Informed Consent in Research

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Historical setting – Human Research

•1946 - Nuremberg Code

A set of 10 principles developed for human research as a result of the Nuremberg Trials post World War 2 with the opening statement:

“The voluntary consent of the human subject is absolutely essential”

•1964 Declaration of Helsinki

A set of ethical principles for human research.

7 revision up to 2013 including a section on Informed Consent.

•1996 ICH Guideline for Good Clinical Practice

Internationally accepted standard for conducting clinical trials. Revised 2016.

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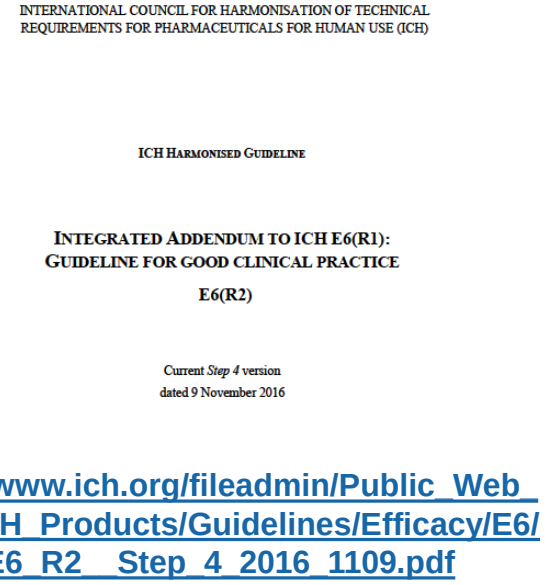
Guidance Documents

https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#block-views-block-file-attachments-content-block-1


INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE (ICH)

ICH HARMONISED GUIDELINE

INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE

E6(R2)

Current *Step 4* version
dated 9 November 2016

http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf

https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018

What is Informed Consent? - ICH

ICH Glossary 1.28 –

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.

National Statement Guiding Principle on Research Participation

“The guiding principle for researchers is that a person’s decision to participate in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.”

The National Statement on Ethical Conduct of Human Research

Informed Consent Procedures

Prior to the beginning of a trial, investigators should:

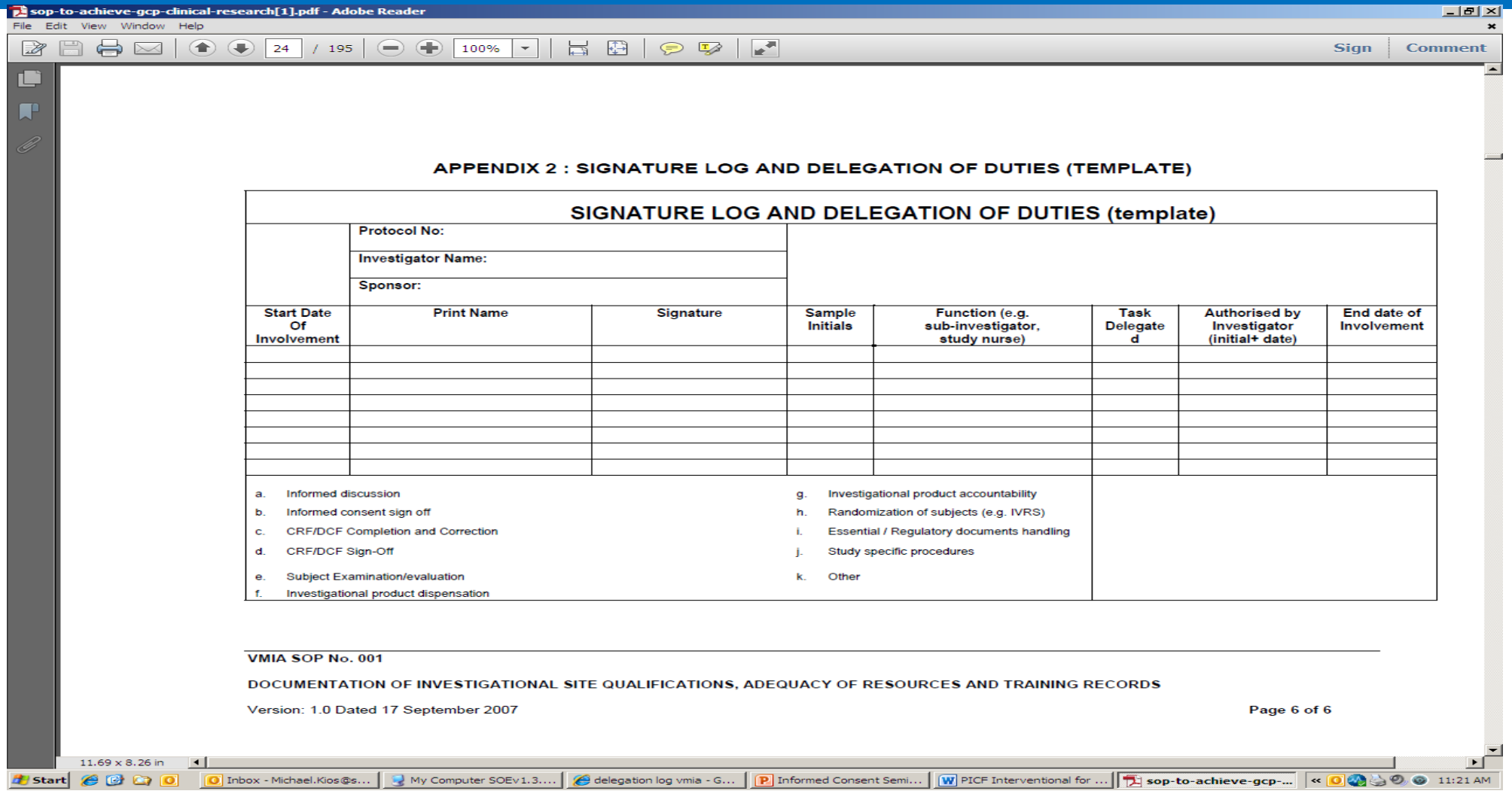
- obtain HREC written approval of the written informed consent form and any other written information to be provided to participants
- ensure the person or persons taking the informed consent have an adequate understanding of the trial and of the informed consent process.

The investigators must comply with all applicable regulatory requirements and the local HREC requirements.

Who Can Take Consent?

- The investigator, or a person designated by the Principal Investigator, should fully inform the participant of all pertinent aspects of the trial including the written information
  - Designation should be fully documented prior to the consent process in the delegation log.
  - Includes sub-investigators, research nurses, study site coordinators.

Delegation Log



APPENDIX 2 : SIGNATURE LOG AND DELEGATION OF DUTIES (TEMPLATE)

SIGNATURE LOG AND DELEGATION OF DUTIES (template)

Protocol No:

Investigator Name:

Sponsor:

Start Date Of Involvement	Print Name	Signature	Sample Initials	Function (e.g. sub-investigator, study nurse)	Task Delegated	Authorised by Investigator (initial+ date)	End date of Involvement

a. Informed discussion
b. Informed consent sign off
c. CRF/DCF Completion and Correction
d. CRF/DCF Sign-Off
e. Subject Examination/evaluation
f. Investigational product dispensation
g. Investigational product accountability
h. Randomization of subjects (e.g. IVRS)
i. Essential / Regulatory documents handling
j. Study specific procedures
k. Other

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Informed Consent Communication

The aim of Informed Consent is mutual understanding between researchers and participants.

This aim requires an opportunity for participants to ask questions and to discuss the information and their decision with others if they wish.”

Informed Consent Requirements

- The delegated person should be fully informed about the project.
- Participants should be given ample time and opportunity for inquiry before deciding to participate.
- All questions about the trial should be answered to the satisfaction of the participant.
- Consent should be taken in the right environment
  - Not in public areas
  - Not when the patient is in distress

The Consent Process

Must:

- Avoid coercion
- Contain no language waiving or appearing to waive the participant’s legal rights
- Be understandable to the participant or witness or legal representative
- The purpose of the trial.
- The participant's responsibilities.
- The compensation and/or treatment available to the participant in the event of trial related injury.

Participant Information and Consent Form PICF:

Informed consent is documented by means of a written, signed and dated informed consent form (PICF).

Participant Information and Consent Forms mostly follow the NHMRC standardised templates https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/how-to-make-an-hrec-application-for-clinical-trials

Participant Information and Consent Form (PICF)

- **There are 20 sections in the PICF – Delete any sections that are not relevant to your study.**
- **Participants may take the PICF home without signing following Informed Consent Interview**
- **Participants may withdraw their participation in a trial without reason.**

13 Different PICF Templates

PICF Interventional for Self
PICF Interventional for Person Responsible/Medical Treatment Decision Maker
PICF Genetic for Self
PICF Genetic for Person Responsible/Medical Treatment Decision Maker
PICF Interventional for Parent and Guardian
PICF Genetic for Parent and Guardian
PICF Participant Partner Pregnancy
PICF Non-Interventional for Self
PICF Non-Interventional for Person Responsible/Medical Treatment Decision Maker
PICF Health and Social Science for Self
PICF Health and Social Science for Person Responsible/Medical Treatment Decision Maker
PICF Non- Interventional for Parent and Guardian
PICF Health and Social Science for Parent and Guardian

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PICF

https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/how-to-make-an-hrec-application-for-clinical-trials

Participant Information Sheet/Consent Form

Interventional Study – *Adult providing own consent*

An **Interventional Study** is defined as administration of a drug, device or procedure that is not part of routine care, including all phases of a clinical trial.

Instructions for Creating a Participant Information Sheet/Consent Form

- **This template is a guide only.**
- For projects that do not involve trialling a clinical drug, procedure or device, one of the other participant information and consent form templates should be used.
- If more than one Participant Information Sheet/Consent Form is required for your research project, please label the different forms clearly for the different participant groups. Please note that if there is a sub-study, a separate form is required.
- There are 20 numbered sections in this template. Please ensure that all relevant sections are included and numbered appropriately in your final document. These headings are included to ensure that all the National Statement and ICH/GCP elements are addressed.
- You should delete any headings and sections that are not relevant to your study and/or modify paragraphs so that they are relevant to your study.
- In this template, there are prompts for the content of your Participant Information Sheet/Consent Form (in *orange italics*) and instructions regarding the format of your document (in *blue italics*). Please ensure that you delete all prompts (*orange italics*) and instructions (*blue italics*) from the final document.
- **Preferred language** recommendations for use in your Participant Information Sheet are in black text with a border around paragraphs. Ensure that the border is removed from the 'Preferred language' sections in the final document. Note that this formatting does not apply to section 20 or to the Consent Form.
- If institutional letterhead/logo is to be used, leave space for the letterhead/logo in accordance with the institution's requirements.
- Include the version date of the document in the footer of each page. Do not use the 'automatic' date insertion function.
- Use the '1 of X' pagination option. Ensure that all references to version date or pagination in the text are correct and consistent with the information in the footer.

PICF – 20 Sections (Interventional for Self)
What Does Participation Involve?

1. Introduction
2. What is the purpose of this research?
3. What does participation in this research involve?
4. What do I have to do?
5. Other relevant information about the research project
6. Do I have to take part in this research project?
7. What are the alternatives to participation?
8. What are the possible benefits of taking part?
9. What are the possible risks and disadvantages of taking part?
10. What will happen to my test samples?
11. What if new information arises during this research project?
12. Can I have other treatments during this research project?
13. What if I withdraw from this research project?
14. Could this research project be stopped unexpectedly?
15. What happens when the research project ends?
16. What will happen to information about me?
17. Complaints and compensation
18. Who is organising and funding the research?
19. Who has reviewed the research project?
20. Further information and who to contact

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The Consent Process – National Statement

(a) any alternatives to participation;

(b) how the research will be monitored;

(c) provision of services to participants adversely affected by the research;

(d) contact details of a person to receive complaints;

(e) contact details of the researchers;

(f) how privacy and confidentiality will be protected; (Storage)

(g) the participant's right to withdraw from further participation at any stage, along with any implications of withdrawal, and whether it will be possible to withdraw data;

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The Consent Process – National Statement

(h) the amounts and sources of funding for the research;

(i) financial or other relevant declarations of interests of researchers, sponsors or institutions;

(j) any payments to participants;

(k) the likelihood and form of dissemination of the research results, including publication;

(l) any expected benefits to the wider community;

(m) any other relevant information, including research-specific information required by the National Statement.

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Obtaining Informed Consent

- Before participation in the trial the written informed consent form (PICF) should be signed and personally dated by **the participant and by the person conducting the informed consent discussion.**
- If a participant or legally acceptable representative is unable to read, an impartial witness must be present during the entire informed consent discussion, and that discussion be held in an appropriate language.

Once Consent is obtained…

- A copy of the signed and dated written informed consent form and any other written information must be given to the participant.
- The original is filed in the study site master file.
- Copies of any updates during the trial should be given to the participant.

When to take consent

- Consent must be given *before* any study related procedures are performed
- Consent must be obtained prior to the performance of any procedure solely for the purpose of verifying a participant's eligibility for a trial
- PICF must be signed *prior* to participation in the trial
- Procedures, performed as part of a participant's routine care can be undertaken prior to giving consent

National Statement Guideline 2.2.5

Consent may be expressed orally, in writing or by some other means, depending on:

(a) The nature, complexity and level of risk of the research; and

(b) The participant's personal and cultural circumstances.

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When is a New PICF required?

- The written PICF should be revised whenever important new information becomes available that may be relevant to the participant's willingness to continue participation in the trial

Essentially when the risk-benefit ratio changes

- new information – pre-clinical, foreign data
- Newly discovered contraindications
- New contact personnel
- Protocol or Investigator Brochure amendments

- **Communicate with Research Support Service if you need advice or urgent approvals are needed**

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Revised PICF

- New participants should sign the revised PICF
- Have active participants review and sign new PICF at their next visit
- Previous participants may need to be informed
- Version control : ensure new version numbers and filing of each version is complete
- **Use the Barcoded PICF**

Translation of PICFs & Interpreters

For non-English speaking participants:

- A PICF that has been translated by an accredited translator into the participant's native language and approved by HREC should be provided to the participant.
- All consent discussions should take place with the participation of an accredited interpreter who will counter sign the consent form to confirm their involvement in the consent process.

Translation of PICFs & Interpreters

For non English speaking participants (HREC approval required):

- Where a translated PICF is not available the participant should be provided with the PICF in English and informed consent should be held with the participant and an accredited interpreter.
- The interpreter signs the PICF stating that they are satisfied that the informed consent process, as explained on the PICF, has been fully explained to the participant and they believe the participant has understood the project and their involvement.

Translation of PICFs & Interpreters

For non English speaking participants:

- The interpreter is the interpreter and cannot act as a witness to the informed consent.
- A family member should not act as an interpreter unless approved by HREC.

Use of Witnesses

Is the Witness:

- Witnessing the participant's signature

OR

- Witnessing the accuracy of the consent process

A witness is not required by the National Statement or ICH GCP, but may be an institutional HREC requirement.

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Use of Witnesses

- If a participant is unable to read, an impartial witness should be present during the entire informed consent discussion

An impartial witness is independent of the study.

- The PICF should be read and explained to the participant

- The participant should give oral consent and sign/date the PICF if capable

Use of Witnesses

- The witness signs and dates the PICF
- The witness (to the consent process) attests that:
  - The information was given accurately
  - Was understood by the participant
  - That informed consent was given freely
- The witness is NOT giving consent on behalf of the participant
- A signature witness only witnesses signing of the consent form.

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Vulnerable Subjects - ICH

A Human Research Ethics Committee should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid to trials that may include vulnerable subjects.

1.61 Vulnerable Subjects

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate.

Vulnerable Participants
National Statement Section 4.3

Vulnerable Participants include:

- Patients with incurable diseases and emergencies
- Unemployed or impoverished persons
- Prisoners and residential care patients
- Ethnic minorities, homeless, nomads, refugees
- Minors (under the legal age of consent)
- Those incapable of giving consent
- Mentally incapacitated e.g. Alzheimer's disease

These relationships may compromise the voluntary character of participants' decisions, as they typically involve unequal status, where one party has or has had a position of influence or authority over the other.

Emergency Situations

- In emergency situations, when prior consent of the subject is not possible, the consent of the subject's legally acceptable representative, if present , should be requested (ICH 4.8.15)
- If this is not possible, enrolment of the participant should follow procedures described in the protocol and approved by the HREC i.e. Procedural Authorisation
- The participant should be informed about the trial as soon as possible and consent to continue participation should be requested

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HREC and Emergency Research

HREC may approve research to be conducted without prior patient consent if:

- It is likely that the research will lead to increased understanding about, or improvements in, the care of this population, and
- The requirements of relevant jurisdictional laws are taken into account, and

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HREC and Emergency Research

- Any risk or burden of the proposed research to this particular participant is justified by the potential benefits to him or her, and
- As soon as reasonably possible, the patient and/or the patient's relatives or legal representatives should be informed of the patient's inclusion in the research and of the option to withdraw from the research without any reduction in quality of care .

- National Statement 4.4.1 and 4.4.14.

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Medical Treatment Planning and Decisions Act 2016

- **The Medical Treatment Planning and Decisions Act 2016 came into effect in Victoria on 12 March 2018. This replaced the Medical Treatment Act 1988.**
- In regard to research, the previous procedure for the "Recruitment of Incompetent Patients into Research" was based on the Guardianship and Administration Act (GAA). Sections relating to guardianship in research in the GAA have been repealed.
- The new "Recruitment of Incompetent Patients into Research Procedure" has been uploaded to **PROMPT** where it is available to Monash Health employees.

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Recruitment of Incompetent Patients into Research

If participant is expected to recover in a reasonable time:
Do not recruit.

A medical research procedure may be administered in the following ways:

- **Permitted under the Advance Care Directive**
- **Consented by the Medical Treatment Decision Maker**
- **"Medical research procedure without consent"**

Note: If a participant is recruited the Investigator must record in the medical records:

- **Patient has no decision making capacity**
- **Patient is unlikely to recover in a reasonable time**
- **Provide reasons for each of the above**

Requirements for recruitment

HREC Approval

Determine if there is:

- **Advance Care Directive**
- **Medical Treatment Decision Maker**

→

A medical research procedure may be administered if:

- **Permitted under the Advance Care Directive**
- **Consented by the Medical Treatment Decision Maker**

When Unable to Locate Advance Care Directive or Medical Treatment Decision Maker

Medical Research Practitioner Believes:

- **The medical research procedure would not be contrary to person's values**
- **No more risk than is inherent in the person's condition**
- **There is reasonable possibility of benefit compared to standard care**

After administering the medical research procedure:

Practitioner to sign a certificate to be sent to Public Advocate and HREC stating:

- **Patient has no decision making capacity**
- **Decision maker cannot be identified**

Note:
The patient must be informed and given the option to continue when decision making capabilities are attained.
The Decision Maker be informed if found and given the option to continue.
A certificate must be sent every 30 days.

VCAT can be consulted for any matter, question or dispute.

Reference: Medical Treatment Planning and Decisions Act 2016. Please note this slide is illustrative and does not cover all aspects of the Act

Consenting Children

- Consent of a child 16 or over must be obtained and is considered the same as an adult consenting

- For children under 16 who have the ability to understand the nature, risks and consequences of the study:
  - Consent must be obtained AND
  - This would be the same as an adult consenting

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Consenting Children

- For children under 16 without the necessary competence to fully understand:
  - Child's parent/legal guardian must *consent*
  - The child must *assent* unless unable to communicate
  - Refusal of the child to assent should be respected unless the child would receive therapy for which there is no recognised alternative

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Version Control

Version Control of a PICF for Multi-Site Research

There may be more than one Master Participant Information Sheet/Consent Form if special consent requirements apply (e.g. consent forms for parents/guardians of children, persons responsible, participant continuation).

➢ **Master Participant Information Sheet/Consent Form**

The Master Participant Information Sheet/Consent Form is for the Coordinating Principal Investigator (CPI) to submit where the Participant Information Sheet/Consent Form is identical for each site in a multi-centre study. The CPI or their delegate must submit a Master Participant Information Sheet/Consent Form to the reviewing HREC. A Master Participant Information Sheet/Consent Form contains the required wording applicable to all study sites, and includes the name and contact details of the reviewing HREC. It should be a generic form for multi-centre research (i.e. no site letterhead).

➢ **Use of Master Participant Information Sheet/Consent Form at sites**

Following HREC approval, the Master Participant Information Sheet/Consent Form must be used at all sites the HREC has approved. The approved document may only be modified to reflect individual sites' details. Permissible changes are:

- Letterhead of the site
- Name of the site where recruitment is to occur
- Name and contact details of the site PI
- Name and contact details of the person dealing with complaints at the PI's organisation
- Local governance changes to the page footer (see instructions below)

➢ **Site Master Participant Information Sheet/Consent Form**

Where there is a specific site policy and standard wording is required by an organisation (e.g. for religious reasons or site policy), the CPI/delegate may also submit a Site Master Participant Information Sheet/Consent Form for review by the HREC.

The Site Master Participant Information Sheet/Consent Form with the special site-specific wording must include the:

- Letterhead of the site that has the special policy requirements
- Name of the site where recruitment is to occur
- Name and contact details of the site PI
- Name and contact details of the person dealing with complaints at that site
- Name and contact details of the reviewing HREC
- Master Participant Information Sheet/Consent Form version date (on which the Site Master Participant Information Sheet/Consent Form is based) and the Site Master Participant Information Sheet/Consent Form version date in the footer of each page
- Front page explanatory statement, e.g. "Based on the *[project title] [HREC Reference Number]* Master Participant Information Sheet/Consent Form *[Version date]*

➢ **Both the Master and the Site Master Participant Information Sheet/Consent Form must be approved by the reviewing HREC. The version date must be the same as that which received HREC approval.**

➢ **Use of footer for version control**

For example:
A Master Participant Information Sheet/Consent Form was approved by a HREC on 17 August 2011 and there is no requirement for a Site Master. The local governance Participant Information Sheet was adapted at a site on 14 September 2011.

Template

Master Participant Information Sheet/Consent Form *[Date]*
[Site Name] Site Master Participant Information Sheet/Consent Form *[Date]* *(Complete if required)*

Local governance version *[Date]* (Site P.I. use only)

Text above the line relates to Master (and Site Master if required) version tracking of **HREC approved versions**.

Text below the line is for tracking of local governance versions that have had details changed for a particular site and do not require HREC approval (i.e. contact details).

Complete

Master Participant Information Sheet/Consent Form 17 August 2011

Local governance version 14 September 2011

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Monash Health PICFs

- Must be created from Master document
- Engage ‘Tracking’ before making any changes
- Insert Monash Health logo
- Insert site specific Investigator(s) and site details
- Insert footer details per guidelines or in the format:

  e.g “Monash Health Main PICF V1.0 dated 27 May 2019 based on Master Main PICF V1.0 dated 01 May 2019”
- Insert Monash Health Radiation Statement (if applicable)
- Insert Monash Health reimbursement arrangement (if applicable)
- Insert Deborah Dell’s details as the local complaints contact person
- Insert Michael Kios’s details as Local Governance Officer

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Participant Information and Consent Form (PICF)

- **Monash Health Logo**
  (On Information Sheet, Consent Form, Withdrawal Form)
- **Check contact details on all relevant sections**
- **Check radiation section** – **Select correct option**
  – **insert RSO required wording**
- **Complaints section to include:**
  Deborah Dell
  Human Research Ethics Manager
  Phone: (03) 9594 4611
  Email: Deborah.Dell@monashhealth.org

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Participant Information and Consent Form (PICF)

- **Footer to include version number and date**
- **Where Monash Health is not the reviewing HREC:**
  The footer needs to include the Master version number and date as well as a Monash Health version number and date.
- **Send the approved Clean PICF to research@monashhealth.org for barcoding**
- **New PICF – New Version Number & Date (Page Numbering)**

***** Pay Attention to Detail**

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Barcoding

Barcoding is required for all Monash Health Participant Information Sheets and Consent Forms for Medical Records purposes.

- Submit request for bar-coding to Research@monashhealth.org along with:
  - Study title
  - Monash Health local reference number
  - Clean versions of Monash Health PICFs (Word)
  - Evidence of approval of Monash Health PICFs

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Office of Research Integrity

http://ori.hhs.gov/TheResearchClinic

THE OFFICE OF RESEARCH INTEGRITY

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Questions

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Progress Reports

Since 2015, there is an annual submission date of 30 April for all progress reports. For more information please visit our website:

http://www.monashhealth.org/page/Research/Human_research_ethics/Instructions_to_researchers_for_Human_Research_Ethics_Committee_application/

Progress Report Forms:

https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting

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Research Support Program

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Research Support Program

Monash Health – Monash University Agreements

Shared Approach to Research for Future Funding

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2019 Seminar Series

Date	Topic
Wednesday 06 March 2019	Research Agreements and Indemnities This seminar will cover the following items: • Various types of research agreements • Monash Health & Monash University funds administration • Research Support Program for future research funding • When indemnities are required and their acceptability
Wednesday 03 April 2019	Safety Reports & Annual Research Reports: SAE - SUSAR - USADE - SSI - USM Progress - Final - Project Who? - What? - When? - Where? - How?
Tuesday 07 May 2019	Human Research Ethics Committee (HREC) Applications Single Site – Multi Site - Beginning to End Making submissions via ERM
Tuesday 04 June 2019	Site Specific Assessment (Governance) Applications Projects Reviewed by Non-Monash Health HRECs Making submissions via ERM
Monday 15 July 2019	Informed Consent in Research
Tuesday 13 August 2019	Low Risk Research Applications via ERM & Quality Assurance Submissions
Wednesday 18 September 2019	Research Ethics & Governance Overview Study Site Master File & Essential Documents Case Report Forms - Source Documents, Data Retention - Record Keeping - Archiving
Wednesday 09 October 2019	Post Approval Submissions & Monitoring ERM - Amendments - Reports - Deviations Processes - Forms - Audits
Monday 11 November 2019	Topic to be announced….

Research Support Services

Research Governance Seminar Series 2019

For Guidance to facilitate Good Clinical Research Practice

12.30 – 1.30 pm

Translational Research Facility
Seminar Room 2
Level 2 (Ground Floor)
Monash Medical Centre – Clayton

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HREC Meeting Dates 2019

HREC Meetings

SUBMISSION DEADLINE	MEETING DATE
16 January	31 January
13 February	28 February
20 March	04 April
10 April	02 May
15 May	30 May
19 June	04 July
17 July	01 August
21 August	05 September
18 September	03 October
16 October	31 October
13 November	28 November (& 05 December overflow)

Low Risk Meetings

SUBMISSION DEADLINE	VIRTUAL MEETING DATE
16 January	31 January
06 February	14 February
20 February	28 February
06 March	14 March
20 March	28 March
03 April	11 April
17 April	26 April
03 May	09 May
15 May	23 May
29 May	06 June
12 June	20 June
03 July	11 July
17 July	25 July
31 July	08 August
14 August	22 August
04 September	12 September
18 September	26 September
09 October 2018	17 October
23 October	31 October
06 November	14 November
20 November	28 November
27 November	05 December (& 12 December overflow)

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