Title: Receiving informed consent

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Document History

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<tr>
<th>Version</th>
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<tr>
<td>1</td>
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<td>2-10-15</td>
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<td>Inclusion of IRAS number in ICF and PIS at 3.10</td>
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1. Scope

1.1 This SOP applies to all University of Aberdeen (UoA), NHS Grampian (NHSG) staff and other collaborators involved in receiving informed consent.

1.2 This SOP does not apply to receiving consent from adults with incapacity or children; which should be written as study specific documents.

1.3 This SOP may also be used by staff from other NHS areas, or organisations, with prior agreement.

2. Responsibilities

Principal Investigator (PI) Ensure all written information 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 the participant(s). Ensure all staff receiving informed consent are adequately trained and 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.’ Research staff receiving consent shall be adequately trained to do so, prepared to take on this responsibility and feel confident to receive consent in line with codes of professional conduct.

3. Procedure

3.1 Informed consent is defined in ICH Good Clinical Practice guidelines as ‘A process by which a

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Key to symbols 🗣️ = Important point to note ⚠️ = Warning
subject voluntarily confirms his or her 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 should protect the research subject’s rights and well-being, their autonomy and should be an on-going process of information exchange.

**Providing Information to Potential Participants**

3.3 ⚠ All individuals asked to consider taking part in research shall be given the fullest possible information about the research, 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.

3.4 ⚠ A potential participant should be invited and encouraged to ask questions about the research, which should be answered to the best ability of the person receiving consent. If additional information is needed, then this should be obtained prior to completion of the consent process.

3.5 ⚠ Participants should be given enough time to read the information about the research. This is defined in the ethically approved protocol.

3.6 ⚠ If a potential participant is unsure about participation, allow extra time for consideration and offer the option of speaking to another member of the research team, or advise the potential participant to speak to an independent person (eg a relative or their GP).

**The Informed Consent Form (ICF)**

3.7 ⚠ The ICF shall be on appropriately headed paper, with the approved version number and date. The ICF must state the study title, IRAS number and if a Clinical Trial of an Investigational Medicinal Product (CTIMP), the EudraCT number (see TMP-QA-5 - Informed Consent Form template).

3.8 ⚠ Only the currently approved version of the ICF may be used for receiving informed consent.

**Receiving Informed Consent**

3.9 Only the 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 study.

3.10 ⚠ The participant’s name and date of birth should be verified. Confirm that the participant has received all appropriate documentation (PIS and any other relevant information) for the study.

3.11 ⚠ Pressure shall not be put on an individual to take part in research.

3.12 The person receiving informed consent must assess the potential participant’s understanding of the research 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, and fully understand the implications of decisions that may be made within the course of the research. Any questions they may have should be answered. ⚠ If there is any doubt as to the potential participant’s understanding, the individual must not be recruited at that time.

3.13 ⚠ 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.

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**Key to symbols**

⚠ = Important point to note  ⚠ = Warning
3.14 🔄 Informed consent must be received **before** the initiation of any procedures, tests or treatments required by the study protocol and which are not considered part of routine clinical care.

3.15 🔄 The person receiving informed consent must ask the participant to read the informed consent statements, initial the boxes on the ICF, write their name in full, sign and date the appropriate sections. The person receiving informed consent must then countersign and date the ICF.

3.16 Consent may only be given verbally or by telephone if approved by a REC. In these instances, a study specific document (SOP or User Guide) must detail the procedure for documenting the consent. 🔄 For CTIMPs, telephone or verbal consents are **not** permitted.

3.17 **Note** - For CTIMPS, a detailed description is required for medical notes (See Appendix 1). In general, the PI or delegate must document in the medical notes the informed consent process. 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.

**After Consent has been received**

3.18 🔄 The original consent form must be placed in the investigator site file. A copy of the consent form is given to the participant and another placed in the clinical notes, or sent to the participant’s GP (if required). The ICF’s must not be stored together with data from Case Report Forms.

3.19 It is good practice to confirm willingness to continue in the study and document this in the medical notes at each visit before procedures are carried out.

3.20 🔄 If changes are made to the study protocol, PIS and/or ICF after the trial has started, then the investigator must contact the appropriate REC to obtain ethical approval for these changes and to discuss the need, or immediacy of need, to re-consent existing participants.

3.21 **Note** - RECs pay close attention to 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 immediately reported in writing to the relevant REC and Sponsor.

4. **Abbreviations and definitions**

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<tr>
<th>Abbreviation</th>
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<tr>
<td>CTIMP</td>
<td>Clinical Trial of an Investigational Medicinal Product</td>
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<td>EudraCT</td>
<td>European Drug Regulatory Authorities Clinical Trial (database)</td>
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<td>ICF</td>
<td>Informed Consent Form</td>
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<td>IRAS</td>
<td>Integrated Research Application System</td>
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<td>PIS</td>
<td>Participant/Patient Information Sheet</td>
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<td>REC</td>
<td>Research Ethics Committees</td>
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5. **Related documentation and references**

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<thead>
<tr>
<th>Reference</th>
<th>Description</th>
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<tr>
<td>TMP-QA-5</td>
<td>Informed consent form</td>
</tr>
<tr>
<td>TMP-QA-13</td>
<td>Site delegation log</td>
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<tr>
<td>TMP-QA-38</td>
<td>PIS guide</td>
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**Receiving informed consent**

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SOP-QA-9 Appendix 1 - Recording the receipt of Informed Consent in medical notes from a participant taking part in a CTIMP

Note

Telephone or verbal consent is not permitted in a CTIMP.

In addition to the signing of the ICF by researcher and participant, the following should be documented in the medical notes:

1. Date (and time) PIS first given to the participant.
   (a) 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 visit.
4. Date and time 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 given to participant.
11. Confirmation that contact details of study staff have been provided.
12. Confirmation of date of follow up visit.
13. The above documentary evidence should be signed by the researcher involved in the visit.
14. At future visits, a simple statement should confirm that participant is still willing to continue in the study.

This is to provide an audit trail showing that no study specific activities occurred prior to obtaining consent.

This process could also be considered as best practice in other research studies.