

SOP Title:	Informed Consent Form Requirements		
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1.0 PURPOSE

This standard operating procedure (SOP) describes the requirements for the informed consent form (ICF) and the process for waiving or obtaining and documenting initial and ongoing informed consent.

2.0 POLICY STATEMENT

Free and informed consent lies at the heart of ethical research involving human research participants. The Research Ethics Board (REB) must review all consent documents and procedures, including recruitment methods. Investigators must obtain informed consent from the potential research participant or from his/her legally acceptable representative prior to conducting any study-related procedures, unless a waiver of the requirement of informed consent has been granted by the REB.

3.0 DEFINITIONS

See Glossary of Terms

4.0 RESPONSIBILITY

All REB members and REO Personnel are responsible for ensuring that the requirements of this SOP are met.

The Researcher is responsible for providing the REB with a detailed description of the rationale for a consent waiver or the consent documents and a description of the consent process. The Researcher also is responsible for providing a description of the recruitment methods and recruitment materials (if applicable).

When a written ICF is used, the Researcher, the research sponsor and the REB are jointly responsible for ensuring that the ICF contains all of the basic elements of consent and the applicable additional elements of consent. The REB is responsible for verifying that the ICF (if applicable) contains the required elements.

The REB is responsible for determining whether informed consent exemptions or waivers are applicable and appropriate.

The REB Chair or designee is responsible for reviewing ICFs or changes to ICFs if the changes meet the criteria for delegated review.

5.0 PROCEDURES

5.1 General Informed Consent Form Document Requirements for All Studies

- 5.1.1 Use language in the ICF that is as nontechnical, as practical and understandable to the participant or the participant's substitute decision maker (SDM) as ranked in the Health Care Consent Act – and the impartial witness where applicable;
- 5.1.2 Use a signature page that has a statement indicating that the participant discussed the information contained in the ICF with the researcher, had all questions answered, and agrees to participate in the study. The page must allow the participant (or SDM) to print his/her name, sign and date beneath this statement;
- 5.1.3 Use a signature page that has a statement beneath the participant's signature that the researcher discussed the ICF with the participant or the legally acceptable representative and answered all questions. The page must allow the researcher to print his/her name, sign and date beneath this statement;
- 5.1.4 If the participant or SDM is unable to read, use a signature page that also has a statement that the participant understands the information in the ICF and agrees to participate in the study. The page must allow the person assisting with the consent process (either an impartial witness or a translator) to print his/her name, sign, and date beneath this statement;
- 5.1.5 Unless otherwise approved by the REB, use the SickKids logo on both the first page and the signature page of the ICF.
- 5.1.6 Include the consent version date and page numbers in the footer of all pages of the consent.

5.2 Specific Informed Consent Form Documentation Requirements

- 5.2.1 Although not all listed elements will be required for all research studies, the REB may ask the researcher to explain why omitted elements are not included for a particular project.
 - A statement indicating that the individual is being invited to participate in a research project;
 - A statement of the research purpose, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, the number of participants involved at SickKids and all sites, a description of research procedures and an explanation of the responsibilities of the participant;
 - All reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation;
 - An assurance that prospective participants:

- are under no obligation to participate; are free to withdraw at any time without prejudice to preexisting entitlements;
- will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation;
- will be given information on their rights to request the withdrawal of data or human biological materials, including any limitations on the feasibility of withdrawals;
- Information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;
- Measures to be undertaken for the dissemination of research results and whether participants will be identified directly or indirectly;
- The identity and contact information of a qualified designated representative who can explain scientific aspects of the research to participants;
- The identity and contact information of the appropriate individual outside of the research team whom participants may contact regarding possible ethical issues in the research;
- An indication of what information will be collected about participants and for what purpose; an indication of who will have access to information collected about the identity of participants, a description of how confidentiality will be protected, a description of the anticipated uses of data; and information indicating who may have a duty to disclose
- Information about payments, including incentives for participants, reimbursement for participants, reimbursement for participation-related expenses and compensation for injury,
- A statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm.

5.3 Specific Documentation Requirements for Clinical Trials

5.3.1 The SickKids Principal Investigator must register a clinical trial in a public trials registry if the study prospectively assigns participants to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome

5.3.2 The ICF for a clinical trial must include the elements required for all studies (Section 5.2 above) and, in addition, the following elements:

- The trial treatment(s) and the probability for random assignments to each treatment;
- A description of those procedures that are investigational and those that are standard of care;
- Information on stopping rules and when the researchers may remove participants from the trial;
- Details on access to the new drug upon trial completion;

- The alternative procedure(s) or course(s) of treatment that may be available to the participant, and their important potential benefits and risks;
- For research involving more than minimal risk, an explanation as to whether compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- That monitors, auditors, the SickKids REB, and the regulatory authorities (where relevant) will be granted direct access to the participant's health records for verification of clinical trial procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written ICF, the participant or the participant's SDM is authorizing such access;
- A statement indicating where applicable clinical trials will be registered and publicly accessible on the Web. For applicable clinical (drug) trials subject to FDA regulations, the following statement must be included on the ICF. : A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

5.4 Specific Documentation Requirements for Research Studies Involving the Collection of Human Biological Material

5.4.1 The ICF for a research study that seeks consent from prospective participants to collect human biological materials must include the elements required for all studies (Section 5.2 above) and, in addition, the following elements:

- The type and amount of biological materials to be taken;
- The manner in which the biological material will be taken, and the safety and invasiveness of the procedures for acquisition;
- intended uses of the biological materials including any commercial use;
- The measures employed to protect the privacy and minimize risks to participants;
- The length of time the biological materials will be kept, how they will be preserved, location of storage (i.e. Company/Institution Name, City, Country) and processes for security, access and disposal, if applicable;
- Any anticipated linkage of biological materials with information about the participants;
- The researcher's plan for handling results and findings, including clinically actionable information and incidental findings.

5.5 REB Review of Required Elements of Informed Consent

5.5.1 The REB members will review the proposed consent process for appropriateness, and the proposed ICF(s) for general readability, for appropriateness of the language and content and for the inclusion of the applicable elements per the organization's guidelines and all applicable regulations;

5.5.2 The REB will ensure that the proposed consent process and ICF provide the necessary elements and conditions for free and informed consent.

- 5.5.3 The REB will review the proposed ICF to ensure that it contains adequate information to safeguard the privacy and confidentiality of research participants;
- 5.5.4 The REB may require a separate ICF for optional procedures or sub-studies (e.g., tissue, blood, genetic testing or specimen banking);
- 5.5.5 Following the review, the REB may approve the ICF(s) as submitted or require changes;
- 5.5.6 When changes are required by the REB and are made by the Researcher, the REB or designee will review the ICF(s) to confirm that the required changes have been made and that the version date has been updated;
- 5.5.7 When the changes meet the criteria for delegated review, the revised ICF will be provided to the REB Chair or designee for review and approval;
- 5.5.8 When changes do not meet the criteria for delegated review, the revised ICF will be reviewed at the next Full Board meeting.

5.6 Revisions to the Informed Consent Form

- 5.6.1 The ICF must be amended whenever important new information becomes available that may be relevant to the participant's consent and willingness to continue to participate.
- 5.6.2 Any revisions made to the approved ICF must be submitted to the REB for review and approval prior to use. Refer to SOP-IV.06.001, Ongoing Review Activities for amendment request submissions to the SickKids REB.

6.0 REFERENCES

See References