CLINICAL RESEARCH - CONSENT TO PARTICIPATE IN HUMAN RESEARCH

POLICY©

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, Good Clinical Practice and the NHMRC National Statement on Ethical Conduct in Human Research.
- Informed consent is integral to the right to information in the Australian Charter of Healthcare Rights and recognised in Professional Codes of Conduct. Additionally, the National Safety and Quality Health Service Standards require all hospital and clinical trial services to have informed consent processes that comply with legislation, lawful requirements, and best practice.
- 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.

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 August 2023	**Review Period**: 3 years
Team Leader:	Quality Research Manager	**Area/Dept**: Research Ethics & Governance

CHANGE SUMMARY

- Not applicable – this is the first version

READ ACKNOWLEDGEMENT

- Read Acknowledge Only – 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.

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Purpose/Scope

To ensure that 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.

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.

In obtaining and documenting informed consent, all persons involved in the research must comply with the National Statement Chapter 2.2, the National Clinical Trials Governance Framework (including the Roles and Functions of Identified Positions) and applicable regulatory requirements and adhere to ICH GCP R2 and to the ethical principles that have their origin in the Declaration of Helsinki.

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.

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.

The PI maintains accountability and responsibility for any delegated activity over the course of the research project. This includes ensuring that informed consent is obtained prior to a participant's commencement in a research project and maintaining informed consent throughout the participant's involvement in the research, unless otherwise waived. This responsibility includes the actions of the research team members delegated under the PI's authority to obtain informed consent, i.e. accountability cannot be delegated.

In some cases, a non-clinician member of a study team may be delegated responsibility for obtaining 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

Abbreviation	Definition
APREG	The Australian Paediatric Research Ethics and Governance Network
NHMRC	National Health and Medical Research Council
e-Consent	Electronic consent
e-Signature	Electronic signature
ICH-GCP	International Council for Harmonisation for Good Clinical Practice Guidelines
ISF	Investigator Site File
PI	Principal Investigator
PICF	Participant Information Sheet and Consent Form
HREC	Human Research Ethics Committee
LNR	Low and Negligible Risk
RGO	Research Governance Office
SCHN	Sydney Children's Hospitals Network
TGA	Therapeutic Goods Administration

Related Documents

1. Research – Authorisation to Commence Human Research in NSW Public Health Organisations PD2010_056
2. Human Research Ethics Committees - Standardised Patient Information Sheets (PIS), Guideline GL2007_016
3. Australian Paediatric Research Ethics and Governance Network (APREG) Guidelines – Clinical trials, the child participant and consent: A practical guide for investigators and sponsors

Equipment and Supplies

Participant Information and Consent Form (PICF)

The PI must ensure that an appropriate HREC has approved all Master templates provided by the Sponsor and site-specific versions of the PICFs based on the Master versions 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.

The PICF comprises of two major elements:

- The participant information sheet which describes the research in clear non-technical language, including the burdens on participation and foreseeable risks
- The consent form which documents that informed consent has been taken, when it was taken, and by whom.

Policy

1.1 Informed Consent Elements

For informed consent to be valid, it must be:

- Freely given
- Specific to the research and/or intervention
- Given by a person who is legally able to consent

Section 2.2 of the NHMRC National Statement provides guidance on what information should be provided during the informed consent discussion, based on the principle that participants are entitled to make their own decisions about participation in research and should be given adequate information on which to base those decisions.

While child consent to medical treatment is legislated, child consent to participate in research is yet to be adequately reflected in Australian law, and similarly the National Statement does not provide any guidance in this area. The Australian Paediatric Research Ethics and Governance (APREG) Network have developed Clinical trials, the child participant and consent: A practical guide for investigators and sponsors to provide guidance to sponsors and researchers on the practical aspects of seeking informed consent in research involving children. This guidance document is considered best practice by the APREG members and is to be read in conjunction with relevant sections of the National Statement and any other legislative or policy requirements.

1.2 HREC and Research Governance Approval of PICFs

For all research projects to be conducted at SCHN, members of the research team must follow SCHN RGO procedures on guidance for submission and approval of PICFs that are approved by an appropriate HREC that is accredited to review research involving children.

For multi-centre projects: the master PICF must be approved by a lead HREC with paediatric accreditation. A full list of registered HRECs is available on the NHMRC website. 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 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 information sheet and consent form templates can be accessed via the Research Ethics website under the Consent & Recruitment section. A site-specific PICF Checklist can be found on the SCHN Research Governance website.

The site-specific PICF must be submitted with the appropriate site logo and PI name and contact information. It is not necessary to include any associate (sub-) Investigators or Study Coordinator names on the PICF. If you want to use the same PICF across multi sites within SCHN 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 or SCHN-Governance email (SCHN-Governance@health.nsw.gov.au) and quote [the STE number]

1.3 Version Control and Filing of PICF Documents

PICFs must be clearly version controlled with the name of the site conducting the research project, the document name, version number and date of version in the footer of the document. Both Master and site-specific document control should be provided in the footer.

Example:

[The Children's Hospital at Westmead or Sydney Children's Hospital]
Master PICF version ##, dated dd-mmm-yyyy
Site PICF version ##, dated dd-mmm-yyyy

An unsigned copy of each approved PICF version must be retained in the investigator site folder for each study. All superseded approved versions of PICFs should be clearly marked as superseded. For research teams that utilise electronic investigator site files, there must be a clear process for marking documents as superseded in the document management system. After the study is completed, an unsigned copy of each approved PICF version must be archived with the other study documents.

A copy of all signed consent forms in their entirety should be sent to Health Information Unit (HIU) to be scanned into the participant's medical record. The original PICF is to be filed with the research team and a copy of the signed consent form should be given to the participant for their own personal records. Original PICFs may be destroyed only after they have been uploaded and undergone risk-based quality control checks for certification as described in the SCHN Procedure (2019-025): Clinical Research – Creating Certified Copies.

1.4 The Consenting Process

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

It is standard practice 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. However, defining the capacity of a child to understand what is being asked of them will vary with the type of research being conducted and the level of maturity of the participant. Assessment of capacity is a matter of clinical judgement and it is the responsibility of the PI to determine if a participant has decision-making capacity to consent.

(Note: The legal definition of a child differs in the different States of Australia. As a result, sometimes 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).

For clinical trials where there are participants aged between 16 and less than 18 that are deemed not to have capacity to consent, these must be approved by the Guardianship Division of the NSW Civil and Administrative Tribunal (NCAT), under Part 5 of the Guardianship Act 1987. A young person under 18 years may have the ability to consent to research provided that they have the capacity to understand the nature of the research and the consequences of their participation. If the PI 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.

All children and young persons should be provided with age-appropriate information in a format that is suitable for them. A written information sheet, short videos, presentations, pictures and/or story books are examples of tools by which investigators can help explain a research project to a young person.

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.

Staff conducting the consent discussion must ensure that informed consent is obtained in a setting free of coercion and undue influence.

Consent discussions may occur over multiple visits and days. 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?

Note: All medical questions must be answered only by medically-qualified persons working within their scope of practice and appropriate to oversee the use of an unregistered medicine, if applicable.

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 documented in the patient’s medical record or written and filed in the participant’s study folder by the person performing the consent process. At a minimum this documentation should confirm the name of the research project being participated in, the date, start and end times of the consent discussion, what topics were discussed in 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.

1.4.2 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 PI-approved delegate who conducted the informed consent discussion(s).

Depending on the risks involved in a young person’s participation in a study, a 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.

Use of Impartial Witness

If the person being asked to provide consent is unable to read, then a witness (i.e. a person who is present during the entire informed consent discussion) signs the consent form in addition to the consent provider and the PI (or delegate).

The witness must be:

- Impartial, i.e. not a member of the study team or under the authority of the PI; and
- Over the age of 18 years
- Not acting as the interpreter

By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained and understood by the participant or their parent/legal guardian, and that informed consent was freely given.

Use of an Interpreter

If the person being asked to provide consent is not fluent in English, then it is essential that a professional and accredited interpreter is present to ensure participant consent is valid and that the consent giver has understood the information provided when the purpose, methods, demands, risks, and potential benefits of the research is communicated (refer to NSW Health Policy Directive PD2017_044 - Interpreters – Standard Procedures for Working with Health Care Interpreters).

The interpreter should sign and date the consent form to confirm that the information in the consent form has been read to them by a qualified interpreter. They should also document their National Accreditation Authority for Translators and Interpreters (NAATI) certification number on the consent form.

Bilingual research staff that have been delegated to consent are encouraged to deliver the informed consent discussion directly in their other language, if fluent, without using an interpreter, but the use of unaccredited bilingual staff to interpret is inappropriate.

Translated information sheets and consent forms can be provided, however on their own and without sighting from a professional interpreter, is not considered sufficient to fully capture informed consent as the participant may not be able to have their questions answered by the PI. The English version of the PICF must be signed in all cases.

Note: the interpreter cannot act as a witness in any consent process where they are already involved as they are not considered independent and impartial.

1.4.3 Telehealth/Electronic consent (e-Consent)

In-person, face-to-face consenting should be undertaken wherever possible. Where this is not possible, consent via telephone, videoconference (telehealth) or electronic consent (e-Consent) may be applicable.

Electronic informed consent refers to the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive websites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent.

All tools, forms and materials require HREC and RGO approval prior to use, as well as with any subsequent modifications.

Telehealth/e-Consent can be undertaken when:

- It is part of a project protocol approved by a HREC
- Consent is obtained under the Guardianship and Administration Act where the participant is unable to consent for themselves and a person responsible cannot be present to consent in person
- Additional or follow-up consent is required when there is a change to the PICF and it would place undue burden on the participant to return to hospital (e.g. a participant lives a great distance from the hospital, their physical condition makes it a burden for

them to attend hospital, or when participants have completed the trial and are no longer attending the hospital).

The e-consent must contain all the elements of informed consent as required by the National Statement Section 2.2 and outlined in Section 1.3 of this procedure.

E-consent can be used to either complement or replace paper-based informed consent processes to meet the needs of the research participant throughout their time on the study. Research participants should be provided the option to use either paper-based or electronic informed consent.

E-consent can occur at the SCHN site where both the investigator and participant are, or it may occur remotely where the participant and their family review the consent document in the absence of any study staff delegated to obtain informed consent. If the consent process is conducted remotely and there are no study staff to witness, the electronic system used to capture e-consent must include a method to ensure that the person electronically signing consent can verify their identity.

The system used to obtain e-consent must be secure with restricted access to ensure study participants confidentiality.

There will be some research projects where it may not be possible or necessary to verify that the person signing the informed consent is the participant or parent and/or legal guardian. Investigators should take a risk-based approach when considering whether participant identity verification is necessary, eg a low risk research project will not necessarily warrant this process.

Electronic Signature (e-Signature)

Electronic signatures (e-Signatures) must comply with all applicable requirements as those of a handwritten signature, and the systems used to capture these signatures should be subject to ICH GCP Section 5.5.3 and international best practice guidelines. The electronic system used to capture e-consent must also record the date that consent was provided.

Consideration must be given as to how the e-signature is created and whether the electronic informed consent document can be produced in hard copy for review by the participant upon request.

For further information, refer to SCHN Procedure (2019-149): Clinical Research – Use of Electronic Signatures.

1.4.4 Who receives copies of the PICF?

Refer to Section 1.2 of this Procedure.

Copies of e-consent provided to the participant can be either paper or electronic. If the e-consent uses hyperlinks, podcasts or other websites specifically related to the research, the information in these hyperlinks should be included in any printed paper copy, if provided. If researchers are unable to provide consent evidence as source data to the participant's medical record, the consent must be documented as a clinical progress note detailing when consent was obtained, who provided consent and what the participant consented to.

1.4.5 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 consent to participation. Implied consent can only be used with HREC approval.

1.4.6 Opt-Out Consent

Chapter 2.3 of the National Statement provides guidance on opt-out approach to consent. This method can be used in the recruitment of participants where information is provided to the potential participant regarding the research and their involvement and where their participation is presumed unless they take action to decline to participate.

While an opt-out approach makes it possible for people to make an informed choice about their participation, this choice can only be made if participants receive and read the information provided, and they understand that they are able to act on this information in order to decline to participate.

If a participant decides to opt-out, their personal, health or sensitive information cannot be used in the research project or sent to a third party. The PI is responsible for ensuring that the participant's data is removed from use within the research project.

Researchers who wish to use this approach must obtain HREC approval prior to use.

For further information refer to the SCHN Ethics website resources section.

1.5 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.

Researchers should consider how burdensome the re-consent process will be on participants and their family when determining whether to obtain written re-consent. For example, a change in PI to a study will impact on existing study documents and require an update to informed consent documents. However, while active participants should be made aware of new trial contact information, this can be done verbally or via an email/letter. A full written obtained re-consent is not necessary in this case. Sites and sponsors should re-consent participants when the changes are so significant that it would require a thorough consent discussion to re-explain the study and that the participants will need to document their agreement to remain in the study.

The participant/parent/guardian should be made aware of new information and invited to consent to continuing participation 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 patient's medical record and participant's research file.

1.5.1 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 consent on their own behalf to continue their participation in the research. This includes consenting participants who have contributed samples to biobanks and/or clinical data registries. All information must be presented again to the participant at the earliest opportunity possible.

The participant should be invited to consent to continuing participation 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, with one copy sent to HIU, and another copy kept in the participant's study file.

1.6 Documentation of Informed Consent

The informed consent process must be documented in the participant's medical record by the consenting PI or delegated research staff member.

This documentation should be performed irrespective of what method was used to obtain consent, ie written, remote, electronic, verbal.

The record should include the following (at a minimum):

- Name of clinical trial/research project
- Date and time the consent discussion took place
- Who was present during the informed consent discussion, including the interpreter if applicable
- If remote consent was conducted, a brief reason for why this method was used and confirmation it was conducted as per Ethics approval
- Confirmation of who signed the consent form and that a copy was provided to the person consenting

Note: if an interpreter was used via telephone or videoconference during an informed consent discussion and is unable to physically sign the consent form, documentation of their accreditation number and the job reference number should be documented in the informed consent record.

1.7 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. If a participant's decision to withdraw is communicated verbally, the study investigator/study staff will need to document a description of the circumstances in the participant's medical record, and this record can be printed and filed in the participant's study file.

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

1.7.1 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 there is no wording in the PICF in regards data usage after withdrawal of consent, the following must occur:

- the level of future data and any biospecimen 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.

1.8 Storage of Informed Consent Documents

- A clean (blank) copy of all approved PICFs must be kept on file.
- During the research, a copy of the original signed and dated consent forms will be sent to SCHN HIU, with the original, or certified, signed and dated consent form filed in the participant's research folder. A copy of the original signed and dated consent form will also be provided to the participant.
- After the study is completed, all signed or certified copies of PICFs should be archived along with all other study essential documents for the duration of time required by HREC, NSW Health Policy, Australian Federal and/or State laws, or ICH-GCP requirements, whichever is longest.
- 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.
- The Sponsor of the research should be consulted prior to any destruction of study specific documentation.

Bibliography

- ICH-GCP: International Conference on Harmonisation (ICH) website: http://www.ich.org
- ICH Guideline for Good Clinical Practice Annotated with TGA comments 9 Nov 2016
- ICH Guideline for Good Clinical Practice (E6 (R2), November 2016)
- National Health and Medical Research Council – National Statement on Ethical Conduct in Human Research, NHMRC, 2007 (updated 2018)
- NSW Civil and Administrative Tribunal (NCAT) https://ncat.nsw.gov.au/case-types/guardianship/clinical-trials.html
- US Food and Drug Administration (FDA) Guidance Document: Use of Electronic Informed Consent Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors, December 2016