Holland Bloorview Research Ethics Board (REB)

Informed Consent Elements Checklist

**(1) ICF elements required for ALL studies**

Information that the individual is being invited to participate in a research project

A statement of the research purpose

Identity of the researcher

Identity of the funder or sponsor

Expected duration and nature of participation

Number of participants involved at Holland Bloorview and all sites

Description of research procedures, including an explanation of the participant’s responsibilities

All reasonable foreseeable risk and potential benefits to the participant and in general that may arise from research participation; when there is no intended clinical benefit to the participant, the participant should be made aware of this

Assurance that the prospective participants:

Are under no obligation to participate

Are free to withdraw at any time without prejudice to pre-existing entitlements

Will be 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 and a description of the process for this to occur as well as for obtaining their ongoing consent

Will be given information on their rights and the process 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

Indicate the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors

A statement concerning any personal benefits that may accrue to the qualified investigator

The 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

Information indicating who may have a duty to disclose information collected and to whom such a disclosure could be made

Information about any proposed data linkages and the likelihood that identifiable data will be created through the linkage

Information about payments, including incentives 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

A statement that outlines the process for termination of participation

A statement that describes the plan for disclosing any material incidental findings to the participant or the participant’s SDM

**(2) The ICF for a clinical trial must also include 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

The particular treatment or procedure may involve risk to the research participant or to an embryo or fetus, should the participant be or become pregnant, that are currently unforeseeable

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 Holland Bloorview 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 informed consent form, the participant or the participant’s legally acceptable representative is authorizing such access

A statement indicating where applicable clinical trials will be registered and publicly accessible on the Web including the name of the registry and the unique identifying code assigned by the clinical trial registry

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 Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

(3) **If a research study seeks consent to collect human biological materials, the ICF must also include 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

The 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, assess 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

IMPORTANT: Refer to REB Standard Operating Procedures [REB-701](http://research.hollandbloorview.ca/Assets/research/Documents/Research%20Ethics%20Board/REB%20701%20Informed%20Consent%20Elements%20July%202014%20FINAL.pdf) for a complete list of general and specific documentation requirements and [REB-702](http://research.hollandbloorview.ca/Assets/research/Documents/Research%20Ethics%20Board/REB%20702%20Informed%20Consent%20Process%20July%202014%20FINAL.pdf)for the process to obtain and document initial and ongoing consent.