraw at any time, and that this will not affect their treatment now or in the future.
- 3.16  Informed consent must be received **before** initiation of procedures, tests or treatments required by the study protocol and which are not considered part of routine clinical care.
- 3.17  The person receiving informed consent must ask the participant to read the informed consent statements, initial the boxes on the ICF (or for e-consent see 3.19), write their name in full, sign and date the appropriate sections. The person receiving informed consent must countersign and date the ICF.  If approved by REC, a completed, signed ICF may be received from the participant by mail. This should then be countersigned by the researcher on receipt.
- 3.18  In CTIMPs & MDCIs, if it is subsequently noted that an ICF was not completed correctly consideration should be given as to whether a new form should be completed, or controlled corrections made. Sponsor can be contacted for advice, if required.

E-consent

- 3.19 Agreement to the statements on the consent form may be recorded by the participant adding their initials, ticks or the answering of 'yes/no' questions.
- 3.20 For studies which involve risks no higher than that of standard medical care, a type written or scanned image of a signature may be used.
- 3.21 For all other studies (where risk is higher than standard medical care) a simple eSignature that involves tracing the participant's handwritten signature using a finger or stylus, or a biometric eSignature may be used; as these permit direct comparison with eSignatures/wet-ink signatures used previously for audit purposes or GCP inspection. Typewritten or a scanned image of a signature should **not** be used. Verification of identity can be confirmed via video, or at a future face-to-face meeting, using official photo ID, and prior to the participant receiving any research intervention. If this is not possible advanced or qualified electronic signatures should be considered.
- 3.22  In studies which are conducted remotely, it may not be possible to verify the participant's identity. In such circumstances advanced or qualified eSignature, as defined above, should always be used.

After Consent has been received

- 3.23 The PI or delegate must document the informed consent process in the clinical notes (See

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Appendix 1). This includes the date that the participant was given the PIS (including version number and date); confirmation of eligibility; participant questions answered; date of consent and who received it. This provides an audit trail showing that no study specific activities occurred prior to obtaining consent.

- 3.24  The original ICF must be placed in the investigator site file. A copy of the ICF is given to the participant, another placed in the clinical notes and a copy sent to the participant's GP (if required). The ICF's must not be stored together with data from Case Report Forms.
- 3.25  For CTIMPs and MDCIs an Alert should be added to Trakcare after the participant has given consent to take part in a study (see appendix 2). In a multi-centre study, for sites outwith NHS Grampian, local guidance should be followed in relation to placing any alerts on medical records.

Ongoing consent

- 3.26  It is considered good practice to confirm willingness to continue in the study and document this at each visit.
- 3.27  If changes are made to the study protocol, PIS and/or ICF, as part an approved amendment, after recruitment to the study has started, the study team shall consider whether existing participants should be informed and/or re-consented.

4. Abbreviations and definitions

CTIMP	Clinical Trial of an Investigational Medicinal Product
EudraCT	European Drug Regulatory Authorities Clinical Trial (database)
ICF	Informed Consent Form
IRAS	Integrated Research Application System
MDCI	Medical Device Clinical Investigation
PIS	Participant/Patient Information Sheet
REC	Research Ethics Committees

5. Related documentation and references

MHRA/HRA/NHS	Joint statement on seeking consent by electronic methods (September 2018)
TMP-QA-5	Informed consent form
TMP-QA-13	Site delegation log
TMP-QA-38	PIS guide
TMP-QA-97	Verbal informed consent form

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SOP-QA-9 Appendix 1 - Recording the receipt of Informed Consent from a participant in clinical notes

In addition to the signing of the ICF by researcher and participant, the following should be documented in the clinical notes, to provide an audit trail demonstrating that no study specific activities occurred prior to obtaining consent.

1. Date (and time, if required) PIS first given to the participant.
Version number and date should be recorded along with the name of the person supplying the information sheet and any discussion that took place at that time.
2. Confirmation of eligibility for the study (medical responsibility).
3. Date of informed consent discussion.
4. Date (and time, if required) informed consent is received.
5. Person receiving informed consent.
6. The discussion that took place, including any questions asked and answered.
7. Version number and date of PIS consented to.
8. Details of randomisation, where applicable.
9. Where participants permit, confirmation that their GP has/will be informed of their consent.
10. Confirmation that a copy of the ICF has been provided to participant.
11. Confirmation that contact details of study staff have been provided.
12. Confirmation of date of follow up visit (if required).
13. The above documentary evidence should be signed by the researcher involved in the visit.
14. At future visits, a simple statement confirms that participant is willing to continue in the study.

A copy of the PIS or a summary of the study may also be added to the clinical notes.

SOP-QA-9 Appendix 2 – After Consent has been received from a participant taking part in a CTIMP or MDCI

An Alert should be added to Trakcare when practical*, after the participant has given consent to take part in a study. Information included within the Alert must include:

1. Name of the Research Study
2. Name of the PI
3. Contact number of the PI and/or study team

*In a multi-centre study, for sites outwith NHS Grampian, local guidance should be followed in relation to placing any alerts on medical records.

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