MRC Clinical Trials Unit

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INFORMED CONSENT

VERSION 6.0

APPROVALS

Authors	**Position**	**Signature**
Dymphna Lee	Trial Manager	Dymphna Lee Digitally signed by Dymphna Lee Date: 2020.08.19 12:21:06 +01'00'
Emma Yates	Trial Manager	Emma Yates Digitally signed by Emma Yates Date: 2020.08.20 18:21:54 +01'00'
Saba Khan	Trial Manager	Saba Khan Digitally signed by Saba Khan Date: 2020.08.19 12:37:14 +01'00'
Aziza Mirza	Research Fellow	Aziza Mirza Digitally signed by Aziza Mirza Date: 2020.08.19 12:24:50 +01'00'
Reviewers	**Position**	**Signature**
Alex Robbins	Trial Manager	Alexandra Robbins Digitally signed by Alexandra Robbins Date: 2020.08.19 12:26:48 +01'00'
Lina Bergstrom-Randall	Trial Manager	Lina Bergstrom-Randall Digitally signed by Lina Bergstrom-Randall Date: 2020.08.19 12:33:46 +01'00'
Marta Campos	Clinical Project Manager	Marta Campos Digitally signed by Marta Campos Date: 2020.08.19 12:53:04 +01'00'
Approver	**Position**	**Signature**
Fleur Hudson	Head of Trial & Study Management	Fleur Hudson Digitally signed by Fleur Hudson Date: 2020.08.19 14:40:07 +01'00'

All appropriate approvals must have been completed prior to uploading to SOPbox.

UPLOAD TO SOPBOX

Name	Position	Signature	Date uploaded to SOPbox
Marta Campos	SOPbox Administrator	Marta Campos Digitally signed by Marta Campos Date: 2020.08.26 15:59:58 +01'00'	26-Aug-2020

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INFORMED CONSENT

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The following symbols may be used in this SOP:

Indicates a link to a related document

Indicates instructions to document trial-specific processes elsewhere

Throughout this document the MRC Clinical Trials Unit at UCL, will either be referred to as 'MRC CTU at UCL' or 'the unit'. In instances where neither read well in the sentence, 'the CTU' may be used.

1 PURPOSE

Informed consent is a key ethical concept in all research involving human participants and is defined by ICH GCP E6 (R2) guidance as:

"A process by which a 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."

The purpose of this SOP is:

- To outline the procedures for the preparation, review and approval of the Patient Information Sheet/Informed Consent Form (PIS/ICF);
- To define the MRC CTU roles and responsibilities involved in the development and amendment of PIS/ICF.

This SOP does **not** cover:

- Ethical principles surrounding the issue of informed consent; these are covered in various other documents (e.g. ICH Good Clinical Practice guidance, Declaration of Helsinki and so on);
- Methods to reach potential study participants, i.e. advertising;
- Other types of contact with study participants, e.g. letters sent during the course of a study, or notification of end of study results.

1.1 PRINCIPLES

The general principles to follow in developing informed consent documents are as follows:

- Documents produced will enable potential study participants to make an informed decision about whether they would like to participate
- Documents produced will comply with applicable regulatory and ethical requirements
- Documents produced must include:
    - All information potential study participants *need* to know to make an informed decision.
    - Where possible what they *would like to know* to make their decision.
- Information will be presented and worded in such a way as to be accessible to and understandable by as wide a variety of people as possible, avoiding coercive phrases and balancing the risks as well as the benefits of participation.
- Where possible, patient and public involvement (PPI) should be sought throughout the document development process to help ensure content is relevant and appropriate to the participant population.
- Documents will function as a clear and auditable record that every participant has provided informed consent prior to study entry.

1.2 TERMINOLOGY

The following table lists common terms and abbreviations used throughout this document.

TERM / ABBREVIATION	MEANING
CI	Chief Investigator
CPM	Clinical Project Manager
EC	Ethics Committee
GCP	Good Clinical Practice
Master Template	Studies conducted in multiple countries must have a master template version of the PIS/ICF which is created according to the lead country's regulations, ethical guidelines and good clinical practice (GCP).
MRC CTU at UCL	Medical Research Council Clinical Trials Unit at University College London
PIS/ICF	Patient Information Sheet / Informed Consent Form N.B these documents will be referred to in parallel throughout this document as one cannot exist without the other
PPI	Patient Public Involvement
PL	Project Lead
RA	Regulatory Authority
SOP	Standard Operating Procedure
TM	Trial Manager
TMF	Trial Master File
TMG	Trial Management Group
TMT	Trial Management Team

2 RESPONSIBILITY AND ROLES

The following table lists the roles relevant to this SOP and a brief description of their responsibilities.

This SOP will be circulated for Read and Understood to all appropriate roles identified in the training matrix.

ROLE	RESPONSIBILITIES
Lead Author (e.g TM / CPM)	• Primary responsibility for the preparation of the PIS/ICF, review, quality control, adaptation to local requirements and collaborator approval. • Ensuring that the PIS/ICF contains appropriate information and is compliant with applicable regulations. • Making any changes to the PIS/ICF througout the duration of the study. • Verifying that the PIS/ICF is approved by the appropriate EC and RA (and any other relevant parties) and receives favourable opinion prior to being implemented in the study. • Ensuring that the final approved PIS/ICFs and related documentation is reviewed, approved and filed in the Trial Master File (TMF).
PPI Contributors	• Assisting with the development and review of PIS/ICF content to ensure it is relevant to, and meets the needs of, potential study participants or those who might read the content on behalf of potential participants (e.g. in paediatric studies).
Reviewers (e.g TMT, TMG Clinicians, Clinical Fellow, Industry Collaborators)	• Reviewing the PIS/ICF and providing written feedback to the lead author; reviewers should ensure the PIS/ICF not only meets the minimum standards but will also be adequate for the study's regulatory needs.
Approvers (CI and PL)	• Reviewing and providing written final approval for the PIS/ICF to the lead author.

3 PROCEDURES

3.1 TEMPLATES

PIS/ICF must be developed using the unit templates in all cases where UCL is the Sponsor of a study or where MRC CTU has been delegated responsibility for PIS/ICF production. These templates are available on SOPbox.

The templates have been designed to include all elements required by the majority of studies, however, additional items may be required (e.g. for some multi-country studies or IMP studies that may be involved in regulatory submissions).

MRC CTU Participant Information Sheet and Informed Consent Form templates

There may be cases where the trial Sponsor is external and requests using their PIS/ICF templates. In this case the trial team should defer to Sponsor decision.

Any decision to use an alternative template for PIS/ICF should be documented in the TMF.

Most PIS/ICFs are expected to be presented on paper, printed from electronic documents. In some settings, in particular internet-based studies, an electronic (online) format might be more appropriate. In this instance, the TMT/TMG should nonetheless adhere to the principles of this SOP as laid out in section 1.1.

3.2 INTERNATIONAL TRIALS: MASTER PATIENT INFORMATION SHEET/INFORMED CONSENT FORM

In the case of multi-country studies, the PIS/ICF may need to be adapted in three key ways:

- Changes in content to ensure adherence to country-specific requirements, including those relating to protection of personal data, all approved GDPR content (where relevant), and privacy laws and regulations;
- Dividing the ICF into separate documents for separate areas of consent, e.g. optional consent items being in a separate ICF to mandatory consent items.
- Translations into local languages, when English is likely not the preferred language for at least a large portion of the local population.

For multi-country studies a “Master” version of the PIS/ICF must be created. This is commonly the PIS/ICF designed and used at the lead country, e.g. England.

The Master template may then need to be adapted according to each country regulations and ethical guidelines as applicable, to create each site-specific version. The local collaborator, monitor or site representatives are responsible for making country-specific adaptations.

The TMT/TMG are responsible for ensuring that the Master PIS/ICF template is prepared according to the lead country’s regulations, ethical guidelines and good clinical practice (GCP).

- The TMT/TMG should ensure that edits to the Master PIS/ICF are made only where appropriate.
- The TMT/TMG should make clear when distributing the Master PIS/ICF to international collaborators which text can be amended and which must not be.

- The TMT/TMG will assign responsibilities to the appropriate country representative for any content changes and/or translations required.

To handle any changes to content (if required):

- The country representative will review the Master PIS/ICF content and tailor it to meet country-specific RA, EC and other requirements;
- The CI, PL and/or TM will be informed of any significant country-specific changes to the Master PIS/ICF before submission to **any** Regulatory bodies or Ethics committees in order to check for consistency across the study. In case of significant changes, the TM will obtain documented approval of the changes from the CI and PL.

The site-specific version will, if applicable, be translated to the preferred language used in that country:

- Translation into the preferred language should be performed by qualified individuals, and a record of who performed the translation should be retained in the TMF. A qualified individual is usually a native speaker of the language to be translated, who is also sufficiently proficient in English to undertake accurate translation of the PIS/ICF. The TMT are responsible for assessing suitability and selection of qualified individuals, this should be based on evidence provided within the qualified individual's CV, and this process should be documented in the TMF.
- If possible, a second independent review should also be sought, to ensure the translation matches the original. This should ideally be perfomed by a health care professional (e.g. a doctor or a research nurse) who has the appropriate scientific and health care qualification and training. The TMT/TMG should obtain from the country representative and/or second reviewer a signed confirmation that the original and translated documents are consistent (e.g a translation verification statement). This should be stored in the TMF.

MRC CTU Translation Verification Statement template

All locally produced versions, including and translations, will need to receive all ethical (and other) approvals, as per local requirements, prior to use in recruiting participants. TMT/TMG should also check that creation of any country-specific versions has not caused any unwanted changes in the document, e.g. changes in formatting or layout.

3.3 VERSION CONTROL

The requirements of the Document Management and Version Control SOP should be followed when versioning informed consent materials.

For further details refer to **Document Management and Version Control** SOP

All approved versions of the PIS/ICF templates must be filed in the relevant section of the Trial Master File (TMF) and in each collaborating centre's Investigator Site File. All previous approved versions of the template should be marked as superseded. The date the new version came in effect must also be documented in the TMF, as during the course of a study different versions may have been applied at different times.

If country specific PIS/ICFs are required, as in an international study, each version of the PIS/ICF must clearly identify the country to which the version applies within the document(s), for example in the header or footer.

A version history document should be created for each trial to record when each version of the PIS/ICF came in to effect. For further details, refer to the version history working instruction.

3.4 DOCUMENT FLOW

Before drafting PIS/ICF content, the TMT should decide how many documents there will be and how they will relate to one another.

Some examples are provided below but these are not exhaustive:

- PIS and ICF are separate – easy to version control updates to each document e.g. participant can take home PIS and consent at a later time.
- PIS and ICF are combined in one document – useful for a short, simple PIS, or for use in countries where site staff express preference of using this format.
- Separate PIS/ICF for biological or other sub-studies – may work best for sub-studies occurring late in the participant's treatment pathway e.g. samples collected at progression, or country specific regulations may dictate separating the documents.

In some circumstances a separate PIS/ICF for registration and randomisation may be considered , for example if a participant is likely to become ineligible for randomisation in the interim . The risk of using a 2 stage consent process should be clearly considered and documented in the trial risk assessment, and other quality management documents such as the monitoring plan, where strategies to quickly identify issues arising from this approach should be described.

The TMT should decide which approach is most suitable for the study and where possible document in the TMF the rationale for choosing the selected approach.

3.5 REQUIRED ELEMENTS

According to ICH GCP E6(R2), the PIS/ICF should, as a minimum, contain the items below. This list is not in order of priority as the priority will depend on the specific trial the PIS/ICF is being developed for, e.g. a low risk observation study will have different considerations compared to a high risk CTIMP:

- That the trial involves research.
- The purpose of the trial.
- The trial treatment(s) and the probability for random assignment to each treatment.
- The trial procedures to be followed, including all invasive procedures.
- The subject's responsibilities.
- Those aspects of the trial that are experimental.
- The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.
- The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.
- The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.
- The compensation and/or treatment available to the subject in the event of trial-related injury.

- The anticipated prorated payment, if any, to the subject for participating in the trial.*
- The anticipated expenses, if any, to the subject for participating in the trial.
- That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.
- That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorising such access.
- That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.
- That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.
- The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.
- The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.
- The expected duration of the subject's participation in the trial.
- The approximate number of subjects involved in the trial.

**Refer to GCP E6(R2) 3.1.9 for further information.*

3.6 TIMING AND RESOURCES FOR DEVELOPMENT

The PIS/ICF should be developed alongside the protocol, and other study-specific documents (including but not limited to Investigator Brochure [IB], SmPC or other product information sources). Please be aware that some funders may require a draft version of the PIS at the initial grant application stage.

3.6.1 CONSENT STATEMENTS

Consent to join each study should be confirmed by participants (or their legal representative) giving written confirmation of consent to a series of statements. The Lead Author should ensure that it is entirely clear and unambiguous on the ICF which items are mandatory and which are optional. The Lead Author along with Reviewers and Approvers should consider whether any consent items should be optional as part of developing the study consent materials.

The following key statements are mandatory for study participation and must always be included:

- The information sheet has been read and understood by the participant/legal representative.
- Their personal identifiers will be stored for the purposes of the trial (which details collected should be specified in the PIS).
- Their medical notes may be looked at by various parties such as sponsor/industry partners/regulators.
- Their participation is voluntary.
- An agreement that they wish to take part in the study.

If potential participants/legal representative cannot agree to any of these, the participant cannot join a given study.

Other statements can be optional for joining the study. Items that might typically be optional include:

- Consent to substudies or future research.
- Consent to samples being used for future research.
- Provision of personal identifiers to allow linkage with public health registries for routinely collected health data.
- Notification to the participant's GP about their study participation.

Consent wording requirements for routinely collected health data may change according to the data provider. Should your trial be planning on collecting routinely collected health data from public health registries, please contact the Trial Conduct Methodology team about your application.

For international trials, please look to each country's regulations about the format of each PIS/ICF. Optional/mandatory statements may differ, or consent for research samples may be required to be in a separate ICF.

3.6.2 OTHER CONSIDERATIONS

Trial teams must consider the following potential issues when designing the PIS/ICF. In some cases it may be best to have separate consent forms and assent forms for the various situations. Some examples are provided below:

Participants lacking capacity (including children) - If the study population includes participants lacking capacity to consent, a legal representative (e.g. parent, carer or legal guardian) must consent on their behalf.

Participant assent - If required by regulations in the country/ies where the trial is taking place, the participant can assent or agree (to the extent to which they are capable). If a participant is able to sign and date the assent form, they should do so alongside their legal representative.

Parent/guardian consent - Trial teams should note and plan for any other country-specific regulations in these situations, for example in some countries where it is a requirement for both parents to attend to provide consent for minors.

Participants who cannot read/write - If a potential participant is unable to read or write (for any reason) to confirm their consent, the PIS should be read aloud to them and they should provide consent orally in the presence of at least one witness. This oral consent should be recorded in writing along with the name of the witness. Trial teams may also consider using thumb print to indicate consent, or if available video recording of participants agreeing to join the trial.

Participants who are unable to consent at the time of trial treatment being administered – If a potential participant requires trial treatment in an emergency but is unable to give assent or consent, and it is not possible to ask for consent from a legal representive, e.g. a critical care trial where participants are very unwell and require trial treatement immediately, if ethically approved, it is possible to administer trial treatment without consent. Consent may then be provided by a parent/guardian/legal-guardian following the emergency. Should the participant become able to provide assent or consent during the course of the study they should be given the opportunity to do so.

Participants who regain ability to consent - In circumstances where a participant is unable to assent or consent at the point of trial entry, a legal representative can provide consent on their behalf. Should the participant become able to provide assent or consent during the course of the study they should be given an opportunity to do so.

Changes in legal representative - In situations where the legal representative of a participant changes during the study, consent must be sought from the new legal representative in order for participant to continue participation in the study.

3.7 PIS/ICF TEMPLATE REVIEW

3.7.1 DOCUMENT-LEVEL QUALITY CONTROL (PRIOR TO USE)

The TMT/TMG should collectively ensure that any PIS/ICFs produced are of high quality. This includes checking that:

- There are no spelling, grammar or typographical errors;
- Information is presented clearly and concisely, without unnecessary use of jargon or complex scientific terminology;
- The documents are correct in relation to the study protocol;
- The documents are adequate for regulatory requirements;
- The ICF document is free of formatting errors that might hinder the clear documentation of informed consent e.g. misalignment between consent form statements and the box used to acknowledge said statement).

Reviewers should ideally include:

- At least one person who has not been involved in the development of the PIS/ICF;
- PPI contributors, if they have not already reviewed;
- TMG clinical members (especially any members not involved in document development so far) or delegated Clinical Fellow;
- Any relevant collaborating groups or industry partners.
- The MRC CTU Protocol Review Committee.

All comments received should be reviewed by the Lead Author(s) of the document and any changes made as appropriate. If extensive or contradictory comments are obtained, the review and revision process may be repeated until the Lead Author, Reviewers and Approvers are satisfied with the PIS/ICF.

This review process should be documented in the TMF, for example by saving key document drafts, annotated copies or copies of communications from reviewers.

In addition to the above, the TMT/TMG should also consider use of a formal checklist approach to confirm the quality of the documents, as this can be helpful in checking for minor errors (e.g. typos).

3.7.2 APPROVAL OF MASTER PIS/ICF

The CI and PL's approval of the Master PIS/ICF must be documented in the TMF (e.g. by filing any correspondence confirming this). The TMT/TMG will then distribute the Master PIS/ICF so that it can be adapted by country representatives to comply with country-specific RA and/or EC requirements.

If any significant changes are required by the country representatives, the CI and PL should approve these again, and this approval should be documented in the TMF.

3.8 ETHICS COMMITTEE AND REGULATORY AUTHORITY APPROVAL

The Lead Author will ensure that written approval of the PIS/ICF is obtained from the appropriate RAs and/or ECs before use at any study sites in a given country.

Note that in a multi-country trial it is possible that parts of the trial, e.g. substudies, may only apply to certain countries. In this case, ethical approval for these apects of the trial should only be submitted to ECs in those countries participating. Clarification should be provided in the cover letters to the ECs of non participating countries so they know not to expect to review substudy PIS/ICFs.

See also Ethics Committee Approval SOP

See also Regulatory Approval SOP

3.9 SITE LOCALISATION OF DOCUMENTS

Collaborating sites will be asked to localise an editable copy of the PIS and ICF, including a local header and contact details for relevant local staff.

Copies of site-specific versions should be sent to the CTU for review prior to site activation and during the course of the study if amendments are made. These should be reviewed on receipt for any issues caused in the process of making the document site-specific (e.g. displacement of important text).

In international trials, local coordinating centres (if these are in place) should take on the responsibility for overseeing creation and review of any site-level adaptation. Please see **Section 3.2** for information on amending the Master PIS/ICF.

3.10 AMENDMENTS TO PIS/ICF

During the course of a study, changes to the PIS/ICF may be required as a result of protocol amendments or the release of new safety information.

The development and review process should follow the process described above for the initial PIS/ICF version. For less significant changes to the PIS/ICF (e.g. formatting, minor wording changes), the review process may be abbreviated, however all changes to the PIS/ICF must be approved by the CI and PL. This approval must be documented in the TMF (e.g. email or TMG minutes).

The TMT/TMG will verify that each revised PIS/ICF is approved by the relevant EC and RA before the new version is used at any investigational sites in a given country. A copy of the revised, approved PIS/ICF must be filed in the TMF alongside relevant EC and/or RA approvals.

3.11 RECONSENT

Depending on the changes made in a PIS or ICF, the TMG (or, if appropriate, TMT) of each study should decide whether reconsent is necessary and appropriate (with the exception of reconsent after transfer of participants between trial sites, which is required by the Participant Transfers SOP). If the TMG/TMT have agreed reconsent is necessary, they should also decide who should be reconsented, i.e. all participants or just a subset.

Where reconsent is not deemed appropriate but it has been decided that new information should be passed onto participants, the TMT should consider creating a participant letter. In some instances the TMT may choose a combination approach of both reconsent and information letter to the participants. See section 3.11.1.

The TMG/TMT should put in place processes to check that participants reconsent in a timely manner, for example, mandatory reconsent logs being completed by all affected sites, or requesting copies of reconsent ICF from all sites. A similar approach should be taken when recording participant letter acknowledgements.

In case of doubt, advice about whether reconsent is required should be sought from the Research Governance Committee.

All decisions about how to inform participants of important changes, and whether or not to ask for reconsent, should be documented, e.g. in meeting minutes.

A decision not to ask participants to reconsent will need to be justified when submitting for ethics and regulatory approval. This reasoning should be clearly set out in the cover letter submitted with the amendment.

3.11.1 INFORMING PARTICIPANTS WITHOUT RECONSENT

When reconsent is **not** deemed necessary but the TMT wish to notify participants of any changes, the following is recommended:

- A participant letter explaining the changes should be developed and EC approval obtained.
- Existing participants should be given the approved letter at their next scheduled visit or via post; they should also be offered the chance to ask their clinician any questions if necessary.
- The TMT should decide which participants receive the letter, e.g. participants on a certain study arm or in a certain comparison, or those remaining on trial.
- The TMT should ensure all participants receiving a letter receive the updated information in a timely manner, e.g. by requesting participating sites to send updated logs of receipt/delivery of the letter.

3.12 INFORMED CONSENT MONITORING

After consent, participants should be given a copy of their signed ICF and PIS. The original should be retained in the Investigator Site File (ISF) and a further copy in the medical notes.

If any copies of the ICF are to be sent to CTU for central monitoring or any other purpose (see **Section 3.14** below for further instructions on storage), direct identifiers must be redacted.

An important part of clinical trial monitoring is ensuring that all study participants have given informed consent to participate, and that this consent is appropriately documented. This oversight includes both the original consent given by the participants when they first entered the trial, and also the timely completion of reconsent processes, if or when these are instigated.

In most cases, some form of centralised monitoring of this process is preferred, possibly linked to the randomisation process (e.g. central review of completed consent forms prior to randomisation, or addition to the randomisation system of a check that consent has been taken appropriately). Further detail about consent monitoring is given in the Monitoring SOP.

See Monitoring SOP for further details about central monitoring of informed consent.

Please note, if TMTs intend for consent forms to be sent to the CTU for central monitoring, specific consent (an optional item on the ICF) should be sought for this from study participants. It should also clearly state that, once monitoring checks have been completed, the ICF will be destroyed and not retained.

The TMT should also ensure that processes are in place to record responses to optional consent items (e.g. with questions on a registration/randomisation CRF) and to act on them accordingly.

Processes for recording consent responses including optional responses and any subsequent actions should be recorded in the Data Management Plan or a working practice document. Where optional consent has been withdrawn during reconsent, the TMT should have a working practice or other action plan in place for notifying statisticians, central laboratories holding participant samples and any other stakeholders as relevant.

3.13 RECTIFYING ERRORS AT CONSENT

Any errors in the consent/reconsent process identified through monitoring (either central or on-site monitoring) should be corrected as soon as possible. Depending on the nature of the error identified, it may be possible to correct it without the need to reconsent the participant. In some cases, full reconsent by the participant may be required. The TMT should discuss any consent errors identified, the potential implications this may have for the continuation of the participant in the trial, and what corrective actions are necessary. When making a decision, the TMT should consider any potential logistical factors whereby full reconsent is not ideal or possible in a timely fashion, e.g a participant lives far away and is not expected back in clinic for a significant period of time.

All of the above should be recorded on the trial deviation log and trial teams should decide on the best course of action to address any errors identified.

Any decisions made by the TMT and all corrective actions deemed required should be documented in the TMF. The consent errors should also be recorded in the trial deviation log.

3.14 STORAGE

It is not recommended for consent forms to be retained long-term at MRC CTU. Where completed ICFs are sent to CTU, the TMT should ensure appropriate measures are in place for short-term secure storage of the consent forms.

Instructions for collecting, storing and destruction of ICFs at CTU should be documented in a working practice or other procedural document.

4 RELATED DOCUMENTS

See also:

- MRC CTU PIS template
- MRC CTU PIS template guidance
- MRC CTU consent form template
- MRC CTU Translation Verification Statement template