Standard Operating Procedure

4.8.2 Participant Information and Consent Form

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Introduction / Background

The International Conference on Harmonisation of Good Clinical Practice (ICH GCP) guidelines and the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research thoroughly describe in detail the use and detail of the participant information sheets and consent forms (PICFs). These principles and requirements apply to all studies conducted by the IMPACCT Trials Coordination Centre (ITCC) and are underpinned by the suite of ITCC Standard Operating Procedures (SOPs).

Objective

This SOP operationalises the national and international requirements by describing:

- the process of developing the master and site-specific PICF(s) for all studies undertaken or auspiced by the ITCC;
- the specific content and detail that needs to be included as part of the master and site-specific PICF(s) for all ITCC studies; and
- the process to be followed if amendments to the master and site-specific PICF(s) are required.

This SOP does not replace other requirements from the ICH GCP, NHMRC and Human Resource Ethics Committee (HREC) documents.

Scope

This SOP applies to all staff involved in clinical studies conducted by the ITCC, including Palliative Care Clinical Studies Collaborative (PaCCSC) and Cancer Symptom Trials (CST), irrespective of individual organisational employment, role or position.

Ownership and Responsibility

The ITCC is responsible for preparing the master PICF and any subsequent amendment as required.

Responsibilities of the IMPACCT Trials Coordination Centre (ITCC)

- To prepare the master PICF and any subsequent amendment(s) for all multi-site ITCC studies and ensure that the contents and detail therein meet the requirements of GCP, the protocol, the approving HREC/s, the recruiting site Research Governance Offices (RGO) and national and international regulations.
- To ensure that the master PICF and any subsequent amendment(s) are provided to the lead site for HREC review and approval as per SOP 6.12 Ethical Approval Review and Reporting.
- To review and approve the site-specific PICF and any subsequent amendment(s) for all recruiting sites prior to local submission for approval by the RGO.

Responsibilities of the Principal Investigator

- To inform the ITCC/Sponsor of any local requirements imposed by the RGO related to the contents of the PICF (e.g. specific text), which need to be included in the master version and approved by the HREC.
- To ensure that the correct Participant Information Sheet and Consent Form (PICF) has been approved (as a master version) by the HREC and subsequently approved for local use by the site RGO and is the only version used at the site

Procedure

1. Preparing the Participant Information and Consent Form (PICF)

- The consent form must meet the requirements of the approving HREC, the NHMRC National Statement on Ethical Conduct in Human Research and ICH GCP guidelines.
- Most HRECs will provide PICF templates containing specific instructions, pre-defined sections, and preferred language recommendations to ensure that all the National Statement and ICH/GCP elements are addressed. These templates are adapted from those developed by the NHMRC for the following types of research and are customised to incorporate any specific requirements of the individual HREC:
    1. Genetic study: non-interventional OR genetic research that has an interventional component that does not involve research on a drug or device.
    2. Interventional study: Involving administration of a drug, device or procedure that is not part of routine care, including all phases of a clinical trial.
    3. Non-Interventional study: Research where no interventional treatment is given to participants other than their routine care.
    4. Health/Social Science Research: Quantitative and/or qualitative research of issues in health and society.
- For each type of study, there are also different categories of PICFs depending on the target recipient who will be reading the document and providing consent:
    1. Self: The potential participant
    2. Person responsible: Persons responsible when the potential participant is unable or not competent to provide consent for themselves
    3. Parent/Guardian: Parents or guardians where the potential participant is a child
- For multi-site studies with sites participating in the National Mutual Acceptance (NMA) system and that are under review by a lead HREC (*refer* SOP 6.12 Ethical Approval Review and Reporting):
    - The ITCC Project Officer or designee will retrieve the appropriate PICF template from the lead HREC's website or request a copy directly from the applicable Research and Ethics Office if not available online.
    - This selected HREC PICF template must be used to draft the master PICF for the study.
- The ITCC Project Officer or designee is to follow all instructions outlined in the template PICF when preparing the master PICF for multi-site studies.
- In addition to the instructions provided within the HREC specific PICF templates adapted from the NHMRC templates, some further considerations are required when preparing the master PICF template for ITCC studies. This is because the PICF template of the lead HREC may not cover additional site-specific requirements of other recruiting site RGOs

(e.g. for catholic institutions), which subsequently need to be included in the site-specific version of the PICF that is based on the HREC approved master study PICF.

- It is essential to ensure that the content and detail in the master PICF meet the requirements of not only GCP, the protocol, and national and international regulations but also the recruiting site RGO to avoid the need for unnecessary amendments to the master PICF, which may emerge during the site-specific assessment stage following initial approval of the study by the lead HREC.

A. Advice on avoiding pregnancy for institutions governed by the Roman Catholic health service

Certain institutions which are part of the Roman Catholic health service do not accept any statements in the PICF to the effect that participants must practise methods of contraception or avoid pregnancy. Under the NMA system, Catholic Health Australia has provided recommended wording for studies involving participants of child-bearing age.

For multi-site studies where pregnancy must be avoided and the approving lead HREC is embedded in the publicly funded health service, Catholic Health Australia's approved wording related to advice on avoiding pregnancy (*refer* to Appendix 2 of the NMA Standard Principles for Operation) must be incorporated as "alternate text for Catholic institutions" in the relevant section of the master PICF for the study. The Catholic wording must be included in the master PICF for all multi-site studies with at least one confirmed participating site that is part of the Roman Catholic health service.

B. Secondary Use of Data

For studies where data that is collected as part of the research project may be used beyond the scope of the study, such as for extended (related research) or unspecified (any future research), appropriate text must be included in the master and/or site-specific PICF clearly explaining the details of the additional use of information that is contemplated and that the participant is asked to provide their consent for the additional secondary use of their data.

C. Data Sharing

For studies involving collaborations and sharing of the data collected as part of the research project with an external party located outside of UTS or Australia, such as an international industry partner or collaborating research group, the master PICF must clearly explain:

1. If the data collected as part of the research project will be shared with an external party and will leave UTS or Australia and the purposes of data sharing.
2. The details of how the data will be transferred, used, stored and destroyed by the external party.

It is imperative that the participant is provided sufficient information to understand what will happen to their data and how it will be used. In addition, a specific data sharing agreement

between UTS and the external party may need to be established.

Other considerations related to data sharing include studies where the participant's personal identifying information may need to be shared with a contracted external vendor for the purposes of the study. For interventional studies, this may include sharing a participant's name, date of birth, and address on a prescription for the study medication shared between the recruiting site and a third-party pharmacy for studies where the study medication is dispensed directly to the participant at home. The master PICF must clearly explain in detail the type of personal identifying information that will leave the site, the reason for this data being shared, how this will be conducted, and who will have access to it. Whenever applicable, it must be emphasised to the participant that UTS/Sponsor will not collect or store any of the participants' personal identifying information.

D. Radiation safety

For studies involving radiation assessments, such as X-Rays, DEXA or CT/MRI scans a site-specific report and authorisation is required. Each report will be accompanied by radiation safety wording to be given to each potential participant within the PICF. Each site has slightly different wording. The wording for each site must be included within the Master PICF and approved by HREC in order to be used by each site.

2. Initial submission of the master PICF for lead HREC approval

- The final draft of the master PICF for a multi-site study will undergo review by the ITCC National Project Officer or designee prior to finalisation.
- Upon finalisation of the master PICF, the ITCC project officer or designee will provide a copy of the final version of the master PICF to the lead site for approval by the lead HREC as per the process outlined in SOP 6.12 Ethical Approval Review and Reporting.

3. Amendments to the master PICF

- The master PICF for all multi-site studies will be amended by the ITCC as required, this may occur in response to but not limited to the following:
    1. Amendment to the protocol
    2. Identification of error or discrepancy
    3. Request by site RGO for the addition of particular information in the site-specific PICF which needs to be included in the master PICF and approved by the HREC
- The current approved version of the master PICF will be amended by the ITCC project officer or designee as appropriate using tracked changes.
- Identification of amendments to the master PICF will be in line with SOP 6.10 Version Tracking.
- The final draft of the updated master PICF for a multi-site study will be reviewed by the ITCC National Project Officer or designee prior to finalisation.

- Upon finalisation of the new version, the PICF will be saved as a clean copy. The ITCC project officer or designee will provide a copy of the final version of the updated master PICF (in tracked and clean format) to the lead site for submission and approval by the lead HREC as per the process outlined in SOP 6.12 Ethical Approval Review and Reporting.

4. Preparation and RGO submission of site-specific PICF for participating NMA sites

- Upon HREC approval of the master PICF for a multi-site study including any subsequent amendments to the master PICF, the ITCC will provide copies of the final approved version of the master PICF to each participating site (refer SOP 6.12 Ethical Approval Review and Reporting).
- The PI or delegated representative at each recruiting site will use the HREC approved master PICF to prepare the site-specific PICF, ensuring that all requirements of their RGO are addressed when drafting the document.
- The final draft of the site-specific PICF must be provided to the ITCC for review and pre-approval prior to finalisation and submission to the RGO for approval per the process outlined in SOP 6.12 Ethical Approval Review and Reporting.
- Some changes to the master PICF that result from requests made by certain RGOs may sometimes not be directly relevant or applicable to other recruiting sites (e.g. inclusion of specific text such as Catholic wording around contraception use).
    - If this is the case, the site RGO must be consulted to determine if an amendment to the current site-specific PICF is required in response to the change in the study master PICF and if the site may continue to use the current RGO approved site-specific version of the PICF instead.
    - Documentation of this correspondence with the RGO must be filed in the relevant section of the ISF.

5. Preparation and HREC and RGO submission of the site-specific PICF for non-NMA participating sites

- For multi-site studies involving a combination of NMA sites and private sites (such as private hospitals) or sites that are not part of the participating NMA jurisdictions and that need to submit single, separate applications to their own HREC or to a private HREC (such as Bellberry):
    - The site Principal Investigator (PI) or their delegated representative (as documented on the Staff Signature and Delegation Log; *refer* SOP 4.2.4 Delegation of Duties) is required to retrieve the approving HREC's PICF template to prepare the site-specific version of the PICF.
    - The site PI or their delegated representative is to follow all instructions outlined in the template PICF when preparing the site-specific PICF version.
- In addition to the instructions provided within the HREC specific PICF templates, the same considerations outlined in Part 1A, 1B, 1C and 1D above must also be incorporated as part of the site-specific PICF for non-NMA participating sites.

- If requested to, the ITCC may provide assistance and support with the preparation of the site-specific PICF for non- NMA participating sites. However, it is a minimum requirement that a copy of the final draft of the site-specific PICF is provided to the ITCC for review and pre-approval prior to finalisation and submission to the HREC.
- The site PI or their delegated representative will submit the final site-specific PICF to the relevant approving HREC per the process outlined in SOP 6.12 Ethical Approval Review and Reporting.
- The same process is to be followed for any subsequent amendments to the site-specific PICF that may be required in response to but not limited to the following:

    1. Amendment to the protocol
    2. Identification of error or discrepancy
    3. Request by site RGO for the addition of particular information within the site-specific PICF

- Following HREC approval, majority of non-NMA participating sites will also be required to obtain additional approval of the site-specific PICF and any subsequent amendment from their RGO as part of the site-specific assessment process (*refer* SOP 6.12 Ethical Approval Review and Reporting).
    - For these sites, the local HREC and RGO review processes coalesce, with RGO review typically triggered in direct response to local HREC approval.
    - The site PI or their delegated representative will usually not be required to prepare a separate submission for the RGO. However, each recruiting site PI must ensure that the appropriate local process is followed to guarantee that all required approvals are obtained.
    - The same requirements apply to private sites required to submit to a private HREC, if these private sites also have a locally defined research governance review process.

Related SOPs

4.2.4 Delegation of Duties
6.10 Version Tracking
6.12 Ethical Approval Review and Reporting

References

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). November 2016 (accessed 03/03/2022)
https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

National Statement on Ethical Conduct in Human Research (2007) - Updated 2018- (accessed 03/03/2022)
https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

National Mutual Acceptance- Single Ethical Review of Multi-centre Human Research Projects, Standard Principles For Operation. November 2018 (accessed 04/03/2022)
https://www.medicalresearch.nsw.gov.au/app/uploads/2018/05/National-Mutual-Acceptance-standard-principles-operation.pdf

History			
Version	Date	Author	Reason
1.0	08/03/2022	C Strauss	New procedure

Approval		
Version	Approval Name	Approval Signature
1.0	Meera Agar