



1. Purpose

The purpose of this SOP is to:

- (1) Outline the process for development, review and approval of written informed consent forms;
- (2) Define the content requirements for written informed consent forms;
- (3) Outline procedures for research sites to administer informed consent to potential study participants in compliance with governing regulations.

2. Responsibilities

Research Site: Responsible for ensuring the local research team adheres to ICH Good Clinical Practices and the procedures as outlined in this SOP concerning the administration of informed consent.

Methods Centre: Responsible for developing written informed consent forms and providing research sites with procedures to ensure compliance with governing regulations.

3. Procedures

3.1 *“Free and informed consent refers to the dialogue, information sharing and general process through which prospective subjects choose to participate in research involving themselves.”*
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

Development, Revision and Approval of Informed Consent Forms

- 3.2 Unless otherwise stated in the study specific work instruction, the procedures outlined in this SOP will be followed for both randomized controlled trials and non-randomized controlled trials.
- 3.3 During study start-up, the Methods Centre (MC) will develop a written informed consent form (ICF) template according to the study specific protocol.
- 3.4 The MC will use the ICF Template Development Checklist (see Appendix 4.1) to ensure the ICF meets regulatory requirements.
- 3.5 If applicable, the ICF template should be forwarded to Health Canada, and any other governing regulators, to obtain approval.
- 3.6 If applicable, any changes suggested by Health Canada, and any other governing regulators, should be reviewed and if deemed appropriate by the Principal Investigator, incorporated into the ICF.
- 3.7 The ICF template will then be submitted to the Methods Centre Research Ethics Board (REB) for approval. Any suggested changes from the REB will be reviewed and incorporated if deemed appropriate by the Principal Investigator.
- 3.8 The MC will then provide the research site with the finalized ICF template.
- 3.9 The research site should adapt the ICF template content to meet local requirements. This includes translating the content to the languages used at the site.
- 3.10 The research site will provide the locally updated ICF to the MC for approval prior to submission to the local Research Ethics Board (REB).



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- 3.11 The MC will review the research site specific ICF to ensure compliance with the study protocol and ICH GCP section 4.8.10. This review will be documented on the Site ICF Review and Approval Form (see Appendix 4.2).
- 3.12 Once approved by the MC, the research site will submit the site specific ICF to the local REB for review and approval.
- 3.13 If applicable, the research site will make revisions to the ICF as required by the REB. Any revisions must be reviewed by the MC and documented on the Site ICF Review and Approval Form.
- 3.14 Once approved by the REB, the version of the approved ICF and approval letter should be forwarded to the MC.
- 3.15 Whenever revision to the ICF is necessary, steps 3.7-3.12 should be followed.

Content Requirements for Informed Consent Forms

- 3.16 The ICF should contain all items outlined in ICH GCP section 4.8.10.
- 3.17 The ICF should contain sections outlining the following:
- 3.17.1 Protocol Title
 - 3.17.2 Qualified Investigator contact details
 - 3.17.3 Purpose of research
 - 3.17.4 Description of research
 - 3.17.5 Potential risks and benefits
 - 3.17.6 Participation
 - 3.17.7 Confidentiality
 - 3.17.8 Contacts regarding study and research related questions
 - 3.17.9 Study participant, legally acceptable representative and research site staff signatures/dates.
 - 3.17.10 Version of ICF document
- 3.18 The language used in the ICF should be non-technical and should be understandable to the participant, the participant's legally acceptable representative, or impartial witness.
- 3.19 Translation of the ICF to another language should be carried out by a qualified or certified individual.

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- 3.20 Individuals delegated by the qualified investigator to conduct informed consent should be qualified by training and experience to perform this task.
- 3.21 Only the version of the ICF that has been approved by the REB should be used to conduct informed consent.
- 3.22 Given the nature of the critical care population (i.e. unconscious and sedated), many participants who are eligible for studies will not be able to give fully informed consent themselves. In these cases the legally acceptable representative will be approached for consent.



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- 3.23 Whenever possible, the consent process will follow a physician update regarding the participant's clinical status to the participant/participant's legally acceptable representative.
- 3.24 An oral discussion should take place between the participant and/or participant's legally acceptable representative, and research site staff outlining all aspects of the study, including the risks and anticipated benefits, which are necessary for the participant to make the decision to participate in the study.
- 3.24.1 The legally acceptable representative may give informed consent in person. This is the optimal condition.
- 3.24.2 Whenever permissible by the local REB, the legally acceptable representative may give informed consent via telephone. The information provided and the decision regarding participation made by the legally acceptable representative should be confirmed by a witness (refer to local policies for specific procedures). A follow-up signature on the ICF will be obtained from the legally acceptable representative at the earliest opportunity.
- 3.24.3 When applicable, the study participant should be given the opportunity to provide confirmatory consent (assent) when and if they become able to do so during the study period.
- 3.25 The prospective participant, or the participant's legally acceptable representative, should be given adequate opportunity to discuss and contemplate the information provided in the ICF.
- 3.26 If the participant or the participant's legally acceptable representative is unable to read the ICF, an impartial witness should be present during the entire informed consent discussion and should confirm with the participant's legally acceptable representative that they understand the information being presented prior to a decision regarding study participation is made.
- 3.27 Prior to any procedure referred to in the protocol being performed, the ICF should be read, understood, signed and personally dated by the participant or legally acceptable representative and by the individual who conducted the informed consent discussion except for telephone consent as outlined in 3.22.2.
- 3.28 Research site staff should document that informed consent was performed and the outcome of the discussion in the study participant's medical chart.
- 3.29 Prior to participating in the study, the participant, or the participant's legally acceptable representative, should receive a copy of the signed and dated written informed consent form and any other written information provided to the participant. Due to the nature of the critical care setting, consent is often obtained outside of regular business hours or via telephone. In these cases, a follow-up signature on the ICF will be obtained from the legally acceptable representative at the earliest opportunity. A copy of the fully signed ICF will be provided to the legally acceptable representative once available.
- 3.30 The fully signed original ICF should be kept with the site regulatory files.
- 3.31 Neither the qualified investigator or study team members should coerce or unduly influence a participant to participate or continue to participate in a study.
- 3.32 If new information becomes available during the study that may be relevant to the participant's willingness to continue in the study, a new ICF should be written. This new version, approved by the MC and REB, should be read, understood, signed and personally dated by all study participants, or their legally appointed representative, who remain active in the study, as well as any new participants.



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3.33 When in doubt about an issue involving free and informed consent, researchers should consult their local REB for advice.

4. Appendix

4.1 ICF Template Development Checklist

4.2 Site ICF Review and Approval Form

5. References

5.1 Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

5.2 Food and Drug Regulations, Division 5: Drugs for Clinical Trials Involving Human Subjects

5.3 ICH GCP Section 4.8: Informed Consent of Trial Subjects



ICF Template Development Checklist

Study Title:	
Principal Investigator:	
Type of Study:	<input type="checkbox"/> RCT <input type="checkbox"/> Non-RCT
ICF Developed By:	
Version Reviewed:	
Reviewed By:	
Date Reviewed:	

Please select the boxes of topics covered in the informed consent. If they are not covered in the informed consent, please provide the reason why.

As per ICH: Good Clinical Practices section 4.8.10, the following essential elements are required to be incorporated into the Informed Consent Form.

GCP Ref (4.8.10)	Essential Element	Y	N	N/A	Location (ICF pg #)
a	The trial involves research				
b	The purpose of the trial				
c	The trial treatment and the probability of for random assignment to each treatment				
d	Description of all study procedures (including invasive procedures)				
e	The patient's responsibilities				
f	The aspects of the trial that are experimental				
g	Reasonably foreseeable risks and inconveniences to the patient				
h	Reasonably expected benefits. When there is no intended clinical benefit to the patient, the patient is made aware of this.				
i	Alternative treatments and procedures available to the patient, including any potential benefits or risks.				
j	Compensation and/or treatment available to the patient in the event of a trial related injury				
k	Any anticipated payment or compensation for participation in the trial.				
l	Any anticipated expenses to the patient for participation in the trial				
m	The patient's participation in the study is completely voluntary. The patient may refuse to participate or withdraw from the trial at any time, without any loss of benefits to which the patient is otherwise entitled.				
n	Monitors, auditors, REBs, regulators may be granted direct access to the subject's original medical records for verification of clinical trial procedures/data without violating the confidentiality of the patient, to the extent permitted by the applicable laws. Signing the consent form is authorizing such access.				
o	Records identifying the patient will be kept confidential. Any publications resulting from this trial will not reveal the patient's identity, confidentiality will be maintained.				
p	The patient will be informed in a timely manner of any information that becomes available relevant to the patient's willingness to continue participation.				
q	The person to contact regarding patient rights and in the event of a trial related injury (usually REB chair)				
r	Foreseeable circumstances in which the patient's participation in the trial may be terminated.				
s	The expected duration of the patient's participation in the trial				
t	The approximate number of patients involved in the trial.				



Site ICF Review and Approval Form

Study Title:	
Principal Investigator:	
Type of Study:	<input type="checkbox"/> RCT <input type="checkbox"/> Non-RCT
Research Site:	
Qualified Investigator:	
ICF Version Reviewed:	

Please verify that the above referenced ICF contains the essential elements as required by ICH GCP section 4.8.10.

GCP Ref (4.8.10)	Essential Element	Y	N	N/A	Location (ICF pg #)
a	The trial involves research				
b	The purpose of the trial				
c	The trial treatment and the probability of for random assignment to each treatment				
d	Description of all study procedures (including invasive procedures)				
e	The patient's responsibilities				
f	The aspects of the trial that are experimental				
g	Reasonably foreseeable risks and inconveniences to the patient				
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i	Alternative treatments and procedures available to the patient, including any potential benefits or risks.				
j	Compensation and/or treatment available to the patient in the event of a trial related injury				
k	Any anticipated payment or compensation for participation in the trial.				
l	Any anticipated expenses to the patient for participation in the trial				
m	The patient's participation in the study is completely voluntary. The patient may refuse to participate or withdraw from the trial at any time, without any loss of benefits to which the patient is otherwise entitled.				
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s	The expected duration of the patient's participation in the trial				
t	The approximate number of patients involved in the trial.				

ICF approved? Yes No ➡ If "No," please comment:

Reviewed By:

Name

Date