CONSENT TO PARTICIPATE IN HUMAN RESEARCH - PARTICIPANT INFORMATION AND CONSENT

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- All research on humans performed at sites, or by employees, of The Sydney Children's Hospitals Network (SCHN) must comply with applicable Federal and State, legislation, regulation, NSW Health Policy, SCHN Policy, Good Clinical Practice (as described in the TGA Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 1) and the NHMRC National Statement on Ethical Conduct in Human Research.
- **This document**
  - Outlines processes for gaining approval for a Participant Information and Consent Form (PICF) and for collecting Informed Consent for all human participants involved in research conducted across by or at The Sydney Children's Hospitals Network.
  - Applicable to all research and is not limited to Clinical Trials.

CHANGE SUMMARY

- Not applicable – new document.

READ ACKNOWLEDGEMENT

- This Procedure should be read and referenced by any person responsible for collecting informed consent relating to research in humans, across The Sydney Children's Hospitals Network.

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1st February 2016	**Review Period:** 3 years
Team Leader:	Clinical Research Centre Manager	**Area/Dept**: Research

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Purpose/Scope

To ensure that written informed consent is appropriately obtained from the participant or appropriate parent/legal guardian of the participant for every research project conducted by any employee or person conducting research on behalf of The Sydney Children's Hospitals Network (SCHN).

This Procedure should be adhered to for all informed consent obtained for research at SCHN relating to research in humans.

For example, ICH GCP defines informed consent as "The process by which a subject voluntarily confirms his or her willingness to participate in research after having been informed of all aspects of the research 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".

Informed consent is not just about getting someone to sign a form, it is a process. This process begins when initial contact is made with potential research participants or their parents/legal guardians and continues throughout the time the person participates in the research.

Expected Results

It is expected that all SCHN research teams will follow the outlined procedures to ensure all research participants at SCHN are appropriately consented to participate in research.

Compliance with these Procedures will contribute to the safety of research participants at SCHN and will ensure all staff at SCHN are compliant with all regulatory requirements for consenting of research participants.

Consenting Responsibilities

The Principal Investigator (PI) of a research project holds overall responsibility and accountability for ensuring that the participant information statement and informed consent document (PICF) conforms to all relevant policies and is submitted to an appropriate Human Research Ethics Committee (HREC) and the SCHN Research Governance Office (RGO) for review and approval prior to use.

The PI also holds overall responsibility for ensuring that participants are adequately informed about the research and freely consent to participate. However, the PI may delegate the responsibility to appropriately qualified and trained persons the tasks of appropriately and completely informing potential participants/parents/guardians; answering their questions about the research; and obtaining signatures from the persons who can provide legal consent for the participant to participate in the research.

In reviewing ethics applications, the HREC is conscious of consenting processes whereby the PI is also the participant's treating clinician, and the conflict of interest that may arise as a consequence of this involvement. Wherever possible, consenting should be undertaken at arms-length of the PI. If this is not possible, the PI should provide clear justification in the ethics submission of how this conflict of interest will be managed.

Accountability for and responsibility for ensuring that informed consent is obtained before a participant participates in a research study and maintaining informed consent throughout each participant's participation in the research, including the actions of the research team members acting under the PI's delegated authority, at all times remains with the PI i.e. accountability cannot be delegated.

In some cases, a non-clinician member of a study team may be delegated responsibility for obtaining the written consent, however this would usually only be in the case of Low and Negligible Risk (LNR) studies and the planned process would need to be advised to the HREC and RGO.

Delegated research team members completing the informed consent process will comply with the following criteria:

- Be prepared and competent to take on the additional responsibility and feel confident with completing the informed consent process.
- Have a comprehensive understanding of the study protocol, including potential pharmacological interactions/treatment toxicities and the associated disease area (if applicable). For non-drug studies a comprehensive understanding of potential complications and short and long term effects of device or procedures will also need to be within the knowledge base of the team member allocated this additional responsibility.
- Receive appropriate training regarding the research and the informed consent process. All training must be documented on a training log.
- Delegation of duties will be documented on a Signature Sheet (also known as a Delegation Log) and signed by the delegate and PI.
- Regular and effective communication is to be maintained with the Principal Investigator who is ultimately responsible for participant care.

Abbreviations and Definitions

NHMRC	National Health and Medical Research Council
SCHN	The Sydney Children's Hospitals Network
ICH	International Conference on Harmonisation
GCP	Good Clinical Practice
IIR	Investigator Initiated Research
ISF	Investigator Site File
PICF	Participant Information Sheet and Consent Form
PI	Principal Investigator
CI	Co-Investigator
HREC	Human Research Ethics Committee
RGO	Research Governance Office
LNR	Low and Negligible Risk
TGA	Therapeutic Goods Administration

Related Documents

- SCHN Clinical Trials Policy No: 1/A/14:9108-01:00
- Research – Authorisation of Proposals to Conduct Research on Humans Policy No: 1/A/15-9060-01:00
- Research – Human and Animal Research & the NHMRC Act 1992 Policy No: 1/A/12:9030-01:00
- Human Research Ethics Committees - Standardised Patient Information Sheets (PIS), Guideline GL2007_016
- Australian Research Council, National Statement on Ethical Conduct in Human Research, NHMRC, 2007 (updated May 2015)
- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA comments, TGA, July 2000

Participant Information and Consent Form

The PI must ensure an appropriate HREC has approved all master templates (provided by Sponsor for multi-centre clinical research, or created by the PI for Investigator Initiated Research (IIR)) and localised PICFs based on the Master version have been reviewed and approved by SCHN RGO prior to their use. A copy of the signed PICF must be provided to the participant and/or the parent/legal guardian. A checklist outlining all required elements for a PICF is at the end of this Procedure Document. The Participant Information and Consent Form (PICF) is made up of two major elements:

- The Participant Information Sheet which describes in clear non-technical language the research including the burdens on participation and foreseeable risks
- The Consent Form which documents that informed consent has been taken, when and by whom.

1 Procedure

1.1 HREC and Research Governance Approval of PICFs

For all research projects, members of the research team must follow SCHN RGO Policies/Procedures on guidance for submission and approval of PICFs that is provided by the SCHN-approved HREC selected by the researchers.

For multi-centre projects: the master PICF must be approved by a lead HREC acceptable to the SCHN RGO. The PI must provide to the HREC any master template version/s of the PICF provided by external Sponsors or developed by the PI. HREC-approved master PICFs and version/s adapted for site-specific use (localised) must also be approved by the SCHN RGO before use.

For single-site projects that will only be active at one SCHN site: you must provide to the HREC any master version/s of the PICF and site specific versions to RGO.

Recommended standardised NHMRC / HoMER Patient Information Sheets can be accessed via the Research tab on the SCHN intranet or by contacting the HREC officers. A PICF Checklist is found at the end of this document (Appendix 1).

The localised PICF must be submitted with the appropriate site logo and PI name and contact information. It is not necessary to include CI or Study Coordinator names on the PICF. If you want to use the same PICF across multi sites within the SCHN network you may use the SCHN logo.

The site version of the PICF should include the following statement at the end of the sheet:

This project has been authorised to be conducted at [name of site]. If you have any concerns about the conduct of this study at this site please do not hesitate to contact the SCHN Research Governance Officer on (02) 9845 3011.

1.2 Version Control and Filing of PICF Documents

PICFs must be clearly version controlled with the name of the document, version number and date of version in the footer of the document.

An unsigned copy of each approved PICF version must be retained in the study files. All superseded approved versions of PICFs should be clearly marked as SUPERSEDED. After the study is completed, an unsigned copy of each approved PICF version must be archived with the other study documents.

All signed PICFs should be archived along with all other study documents for the duration of time required by the HREC, NSW Health Policy, Australian Federal and/or state Laws and Regulations, or ICH GCP requirements, whichever specifies the longest duration of document retention. At the time of writing of this Procedure the local standard for SCHN paediatric projects is: *a minimum of 15 years or until the youngest participant has, or would have, reached the age 25.*

1.3 The Consenting Process

1.3.1 Discussion with a participant/parent/guardian and child /young person

It is ideal to include young people in the consenting process; however distinct from medical treatment consent in Australia, due to the ambiguity of Australian legislation related to medical research consent, it is a SCHN requirement that for all research participants under the age of 18 years, informed consent of a minor participant must be underpinned by informed consent by their parent/guardian before any research-related procedures are carried out. NB The requirement of parental consent may be waived if a specific exemption for parental consent has been obtained for the project, from the lead HREC, in accordance with Section 4.2.9 of The National Statement.

If the PI or delegate perceives that the young person has capacity to provide some level of consent it is acceptable for the young person to co-sign the consent form with the parent/guardian.

The HREC and RGO approved PICF must be given to the participant/parent/guardian (or legally acceptable representative) for review prior to signing to allow adequate time and

opportunity for them to read the information sheet. The PI or delegate should also describe to the participant/parent/guardian in clear terms the information contained within the PICF and answer to the satisfaction of the participant/parent/guardian any questions that the participant/parent/guardian might have.

The study staff must ensure that informed consent is obtained in a setting free of coercion and undue influence.

The study staff must provide the consent giver as much time as needed in the informed consent discussion to address all questions and concerns. It may be appropriate to ask the participant/parent/guardian to consider some of the below points, as well as any other points the PI or delegate thinks are important:

- How often they will be required to attend or receive assessments, or appointments?
- Will the frequency of attendance at the hospital for appointments affect their employment or a young person's school attendance or activities? If so, will the place of employment or school be supportive?
- Are there any required visits that they will not be able to attend for any reason e.g. planned holiday, planning to migrate to another area too far away to permit continuation in the research? If so, they should advise the research team at the beginning so the research team can determine with reference to the Protocol and/or Sponsor if a means of fulfilling the protocol requirements can be identified.
- If there is requirement for completion of a diary or questionnaire, will they be able to complete this at the required frequency?

After completing the informed consent discussion, the study staff member must ensure that the participant/parent/guardian understands the information provided in the participant information statement and consent form. One way of ensuring the information has been understood is to ask the participant/parent/guardian to describe the study and its processes and to ask a question like "Do you understand enough about this research to be able to explain it to someone at home?"

Confirmation of the appropriate completion of the consenting process must be written into the patient or study notes by the person performing the consent process. At a minimum this confirmation should confirm the name of the research project being participated in, the date of the consent, the process of consent, the version of the consent document, and that a copy of the fully signed consent has been given to the participant/parent/guardian.

1.3.2 Signing of the PICF

When the study staff form the view that the participant/parent/guardian understands the information fully, the staff may ask the participant (or legally acceptable representative) if he or she accepts to be enrolled in the study.

For participants who are minors, at least one parent or legally acceptable representative is required to give written informed consent, as per NHMRC National Statement, section 4.2.7 (i).

The written informed consent form should be correctly completed and signed and dated by the person giving the consent and the PI or HREC-approved delegate who conducted the informed consent discussions.

Depending on the risks involved in a young person's participation in a study, an HREC may request that both parents provide informed consent in writing. This will be assessed by the HREC and stated in the approval letter granting permission to conduct the study.

1.3.3 Who gets copies of the PICF

A copy of the correctly completed and fully signed and dated written informed consent must be provided to the participant/parent/guardian prior to participation in the research.

1.3.4 Implied Consent

In some circumstances, consent may be implied instead of signing an actual document. Use of implied consent is limited to certain situations, for example, in survey or questionnaire type research where completion of the questionnaire *implies* the persons participation. Implied consent can only be used with HREC approval.

1.4 Updating the PICF and Re-Consent

The informed consent process does not cease once an informed consent form has been signed, the practice of providing information is an ongoing process throughout a research study.

If during the course of a study new information becomes available that may be relevant to the participant or may affect the willingness of the participant/parent/guardian to continue the participant's participation in the research, that information must be presented to the participant/parent/guardian in an appropriate manner including in writing and at the earliest opportunity possible in line with the seriousness and significance of the new information to the participant. This may require the writing of new documents or revision of documents to be given to participants/parents/guardians. New documents and documents which have been revised require review and approval by the HREC supervising the project and the SCHN RGO.

The participant/parent/guardian should be made aware of new information and invited to consent to continuing participation (re-consent) by signing the revised approved PICF. This re-consenting process should take place as soon as possible after the revised PICF has been approved by the HREC and RGO, and prior to any further study activities being performed for that participant. Confirmation of the new consent should be recorded in the participant's study or patient file.

1.4.1 Re-consenting participants who reach the age of 18 years

If during the course of a study the participant reaches the age of 18 years, the participant should be approached to re-consent on their own behalf to continue their participation in the research. This includes re-consenting participants who have contributed samples to biobanks. All information must be presented again to the participant at the earliest opportunity possible. The participant should be invited to consent to continuing participation (re-consent) by signing the currently approved PICF and the process should be documented in the participant file with dates. A copy of the fully signed consent document should be given to the participant to keep, and a copy should be kept in the participant's study or patient file.

1.4.2 Use of an Interpreter

It is imperative that a professional interpreter is present to ensure participant consent is valid and that the participant has understood the information provided when the purpose, methods, demands, risks and potential benefits of the research is communicated to a person who is not fluent in English.

1.5 Withdrawal of Consent

Participants/parents/guardians may decide to withdraw from some elements or all participation in a research project at any stage. In doing so, they must understand that withdrawing consent will not affect the participant's care, their relationship with the treatment team or their relationship with SCHN.

Some studies will have a revocation/withdrawal of consent document that can be signed and filed. In the event that a participant's decision to withdraw is communicated verbally, the study investigator/study staff will need to document a description of the circumstances, sign and date the declaration and file this in the participant's study file. The declaration must specify the reason for withdrawal.

If a participant/parent/guardian withdraws consent for participation in a research project the date of notification of withdrawal should be recorded in the participant files, along with an outline of the stated reason.

1.5.1 Use of data after withdrawal of consent

All PICF documents should contain reference to what data will or will not be used after a participant/parent/guardian withdraws from the research and that any information collected to date will or won't be destroyed. The participant/parent/guardian should be reminded of this wording and this activity should be recorded in the participant file.

If, for some reason, there is no wording in the PICF in regards data usage after withdrawal of consent, the following must occur:

- the level of future data usage consented to by the participant/parent/guardian should be clearly recorded in the participant file in detail, and;
- any action must be completed to ensure the site is in compliance with this altered consent for use of data.

1.6 Storage of Informed Consent Documents

- A clean (blank) copy of the approved PICF must be kept on file.
- During the research, the original signed and dated consent forms will be filed in the participant's source document file.
- At SCHN, the written consent along with all study documentation and a copy of the study specific medical records must be kept for at least 15 years or until after the youngest participant has, or would have reached the age of 25, whichever is longer.
- The Sponsor of the research should be consulted prior to any destruction of study specific documentation.

References

- NHMRC: National Statement on Ethical Conduct in Human Research 2007 (updated May 2015)
- TGA: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95, July 2000)
- ICH-GCP: International Conference on Harmonisation (**ICH**) website: http://www.ich.org
    - ICH Guideline for Good Clinical Practice (E6(R1), June 1996)