

# SickKids Research Ethics Handbook



**CLINICAL  
RESEARCH  
SERVICES**



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## WHAT IS RESEARCH ETHICS?

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) defines research as "any scientific undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation."

Research ethics review is a process of initial and ongoing review and monitoring of research involving human participants to ensure ethical acceptability.

The process requires the independent evaluation of all proposed research by an independent committee of people with varied backgrounds who use their knowledge and expertise to examine the research study from the perspective of prospective participants.

The underlying core principle that the research ethics review is guided by is the respect for human dignity. Respect for human dignity is expressed through the three core principles - Respect for Persons, Concern for Welfare, and Justice.

### **Respect for Persons**

Respect for persons recognizes the intrinsic value of human beings and the respect and consideration that they are due; considers how people of all ages are treated as research participants; incorporates the moral obligations to respect autonomy; and protects those with developing, impaired or diminished autonomy.

### **Concern for Welfare**

Concern for Welfare considers the impact on individuals of factors including physical, mental and spiritual health, as well as their physical, economic and social circumstances; encompasses factors including privacy and control of information about the person and the assessment of foreseeable risks and benefits; and the treatment of data and human biological materials according to the free, informed and ongoing consent of the person who was the source of the information and materials.

### **Justice**

Justice which recognizes the obligation to treat people fairly and equitably.

Researchers who familiarize themselves with the policies, procedures, guidance documents and templates on this website prior to submitting the REB will benefit by minimizing or eliminating the revisions required for review before a study can begin. Our guidance documents and templates are updated as our office continues to improve our efficiency in review. Therefore, researchers are advised to download templates directly from this site for each use to ensure compliance. Revision dates for SickKids forms will be noted on the last page of each form template.

## THE REB PROCESS

The SickKids REB is mandated to ensure that the safety and welfare of participants are adequately protected and that research complies with TCPS2 guidelines, SickKids Institutional Guidelines and SickKids Research Ethics Board's guidelines/SOPs.

In accordance with the Tri Council Policy Statement 2 (TCPS2) guidelines, SickKids REB review is based on the general principle of proportionate review (i.e., the higher level of risk, the higher the level of scrutiny in the review).

If you are unsure if your project requires REB review, please review the scope of the REB on page 12.

## Determining Level of Review

The REB determines the level of review for each research project by assessing the foreseeable risks, the potential benefits, and the ethical implications of the research (TCPS2 Article 6.12). Level of review is assessed throughout the lifecycle of the project.

There are two levels of review used by the REB:

1. Full Board Review
2. Delegated Review
  - Secondary Use Review

If a research study involves greater than minimal risk, it will be reviewed by the REB full board. Amendments that are considered to be greater than minimal risk, certain renewal applications, and select adverse events (at the decision of the Chair) will also be reviewed by the full board. Minimal risk studies are reviewed via a delegated review process. Studies involving the secondary use of data or tissue will undergo an expedited delegated review called a "secondary use review".

## REB Review Process

Applications for research ethics review can be submitted at any time. All applications, whether for initial, ongoing, or continuing review, undergo the same general review process.

### Initial screening

All applications received by the Research Ethics Office (REO) go through an initial screening process performed by the REB administrative coordinator. This is a simple review of the application and associated study documents to ensure that:

- Information in the REB application form is complete, research category is correct
- All the required documents have been submitted
- All required departmental costing and sign-offs have been obtained
- All the documents have version dates
- All documents are properly formatted and use the most current SickKids REB templates (e.g., Consent/assent forms; tracked changes and clean versions of applicable documents for amendments)

If all the requirements have been met, the application will be accepted for REB review. Applications that do not meet submission requirements will be sent back to study teams as incomplete.

After an application is accepted for REB review, its risk will be determined and the level of REB review will be decided. Studies with greater than minimal risk will undergo *full board* review, while studies with minimal risk will undergo *delegated review*.

## Full Board Review Process

### Full board pre-review

Once an application has been assigned to full board review, an REB coordinator will confirm that the application requires full board review and will review the application to ensure that the submission is complete, that the language in the consent/assent forms is appropriate, and that all documents are comprehensive and detailed. Changes to the application may be required before it can be added to a full board meeting agenda. Once all requirements have been met, the application will be assigned to be reviewed at the next available REB full board meeting.

### Full board meeting

Full board review meetings are conducted twice a month. The SickKid REB uses a primary/secondary reviewer system.

### Primary/Secondary Reviewer System

Full board applications are assigned to a primary and secondary reviewer. In the primary/secondary reviewer system two board members are responsible for an in-depth review of the study application, the study. The research ethics coordinator, in consultation with the REB Chair, assigns primary and secondary (and occasionally tertiary) reviewers based on the expertise required for each submission:

- The primary reviewer is the person with the most applicable scientific expertise in the area of research.
- Secondary (and, when required, tertiary) reviewers are individuals with additional expertise required for the study. For studies involving vulnerable populations, members who are knowledgeable about and experienced in working with the specific vulnerable population may be assigned as secondary or tertiary reviewers.
- If it is determined that appropriate expertise is not available within the REB membership, an internal or external consultant may be sought for a review.

All other REB members are encouraged to also provide their comments/concerns with the studies.

### Post review follow-up

Questions or concerns that arise from the full board meeting will be conveyed to the PI/study team by the designated research ethics coordinator. Once all comments/concerns have been addressed and all documents have been revised by the PI/study team, the responses will be reviewed by the same research ethics coordinator in consultation with the REB Chair.

In most cases, the study will receive final REB approval when all concerns are sufficiently addressed. However, for SickKids PI initiated Health Canada regulated studies, *provisional* REB approval will be granted, pending regulatory approval. Once the regulatory requirements have been met, study documents will be re-reviewed by the research ethics coordinator and final REB approval will be provided.

### Delegated Review Process

Applications determined to be minimal risk will undergo a delegated review process by a sub-committee of the REB consisting of the REB Chair or Vice-Chair, an REB coordinator/analyst and, if required, one or two REB board members with relevant expertise. Delegated reviews occur outside the monthly meetings and are reported to the full board.

### Delegated Pre-Review

Once an application has been assigned to delegated review, an REB coordinator/analyst, in consultation with the REB Chair/Vice Chair, will review the application to ensure that the submission is complete, that supporting documents conform to SickKids REB templates/requirements, and that all identified ethics queries are addressed. In most cases, changes to the application will be required before it can be sent for final review and approval by the REB Chair/Vice Chair. Once the REB coordinator/analyst is satisfied that all concerns have been adequately addressed and that study is approvable, the application will be sent for delegated review by the REB Chair/Vice Chair.

### Delegated Review

The REB Chair/Vice Chair will review the application and all correspondence. In some cases, additional concerns may be identified; these will be relayed to the REB coordinator/analyst who will convey the

concerns back to the study team. Once all concerns have been addressed, the application will be approved by the REB Chair/Vice Chair.

### Secondary Use Review (aka Retrospective Review)

If your study has been deemed to be minimal risk *and* involves the use of secondary data/tissues only, your study will undergo a secondary use review process. Secondary use review is an expedited delegated review process. Although the review process is the same, the requirements for a secondary use study are different than for a prospective study – see the secondary use guidelines on [here](#) for further information.

### REB Review Decisions:

For full board review studies, decisions are made either by consensus or a majority vote by the REB members present at a Full Board meeting. Decisions are relayed in writing to the research team. For delegated review studies, decisions are made by the REB Chair/Vice Chairs, in consultation with other REB members when necessary. The REB may make one of the following determinations as a result of its review of the study application:

- *Approval:* The study protocol and supporting documents are approved as submitted.
- *Approval with Modifications/Clarifications:* The study protocol, and supporting documents are approved provided that certain conditions are met or required changes are made.
- *Deferral:* The REB decision on the study protocol and supporting documents is being deferred because the documents do not have sufficient information to arrive at a determination, or extensive revisions to any part of the research study are required. The application will be reviewed at a future date when the additional information or revisions are received.
- *Not Approved:* The REB is rejecting the study protocol and supporting documents because it fails to meet the ethical standards for approval and revisions are unlikely to enable the REB to reach a positive determination

### Withdrawal of Applications

Applications may be withdrawn at the request of the PI, or by the REB if the PI failed to respond in a timely manner to requests for more information.

### REB Approval

Research activities involving participants, including recruitment, may not start until the study has REB approval. In order to be approved by the REB, the research must comply with TCPS2 guidelines, SickKids Institutional Guidelines and SickKids Research Ethics Board's guidelines/SOPs. REB approval is issued by way of an REB Approval Letter.

### In-Principle Approval

Studies that are subject to Health Canada regulations and that do not have a No Objections Letter (NOL) as of the REB meeting date may be given in-principle approval until the NOL is received. If changes are made to the application in between the in-principle approval and the receipt of the NOL, the changes may need to be re-reviewed by the REB.

### REB Approval Letters

The REB approval letter lists the REB approval date, the expiry date, and all approved study documents. REB approval letters are uploaded to the approved application by the Research Ethics Coordinator/Analyst. It is the responsibility of the PI/study team to ensure that the documents listed in the REB approval letter are inclusive, complete and accurate. If there are any discrepancies, this should be brought to the attention of the REB coordinator/analyst immediately. Only the most recently REB approved versions of documents, as listed in the approval letter, can be used.

The PI/study team is responsible for ensuring that all other necessary documentation has received approval before the research study commences. This may include legal agreements (liaise with the legal services) or the creation of a cost centre (liaise with finance/grants management).

### Submitting a new study to the REB

All study submissions must be sent to the REB through the eREB system in order to be reviewed. If you are unsure if your study requires REB review, please see the section on what requires REB review. For guidance on how to submit an initial application on the eREB, see the [Guide to the eREB](#).

### Initial Submission Requirements:

For all new study applications your submission should include the following:

- A complete eREB Main Application
- A study protocol - a detailed description of your research including your hypotheses, methods/procedures to be used, details of the study population, description of steps you will take to minimize risk to participants and to ensure confidentiality
- Consent/assent forms and any applicable translations\*\*
- Any data collecting tools (e.g., data collection forms, case report forms, etc.) \*\*
- Sign-off from associated SickKids departments (Diagnostic Imaging, Pharmacy, or Department of Paediatric Laboratory Medicine) \*\*
- Any surveys, questionnaires or interview questions you will use
- Any recruitment materials you may use to enlist participants (e.g., contact letters, emails, phone scripts, flyers, etc.)
- A detailed description of any secondary data you will use, including its source, the variables to be collected, any merging you will do with other data sources, and any agreements you have made with the owners/custodians of the data

\*\*Please see our [Forms and Templates](#) section, if you require any assistance in creating or obtaining these documents

**Applications that do not include all required documents with appropriate formatting will not be accepted for REB review.**

The Principal Investigator for a new study must have an active research institute (RI) appointment at SickKids. All initial submissions require sign off from the Division Head. If the Division Head is the PI or a co –investigator on the study, then their delegate or next senior supervisor can provide sign off.

### Ongoing Review Submissions

Research is subject to continuing ethics review from the date of initial REB approval throughout the life cycle of the project (TCPS2 Article 2.8). Changes to the study protocol or study documents are also subject to ongoing review via an **amendment application**. Other continuing review applications include **unanticipated problem reports** and **staff change forms**. All ongoing review applications may be subject to either delegated or full board review.

### Amendments

During the life cycle of a study, changes to study procedures or documents may need to occur. An amendment application is required to request REB approval of these changes to an approved and ongoing study; the amendment application, along with all amended study documents, must be submitted to and be approved by the REB *prior* to implementing the proposed changes.



Amendment changes may be major or minor. However, amendment changes to studies should be within the scope of the original study goals. Amendments that change the scope or objectives of the current study may need to be submitted as a new study. If you are unsure whether your change(s) should be submitted as an amendment or a new study, please contact the [Research Ethics Office](#).

Examples of study changes that require an amendment application include:

- changes in the number of participants
- changes in the consent/assent forms
- funding changes
- protocol changes
- changes in recruitment methods
- study site changes
- changes to the study title
- Investigator Brochure Submissions

To be considered complete, amendment applications must contain:

- A list of all changes to study procedures and documents
- Tracked changes and clean versions of all amended study documents
- Rationale for all changes

#### [Delegated review of amendment applications](#)

In general, minor changes are approved via delegated review.

For studies initially approved via delegated review, an amendment can undergo delegated review if:

- The amendment does not change the risk level beyond minimal risk
- The amendment does not involve any procedures that are outside of the scope of the initially approved protocol

For studies initially approve via full board review, an amendment application can undergo delegated review if:

- The amendment does not pose an increased risk to subjects AND
- The amendment constitutes a minor change to previously approved research

Examples of minor changes that may qualify for delegated review include:

- Administrative changes
- Editorial changes on study documents (e.g., consent form, recruitment tools, questionnaires)
- Small changes to re-imburement of participants
- Translations of materials already approved by the REB

#### [Full board review of amendment applications](#)

Amendments that involve adding procedures that are greater than minimal risk will be referred to the Full Board for review and approval.

Examples of major changes that may require full board review include:

- Any changes that adversely affect the risk/benefit ratio
- Significant changes in study design, such as the addition of a new subject population or the elimination of a study arm
- Changes to or new study documents to be distributed to participants that include information or questions that are substantively different from materials already approved by the REB
- New or revised financial conflict of interest management plan

## Unanticipated Problems (UP) and Adverse Events (AE)

Unanticipated Problem (UP) and Adverse Event (AE) forms report unexpected events that may have affected participants or the research process. Depending on the nature of the event, some UPs are required to be reported to the REB with 15 days of the UP occurrence, while others can be reported yearly as summary safety updates along with the renewal. Please refer to the document on reporting UP for guidance.

Only events that qualify as UPs should be reported to the REB. In order to satisfy the criteria of a UP, the event must meet the following 3 criteria:

1. Unexpected –in terms of nature, severity or frequency;
2. Related or possibly related to participation in the research;
3. The event suggests that the research places research participants or others at a greater risk of harm.

When reviewing a UP, the REB will:

- Assess the appropriateness of any corrective or preventative measures proposed by the sponsor and/or researcher;
- Consider any additional appropriate measures that may or may not have been identified or proposed by the sponsor and/or researcher;
- Consider whether the event reflects a change in the risk/benefit ratio and acceptability of the study;
- Consider whether some of or all of the research participants should be notified of the events (e.g., if the event may affect the participant's willingness to continue participation in the research);
- Consider whether suspension or termination of the ethics approval of the research is warranted.

When a UP is submitted to the REO, the submission will be reviewed by one of the research ethics coordinators/analysts and REB chair/vice-chairs. If the UP does not raise concerns and does not appear to involve risks to research participants or others, the research ethics coordinator and Chair/Vice-Chair will acknowledge the report and no further action is required. If the UP requires immediate action to protect the safety of research participants, the REB may suspend ethics approval of the research study pending review by the full board.

## Staff Change Forms

Over the course of the study, you may need to add or remove investigators, collaborators and study team members, or change the contact information for a study. Staff change forms should only be submitted if:

1. There is a change in study team members that affects REB approved documents (e.g., consent forms, recruitment materials)
2. There is a change in who needs access to the eREB (e.g., for the addition or removal of a research coordinator)

Once a staff change form and all amended documents have been received, the submission will be reviewed by a research ethics analyst and approved by an REB vice-chair.

**NOTE:** If the staff change does not require changes to REB-approved documents, it does not need to be submitted to the REB for approval. However, you must keep your own study documentation related to the change in staff (e.g., updating delegation log, training, etc.). It is the responsibility of the PI to ensure that those individuals being added to the study are SickKids compliant and have completed the necessary training such as (TCPS2).

Medical Records (i.e., EPC) no longer requires the REB to approve staff members for access to medical records. Please contact EPC directly if you would like to a new study team member to have access to EPC for an REB approved study.

### **Continuing Review/Study Renewals**

SickKids REB provides approval of studies for one year, and all studies are subject to continuing review on an annual basis (TCPS2 Article 6.14). To report the study's progress and request re-approval, study teams must submit an REB renewal application.

Expiry dates for studies are listed on the initial REB approval letter, subsequent renewal approval letters, and on the eREB. The REB does not provide extensions in ethics approval under any circumstances.

The REB sends renewal reminders to study teams approximately 6 weeks before their study's expiry date; however, study teams should not rely exclusively on these reminders for timely renewal.

### **Deadlines for renewal submissions**

Renewal applications must be completed and submitted at least 10 business days before their expiry date. For renewals requiring full-board review, applications must be submitted at least 10 business days before the full board meeting that precedes the study's expiry date. Note that renewal applications may be sent back to study teams with outstanding questions; these must be addressed before the study's expiry date in order to ensure timely processing.

If renewals are submitted later than 10 business days before their expiry date, their approval may lapse. If a study's ethics approval lapses, study activity must be put on hold until the study's renewal application is approved.

Renewal applications can be submitted up to 3 months prior to expiry date. Please note that due to the high volume of renewal applications the REB receives, processing of renewal applications is prioritized based on expiry date

### **Delegated vs. Full Board Renewal Process**

REB renewals can be reviewed through a delegated process or at a full-board meeting. The type of review required is proportionate to the degree of potential risk to research participants.

Studies that were initially approved via an expedited/delegated review process may be renewed via delegated review.

Studies that were initially approved at a full-board meeting AND that must comply with US OHRP regulations (e.g., are FDA regulated studies, are NIH funded studies) *may* require full-board review of renewals. See the [OHRP website](#) for further information.

If you are unsure if your study requires delegated or full board review, please contact the Research Ethics Office.

### **Lapsed approval**

If a renewal application is not approved prior to the study's expiry date, its ethics approval will lapse. For studies with lapsed approvals, all activities related to the study must be suspended.

If a study is in the "lapsed" state on the eREB, no other applications related to the study can be submitted until the renewal is approved.

If the study is not renewed within 6 months after the study expiry date, the REB will close and archive the study off-site. To re-open a study after it has been closed a new REB main application is required.

If research participants are actively enrolled in a clinical trial and the study lapses, please contact the Research Ethics Office.

### Study Closures

The TCPS2 (Article 6.14) states that the PI is responsible for filling out an end-of-study report.

It is SickKids REB policy that studies remain open until all recruitment is complete, data is collected, analysis is complete and work arising from the research has been accepted for publication. If a study needs to be closed for a reason other than study completion, there must be no ongoing study activity and an explanation as to why the study is being closed must be provided to the REB. Once all necessary documentation has been received by the research ethics analyst and all concerns have been addressed sufficiently, the application will be approved by an REB vice-chair.

**Note:** Currently, studies can be closed 3 months before their expiry date on the eREB through an REB renewal application

Studies that are not renewed within 6 months of their expiry date will automatically be closed by the REB and archived. To re-open a study after it has been closed, a new REB application is required.

## SCOPE OF REB

All research conducted by staff at SickKids, irrespective of where the research will be conducted, where the participants will be recruited, or where the funds will be administered must obtain prior SickKids REB written approval before the study may commence (ref. TCPS 2, Article 2.1). This includes human data, remains, cadavers, tissues, biological fluids, or foetal waste tissue.

The following kinds of research require review and approval by an REB before the research begins:

- Research involving living human participants.
- Research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses.
- Research involving secondary use of data (use of data initially collected for another purpose) - health records, employee records, student records, computer listings, banked tissue - if any form of identifier is involved and/or if private information pertaining to individuals is involved.
- Research about a living individual in the public arena if s/he is to be interviewed and/or private papers accessed.
- Quality improvement/assurance studies and program evaluations which address a research question. Program Evaluation: REB review is required only if a QI or PE meets the TCPS2 definition of research or serves as a component of a research project.

The following kinds of studies **do not** require ethics review (TCPS 2 Articles 2.2 to 2.4).

- Research about individuals in the public arena using only publicly available or accessible records without contact with the individual/s.
- Research involving naturalistic observation in public venues.
- Quality assurance studies, program evaluations, performance reviews, and testing within normal educational requirements if there is no research question involved.
- Research based on review of published/publicly reported literature.
- Research involving secondary use of data (Article 5.5) or samples which is provided **without any identifiers** (completely anonymous) or group of identifiers which would allow attribution of private information to an individual.

- Consulting, unless carried out under the auspices of SickKids.

Activities outside the scope of research subject to REB review may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than an REB.

What requires review depends on the exact context of your research. If in doubt about the applicability of the TCPS 2 or the requirement for REB review of a particular research project, the researcher should consult the REO at [reb.admin@sickkids.ca](mailto:reb.admin@sickkids.ca).

*\*\*\*No intervention or interaction with human participants in research, including recruitment and collection of data, may begin until the research protocol, consent documents and recruitment materials have been reviewed and approved by the SickKids REB. \*\*\**

## US FEDERAL WIDE ASSURANCE (FWA) & REB REGISTRATION

### FWA Information

An institution that is engaged in human subjects research that is conducted or supported by any agency of the U.S. Department of Health and Human Services (HHS) must have an assurance of compliance with the HHS regulations for the protection of human subjects. This assurance is called a Federal Wide Assurance (FWA) and is approved by the Office of Human Research Protections (OHRP).

**SickKids's FWA#:** 00000281

The expiration date for this assurance changes frequently. If you need the expiration date, please visit <http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc> , enter the FWA Number above, and click "Search".

### Department of Health and Human Services

Each SickKids REB panel is registered with the Department of Health & Human Services. Registration numbers for SickKids REB panels are:

- IRB00000983 (Panel A)
- IRB00007529 (Panel B)

### Office of Human Research Protections

The Institution or Organization (IORG) number is a unique number assigned by OHRP to an institution or organization the first time an institution or organization registers an IRB.

The IORG number for SickKids is IORG0000643

## PARTICIPANT RECRUITMENT

Participant recruitment is the seeking out of individuals, groups or communities that meet the inclusion criteria of a study. It involves the identification of potential participants, initial contact with potential participants to introduce them to the study, and actual recruitment of participants (e.g. screening and informed consent).

## Ethical Considerations

According to TCPS2 (Article 3.1), the approach to recruitment is an important element in assuring the voluntariness of participation. In particular, how, when and where participants are approached and who recruits them are important elements in assuring (or undermining) voluntariness. Study teams should consider how their recruitment process may affect potential participant's privacy, as well as the potential for undue influence in the recruitment process.

### Identification of Potential Participants

Depending on the study population, potential participants may be identified via a review of medical records, staff records, student/trainee records, or they may self-identify (e.g., community members, healthy controls after learning about the study).

#### Via Medical Records

Medical records include clinic and hospital charts (e.g., EPC, KidCare) as well as clinic databases. In general, accessing medical records for research activities requires prior written consent.

#### Pre-screening of medical records

The REB may grant a waiver of consent when medical records are being pre-screened to identify potential participants. Study teams must request this waiver and provide justification in the REB application. This pre-screening process involves access of minimal information (e.g., age, medical condition) to identify potential participants; no information should be recorded as part of this process. Individuals who access medical records for pre-screening purposes should be involved in the patient's care (e.g., physician, nurse, clinic administrator).

The pre-screening process differs from the more in-depth screening process (e.g. eligibility determination) which typically involves a detailed review of patient records and requires patient consent prior to accessing the records.

#### Via Staff Records or Student/Trainee records

Access to staff/student lists and other information related to a potential participant's employment/education is restricted to persons who are directly involved in the individual's work/education. Access to staff/student data for research purposes requires documented permission from the custodian of the information.

#### Via Self-Identification

Potential study participants may self-identify or express interest to be part of a study as controls after hearing about the study through various promotional materials (e.g., poster advertisements). Some may also be identified via secondary recruitment through family members and friends.

### Initial Contact

Initial contact involves informing the potential participant about the study and gaining consent for further contact from the study team. The methods used to contact a potential participant should not intrude on the individual's life or privacy, and the potential for undue influence should be mitigated. The following general rules should be followed when establishing initial contact:

1. Initial contact of a potential participant should be made by someone who the participant expects to have relevant information about them.
  - **Patient/Parent Participants:** A person who is part of the individual's circle of care or someone the patient/parents know should make the initial contact. A person's circle care includes any member of the health care team which provides direct care to the patient or assists with providing the care required.

- For high risk studies such as clinical drug trials or new device trials, initial contact will need to be done by a member of the potential participant's treating team such as the treating physician or nurse involved in the patient's care. For low risk studies such which do not involve new drug treatments or devices (i.e. surveys, questionnaires, interviews), study staff may be introduced by any of the members of the potential participant's circle of care, including admitting staff, reception, etc.
  - **Staff Participants:** The potential participant's work supervisor should issue information about the research study (e.g., through communications/announcements or materials distributed during staff meetings) to potential participants on behalf of the study team
  - **Student/Trainee Participants:** The institution's training division or course instructor should make the initial contact with the potential student/trainee participants using study information provided by the study team.
  - **Members of a Health Professional Society:** The head or a known representative of the society should issue communications on behalf of the study team.
  - **Community Members/Healthy Controls:** Community members/healthy controls will contact study teams based on advertisements/media that inform them about the study. They consent to be contacted by informing a study team member that they are interested in the study.
2. Initial contact should not be conducted in open/public areas where there is no expectation of privacy (e.g., clinic waiting rooms)
  3. If a potential participant has previously participated in a research study, they may be contacted directly by a member of the research staff only if they previously consented to be contacted for future research.
  4. If the contact information of a potential participants is available through another organization (e.g., government or non-government officials, business leaders, organizational staff, etc.), the researcher should first seek institutional, organizational or agency approval prior to contacting these individuals.

### Initial Contact Involving Dual-Role Researchers

Dual-role researchers should be aware of the potential for undue influence and research benefit misconception (or therapeutic misconception) when inviting their own patients, students, employees, colleagues or subordinates to participate in research. The trust and dependency inherent in clinician-patient, teacher-student, and supervisor-employee relationships may unduly influence voluntariness to consent to research. Strategies to mitigate undue influence and research benefit misconception should be developed.

### Acceptable Recruitment Methods

The following is a list of the recruitment methods that are accepted by the SickKids REB.

#### Direct Contact

##### In person

Recruitment to a study may occur in person. In this case, initial contact should be made by a member of the circle of care or someone the potential participant is familiar with. At this point, permission to share the potential participant's contact information with the study team is obtained. Consent to be contacted should be documented in the patient's clinic and/or research file. Once this consent is obtained, study teams may follow up with potential participants to provide them with further information regarding the study and obtain consent.



### Over the phone

Potential participants may be recruited to a study over the phone. Prior to calling potential participants, they should be introduced to the study via an introductory letter (see below).

A recruitment script is required to standardize information provided to potential participants. The recruitment script and all follow-up contact scripts should be submitted to the REB for review and approval.

### Introductory Letters

Introductory letters inform potential participants about a study and provide them with a way to contact the study team for more information, to indicate interest or to decline being contacted. It should be sent by someone the potential participant is familiar with, such as someone involved in their care or who would have access to their personal information.

Introductory recruitment letters should include the following:

1. **The method that the study team will use for follow-up contact:** this includes when potential participants can expect to be contacted, and who will contact them. A period of 2-3 weeks after the letter is sent is a reasonable time frame for follow-up. A maximum of 3 follow-ups with the potential participant are permitted; after this, if no contact has been established, then a potential participant is deemed as having refused to be part of the study.
2. **How to opt-out of the follow-up:** provide the name and contact information of a study team member who can be contacted to opt out of being followed up. A self-addressed stamped envelope that can be mailed back to the study team or an opt-out card can also be used. If an opt-out card is used, it should not contain any personal health information.
3. **Instructions for next steps,** such as contacting the study team to indicate interest, meeting with the study team member at the next clinic visit, etc.

The introductory letter, recruitment script, and all follow-up contact scripts should be submitted to the REB for review and approval. Please see the 'templates' section of the REB website for introductory letter templates that can be used.

### Mailed out introductory letters

A mailed-out letter is considered a secure form of communication. For this reason, a limited amount of personal health information (PHI) can be included in the letter, as long as it is sent from and individual the potential participant would recognize as having access to their personal information.

### Recruitment Email

Email is considered a non-secure form of communication as it may be accessed by unauthorized third parties. As a result, consent to be contacted about a research study should be obtained prior to sending out study information in an email. When consenting to contact, the potential participant should be informed that email communications are not secure and that personal information may be included in the email. This consent should be documented in the study files.

When using email for recruitment of study participants, the following guidelines need to be followed:

1. Use encrypted email whenever possible;
2. The sender's SickKids email account should be used;
3. Do not use mass emails;
4. Do not send emails with sensitive personal information;
5. Forms containing personal health information (e.g., consent forms that describe specific disease conditions) should not be included in the email
6. Do not ask participants to return forms with personal information through email



The SickKids REB requires the following information and documents be submitted with the application:

1. Information about the source of the email list and whether consent has been provided to be contacted by email;
2. A copy of the proposed email text, subject line and any graphic used in the email;
4. A copy of any follow-up emails and frequency with which these are to be sent. A maximum of 3 follow-up emails are permitted; after this, if no contact has been established, then a potential participant is deemed as having refused to be part of the study.

### **Study advertisements**

Study advertisements include study posters/flyers, study brochures, direct media advertisements, and internet/social media web posts. In general, study advertisements should include the following basic information:

1. Study title
2. Who is being recruited including the main criterion (disease condition, healthy volunteer, age etc.) or other inclusion criteria
3. A brief summary of what the study involves in an easy-to-read format, preferably a bulleted format
4. A statement that participation is voluntary
5. Compensation information may be included but should be stated in a manner which should not influence the decision to participate
6. Name and contact information of the study team

All study advertisements must comply with institutional guidelines for formatting and content and should be submitted for review and approval by the SickKids Public Affairs Office prior to submission to the REB.

### *Study Posters and Flyers*

Study posters and flyers are used to recruit potential participants internally. They are site-specific.

### *Study Brochures*

Study brochures contain basic information about the study and may be distributed in clinic and other public areas.

### *Direct media advertisements*

Direct media advertisements include newspaper ads, radio and TV announcements, and bulletin board ads. If you are using radio or TV ads, the REB must view the recording. All other ads are also subject to REB review.

### *Social Media or Other Web Posts*

Messages posted on social media (e.g. Twitter, Facebook, discussion forums) should contain basic information about the study, subject to character and space limits.

Posting study information on other websites (e.g., professional website, foundations, or support groups sites) requires proof of sign-off from the organization or group that own the website. Content posted should contain the basic information required for recruitment materials, subject to space and character limits.

### **Third Party Recruitment and Snowball Sampling**

Third party recruitment involves asking research participants to identify other potential participants. In most cases, the SickKids REB will not allow third party recruitment for because it places an additional burden on research participants, it may generate undue influence to participate in the study, and it may

violate privacy laws. However, the REB may allow third party recruitment in some cases with appropriate justification (e.g., research on genetic or hereditary conditions which may run in families)

In these cases, the REB will require information on how third-party recruitment will be operationalized. All materials distributed to third parties will need to be submitted for review and approval.

### Unacceptable Recruitment Methods

The following recruitment methods are *not* accepted by the REB:

- **Finder's Fees / Recruitment Incentives:** The SickKids REB prohibits the acceptance or use of finder's fees, direct recruitment incentives, or bonuses of any type to recruit and enroll study participants.
- **Cold Calling:** Unless the potential participant has previously consented to be contacted for future research, the use of "cold calls" to recruit participants to research studies is not allowed. An introductory letter or other informational material must be sent first or given directly to participants prior to telephone contact.
- **Recruitment materials that describe more than one research study:** Recruitment materials that describe more than one research study are called general advertisements. The SickKids REB prohibits the use of general advertisements because it is difficult to keep the information up to date due to modifications made over the life cycle of several studies. Advertisements must be study-specific.

### What the REB requires

Study teams must provide the REB with the details of all recruitment activities. For studies that involve multiple arms, recruitment information for *each* participant group must be provided. Information on the following items related to identification, initial contact and recruitment of research participants must be provided:

1. **Recruitment Methods:** Identify all methods of recruitment (e.g., direct contact, introductory letter, email, brochure, advertisement, etc.). All associated documents must be provided to the REB.
2. **Contact Information:** The source of the contact information (e.g., medical records, staff/student records, self-identification) must be provided. Information regarding how the researcher obtained permission to access contact information, what specific contact information will be collected, and who will collect the contact information must be provided.
3. **Pre-screening activities:** Information about who will be pre-screening, what information will be looked at and a justification for accessing the records prior to consent.
4. **Initial Contact:** Information regarding who will make the initial contact, their relationship to the potential participant, and how contact will be initiated (e.g., in person, introductory letter, etc.) must be provided.
5. **Follow-Up Contact (if any):** If your recruitment plan involves follow-up contact with potential participants describe the manner in which individuals will be contacted, who will conduct follow-up, and how frequently this will occur (e.g., follow up with potential participants after initial contact via phone, email, or in person during a clinic visits).
6. **Screening Procedures:** Potential participants may need to be screened for eligibility for the study prior to study enrollment. Any screening procedures will need to be described including who will be conducting the screening procedures. If you will collect personal information or data from potential participants during the recruitment and/or screening process, you should describe what data will be collected and how this will be done.
7. **Retention of Data from Screening Process:** Data from the screening process should not be retained without prior consent from potential participants who either fail the screening process or declined to participate in your study. If you plan to keep data, you need to identify what data is

being retained and provide justification. If data will not be retained, how they will be destroyed should be described

8. **Privacy Protection:** Describe any provisions to protect the privacy and/or confidentiality of potential participants. This is particularly important when conducting research on sensitive topics, health-related issues, controversial issues, etc. Such provisions may be as simple as sending a recruitment letter in an envelope rather than sending a post-card.

## OBTAINING CONSENT FOR RESEARCH

Obtaining consent, or the **consent process**, is different from the **consent form**. The consent process is an educational process involving information exchange between the researcher and the potential participant. The consent form formalizes the agreement to participate and documents the process.

### Principles guiding the consent process

Three overarching principles guide the consent process:

1. Consent must be **voluntary** (TCPS2 Article 3.1)
  - Consent should be free of undue influence, coercion, and incentives
  - Consent can be withdrawn at any time
  - If a participant withdraws consent, the participant can also request the withdrawal of their data or biological materials
2. Consent must be **informed** (TCPS2 Article 3.2)
  - All information necessary for making an informed decision to participate in the research project must be disclosed
3. Consent is an **ongoing process** (TCPS2 Article 3.3)
  - Researchers have an ongoing duty to provide participants with all information relevant to ongoing consent to participate in research

### Essential elements of the consent process

An effective informed consent process involves the following elements:

- Consent discussion happens in a manner and location that ensures participant privacy
- Potential participant is given all relevant and necessary information about the study in and at a language level that is understandable to the participant
- Potential participants are informed of the purpose of the research study, the risks and the potential benefits
- Potential participants are informed of what procedures are necessary and optional for the research study
- Appropriate individuals with relevant expertise are available at the time of consent to answer any and all questions posed by potential participants
- Potential participants are given adequate time to consider all their options before they make a decision regarding the research study
- Potential undue influence and coercion is mitigated
- Potential participants are informed that clinical care will not be affected by their decision to participate or not in the research study
- The possibility and meaning of incidental findings as a result of research participation is discussed, if applicable
- Potential participants are informed of the extent to which anonymity and confidentiality can be assured in publication and dissemination of results, and of the potential re-use of data.
- The dialogue between the research team and participants is ongoing; participants are updated, informed, and re-consented at appropriate times and as new information become available

Study teams must both *inform* participants and *ensure their understanding* of the above.

### Responsibility for Obtaining Consent

The Principal Investigator (PI) is responsible for ensuring that the consent process is followed, and for the actions of any member of the research team involved in the consent process (TCPS2 Ch. 3).

In general, the PI should not obtain consent from study participants. The PI can introduce the study to potential participants and answer questions regarding the study, but consent should ideally be obtained from another member of the study team who is not directly involved in the patient's clinical care. This minimizes any potential form of coercion or undue influence. Individuals who obtain consent must be delegated by the PI to do so, and they must be trained and qualified for the consent process. Formal delegation of this role should be documented in a delegation log.

In rare circumstances, it may be appropriate for the PI to obtain consent (e.g., study population only available for consent during off-hours when no other study team staff are available). These are considered on a case-by-case basis; contact the REO if your study requires the PI to obtain consent.

### Timing for Obtaining Consent

Sometimes the research information to be imparted to potential participants is complex or possibly distressful. Time to absorb and appreciate the information may be necessary. In these circumstances, the researcher should present the information and discuss the issues with potential participants on more than one occasion or allow a period of time to elapse between imparting the information and requesting a signature on the consent form. During this waiting period, potential participants should be encouraged to discuss their possible participation with family members, close friends, or trusted advisors. With REB approval, other approaches to communicating complex information can be used, including the use of audio-visual materials and brochures.

### Assessing Participant Comprehension/Understanding

Researchers must ensure that participants genuinely understand the research; they should not rely solely on the participant to ask questions about the research. Prior to obtaining consent, researchers should prepare questions to ask potential participants to assess their comprehension of what participating in the study entails. Asking questions can further the discussion, elicit questions from the potential participant, prompt the potential participant to think more carefully about the project, and help the researcher decide whether the person has adequately understood the project.

Useful questions will be open-ended and non-directive; they should not be yes/no questions. Open-ended questions often start with "what," "where," "how often," "when," and "please describe."

Examples of open-ended questions to be used to assess participant's understanding are:

1. Describe in your own words the purpose of the study?
2. Can you explain to me what you will have to do if you are in the study?
3. Can you please describe the alternatives to participation in this study.
4. What more would you like to know about the study?
5. What are the possible risks if you are in the study?
6. What are the potential benefits if you participate in this study?
7. How long does your participation in this study last?
8. Where will the study take place?
9. Who do you contact if you have questions or side-effects during the study?

Examples of close-ended questions that are **not** helpful in assessing comprehension of the study:

1. Do you understand what we are asking you to do?
2. Do you have any questions for me?
3. Do you understand that there are risks to participating in this study?
4. Do you need any more information before you make your decision to participate?

## Capacity to consent and assent

### Capacity

In Ontario, there is no age to consent or assent. Capability to consent is based on capacity; capacity varies between individuals and may vary according to the complexity of the choice being made, the circumstances surrounding the decisions, or the point in time at which consent is sought. To consent, the participant must be able to understand relevant information about the research project, and to appreciate the reasonably foreseeable consequences of participating or not participating in the research (TCPS2 Ch. 3C).

With research involving children, participants may or may not have the capacity to consent to the study. If the child has capacity, then they must be consented to participate in the study and their parent/guardian *may* need to consent to their participation. If the child lacks capacity, then they should be assented to participate in the study and their parent/guardian *must* consent to their participation. Potential participants should not be excluded from research on the basis that they lack capacity as this goes against principles of justice.

### Who should assess capacity?

In general, the person who assesses capacity must have knowledge of the procedures and be able to assess the potential participant's understanding and appreciation of the research. However, the appropriate person to assess capacity depends on the type of study.

For studies that involve interventions, a regulated health care professional should assess capacity (Health Care Consent Act). For studies that do not involve an intervention, the appropriate individual to assess capacity depends on the risk of the study. For higher risk studies, a health care professional remains the appropriate individual to assess capacity. For lower risk studies, individuals knowledgeable in child development and the research in question may be able to assess capacity.

### Why should capacity be assessed?

Initial capacity assessment ensures that participants are capable of consenting and that they know what they are consenting to. It also helps to ensure that all potential participants are given an opportunity to consent to research. Lack of decision-making capacity is not a reason to exclude participants from research nor should it be used to inappropriately include participants in research.

Capacity should also be regularly assessed. There should always be a plan to assess capacity at regular intervals, especially for longitudinal research studies. As children grow and develop, they may gain capacity to consent to the study. See below for guidance on ongoing consent.

### Where should capacity to consent be recorded?

For research purposes, it is best practice to document capacity assessment on a research study document (e.g., an enrollment log) so that children who had previously assented can be consented to participate later during the study.

For clinical trials that are regulated by Health Canada, please refer to the RQRM guidelines on where and how capacity to consent should be recorded.

### Assent

Assent is a child's affirmative agreement to participate in research. Assent should be obtained when the participant has some ability to understand the significance of the research (TCPS2 Article 3.10). Like the informed consent process, the assent process is intended to be an ongoing, interactive conversation between the research team and the child or adolescent lacking the capacity to give informed consent.

The assent process should involve taking the time to explain to the child, at whatever age they can begin to understand, what is going on in the proposed study, why the study is being done, what will be done to them, and that if they object, the research will be terminated and they will not be punished. Prospective participants' dissent precludes their participation; expression of dissent or signs suggesting they do not wish to participate must be respected.

### Process and Documentation of Consent

Consent can be obtained in writing (in person or via mail/email), verbally (over the phone), or be implied. In all methods of obtaining consent, the consent process must be documented (TCPS2 Article 3.12, GCP 4.8). Templates for different consent processes (i.e., consent form, introductory letter, telephone script etc.) are available in the template section of the REB website. All consent forms used for SickKids studies should conform to this template.

### Obtaining Written Consent in Person

Most often, written consent is obtained in person. When obtaining consent in person, consent should be documented using an informed consent form.

The following is an example of how consent can be obtained in person:

1. The PI or a person known to the participant (e.g., person in circle of care) introduces the study to the potential participant and asks if they are interested in learning more about it.
2. The PI, research nurse, or research coordinator (as appropriate) explains the study in a private area with a consent form.
3. Sufficient time for questions and consideration is provided.
4. A person outside of the circle of care (e.g. research coordinator) obtains consent. Both the participant and person obtaining consent sign and date the consent form.

If the research study is obtaining written consent in person, the following information and documents should be submitted to the REB for review:

1. Consent form for participant and/or parent guardian
2. Assent form, if applicable
3. Information regarding who will make initial contact with potential participants, who will explain the study, and who will obtain consent

### Obtaining Written Consent Via Mail/Email

Obtaining written consent via mail/email may be considered on a case by case basis. When obtaining written consent via mail/email, consent should be documented using an informed consent form. Consent via mail/email may be considered when the study is minimal risk, when it is not possible to complete the consent process in person (e.g., because the research is recruiting healthy participants from the community), when there has been a change to the informed consent form that may affect a participant who has already consented but who is not scheduled for a study visit, or in other exceptional circumstances.

The following is an example of how consent can be obtained via Mail:

1. Contact potential participants via telephone or email as preferred/expected by potential participants. Explain consent process and answer questions.



2. Mail one or two consent forms signed by the person obtaining consent to potential participants with a pre-paid envelope and a letter of information.
3. Participant signs the consent form(s). Participant mails back the signed consent form to the study team, and keeps the duplicate consent form, if applicable.
4. Person obtaining consent calls the participant to ensure they understood the consent form and what is required of them as participants of the research. If only one consent form was initially sent to the participant, a copy of the signed form should be sent back to them.
5. All steps taken to obtain consent (initial contact, mailing of consent forms via mail, follow up contact with participants) must be documented appropriately in the study binder.

If the research study is obtaining consent via mail, the following information and documents should be submitted to the REB for review:

1. Explanation as to why in person consent is not possible
2. Introduction/information letter to the potential participants from member(s) of their circle of care. The information letter should explain what to expect in the consent process and what they should do if they would like to participate.
3. All telephone and or email scripts
4. Research study recruitment advertisements, posters

#### Obtaining Verbal Consent Over the Phone

Verbal consent involves reading a verbal version of a consent form to participants who then give their verbal consent. Verbal consent is generally obtained over the phone, and it is not acceptable to use when obtaining consent in person. When obtaining verbal consent, consent must be documented in writing by the person obtaining consent.

Consent over the phone may be considered when the study is minimal risk and it is the only feasible method of obtaining consent from participants (e.g., when recruiting participants and completing surveys over the phone).

The following is an example of how verbal consent can be obtained over the phone:

1. An introduction/information letter from member(s) of the participant's circle of care is sent to the family. The information letter should briefly explain the purpose of the study, why the participant is being contacted, and what the participant can do if they do not wish to be called.
2. A member of the study team (not the PI) calls the participant and explains the study using a verbal consent script.
3. The person obtaining consent provides opportunity for questions and verifies the participant's understanding of the study.
4. The person obtaining consent documents all the conversation, including all questions asked by the participant and whether or not the participant consented to the study.

If the research study is obtaining verbal consent, the following information and documents should be submitted to the REB for review:

1. Introduction/information letter to the potential participants from member(s) of their circle of care.
2. A written script of verbal consent
3. Details about who will obtain verbal consent and how
4. Where and how verbal consent will be documented.
5. All other study documents that may be communicated to the participants such as:
  1. Study recruitment advertisements, posters
  2. Any email templates
  3. Scripts to follow-up phone calls

### Implied consent

In implied consent, participants indicate that they knowingly agree to participate in the study by completing a research activity (e.g., by completing a survey, interview etc.). It does not require a signed consent form, but it does require provision of information to research participants.

Implied consent is acceptable for some minimal risk studies. It is most commonly used in research that involves surveys, where completion and return of the survey indicates consent.

The following is an example of how implied consent can be obtained:

- i. Along with the research activity (e.g., survey), participants are provided with a written study information summary/letter or presented with this information verbally. Information regarding the purpose of the research, the time involved, statement regarding risks and benefits to participants, contact information for questions about the research, and contact information for questions about rights as a research participant should be provided to participants.
- ii. Participants complete the study activity and return any relevant documents to study team, implying their consent.

If the research study is using implied consent, the following information and documents should be submitted to the REB for review:

1. An explanation as to why implied consent is appropriate
2. The written study information summary/letter OR script for verbal explanation of study
3. Implied consent statement must appear on the relevant study documents (e.g., survey)

If you are unsure whether or not your study qualifies for implied consent, please contact the REB.

### Alterations and Waivers of Consent

Consent should always be obtained from participants prior to the conduct of research. However, certain types of research require alternate processes for seeking consent, and in some circumstances a waiver of consent may be appropriate.

### Waivers for Secondary Use (aka Retrospective) Studies

For studies which require secondary use of identifiable information (e.g., health charts, previously collected biological specimens) or secondary use of biological samples, researchers must obtain consent unless the researchers satisfy the REB that all of the following apply (TCPS2 articles 5.5A and 12.3A):

- a. identifiable information/human biological material(s) is essential to the research;
- b. the use of identifiable information/human biological material(s) without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
- c. the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information/human biological material(s);
- d. the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
- e. it is impossible or *impracticable* to seek consent from individuals to whom the information relates or from whom the materials were collected; and
- f. the researchers have obtained any other necessary permission for secondary use of information/human biological material(s) for research purposes.

Note that the TCPS2 defines impracticable as "incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience." Consent may be impossible or impracticable when the group is very large, when its members are likely to be deceased, or difficult to track down. Resources required to contact individuals and seek consent may also impose undue hardship on the researcher. In these instances, a waiver of



consent may be appropriate. In order to obtain a waiver of consent, study teams must provide sufficient information to the REB to demonstrate that obtaining consent is impracticable.

For studies which require the secondary use of non-identifiable information (e.g., results from anonymous surveys), researchers must seek REB review but are not required to seek participant consent. Researchers must "establish to the satisfaction of the REB that, in the context of the research, the information to be used can be considered non-identifiable for all practical purposes" (TCPS2 article 5.5B).

If researchers wish to contact individuals for whom a consent waiver was previously provided, REB approval for the plan for making contact is required prior to making contact (TCPS2 articles 5.6).

#### [Waivers and Alterations for Prospective Studies](#)

There are some research questions that cannot be answered without an alteration to consent requirements. The REB may approve research that involves an alteration to the requirements of consent if the study team demonstrates that all of the following apply (TCPS2 article 3.7A):

- a. the research involves no more than minimal risk to the participants;
- b. the alteration to consent requirements is unlikely to adversely affect the welfare of participants;
- c. it is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;
- d. in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and
- e. the plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with TCPS2 [Article 3.7B](#).

#### **Ongoing Consent**

All researchers, irrespective of risks and potential benefits of the research study, should maintain an ongoing consent process with participants. (TCPS2 article 3.3) Research team should engage participants in discussions throughout the research study. This does not mean that participants are asked to re-sign consent forms at regular intervals; however, re-consenting participants may be necessary in the following instances:

1. Participants who assented previously to the research study now have the capacity to consent for themselves (TCPS2 Article 3.9);
2. Significant new findings were developed or discovered during the course of the research which may affect participants' willingness to continue participation in the research study (e.g., change to risk/benefit ratio);
3. Consent form is updated with changes in study procedures or other significant information.
4. The original consent was improperly obtained:
  - Consent was obtained using the wrong version of the consent form
  - Research procedures, risks and potential benefits of the research study was not discussed during the consent process
  - Consent was obtained by an unauthorized individual.
5. Transfer of care of research participants from paediatric to adult care;
6. PI or one of the investigators have a conflict of interest to declare

If you have questions about when re-consent should occur, please contact the Research Ethics Office.

## Overview of Consent Do's and Don'ts

DOs	DON'Ts
DO use the SickKids consent templates available on the SickKids REB website	DON'T use altered approved consent forms without REB approval
DO update your consent form with changes of study procedures and/or identify new risks	DON'T state that it is a 'REB' approved research study as it suggests a guarantee of safety and this is not true.
DO obtain REB approval before using a revised consent form before re-consenting participants	DON'T confuse initials with checkmarks or "X"s.
DO verify that each participant is given a signed and dated copy of the consent form at the time of initial consent	DON'T include consent instructions that you do not follow; it may be considered noncompliance
DO keep all original signed consent forms with research study records	DON'T omit signature or date signed by person obtaining consent.
DO verify that person obtaining consent has signed, when applicable.	DON'T enter dates for participants – they must write it themselves.
DO verify that the participant signs and dates the informed consent form/assent form, otherwise it is not valid and you will not be allowed to use the data.	DON'T correct errors for anyone other than yourself on the form itself.
DO train the research staff about the consent process before beginning a study.	

## PRIVACY AND CONFIDENTIALITY

Researchers have an ethical duty to treat personal information in a confidential manner so as to protect the privacy of participants. Privacy risks may arise at all stages of the research life cycle, from initial collection of information, to data analysis, dissemination of findings, storage and retention of information, and disposal of records or devices on which information is stored. As a result, researchers must develop a plan to ensure the confidentiality of all personal information throughout the research life cycle; this is in accordance with both [TCPS](#) and the [Personal Health Information Act \(PHIPA\)](#).

### What is personal health information?

PHIPA defines personal health information (PHI) as identifying information about an individual in either an oral or in a recorded form if the information:

- relates to the individual's physical or mental health, including family health history,
- relates to the provision of health care, including the identification of persons providing care,
- is a plan of service for an individual requiring long-term care;
- relates to payment or eligibility for health care;
- relates to the donation of body parts or bodily substances or is derived from the testing, or examination of such parts or substances,
- is the individual's Provincial health number; or

- identifies an individual's substitute decision-maker.

Any other information about an individual that is included in a record containing personal health information is also included in this definition. This definition does not include information about an individual if the information could not reasonably be used to identify the individual.

### What is identifiable information?

According to the TCPS (Chapter 5), information is identifiable if it may reasonably be expected to identify an individual, when used alone or combined with other available information. Information is non-identifiable if it does not identify an individual, for all practical purposes, when used alone or combined with other available information.

The following categories provide guidance for assessing the extent to which information could be used to identify an individual:

- **Directly identifying information** – the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).
- **Indirectly identifying information** – the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).
- **Coded (de-identified) information** – direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary).
- **Anonymized information** – the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
- **Anonymous information** – the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

Ethical concerns regarding privacy decrease as it becomes more difficult (or impossible) to associate information with a particular individual. These concerns also vary with the sensitivity of the information and the extent to which access, use or disclosure may harm an individual or group.

### What are the SickKids REB requirements for protection and storage of data?

#### [Protection during data collection and analysis](#)

The collection of any identifying information (direct or indirect) must be justified to the REB (e.g., date of birth is required to determine age of participants). Where possible, the amount of information collected should be the minimum required to answer the research question (e.g., collection of date of birth in mm/dd/yy format only when age in days is required).

No directly identifying information (e.g., MRN, participant name) should appear on the data collection form. A master linking log/code breaking form can be used to link the participant's identifier to a study ID. Only the minimum amount of information required to identify a participant (e.g., MRN) should appear on the master linking log. The study ID can NOT contain any identifier or derivative of an identifier (e.g., partial MRN, year of birth, year of admission). The master linking log must contain 1) the study's title, 2) a version date, and 3) a confidentiality disclaimer (e.g., "Confidential information – keep separate from study data"). Access to the master linking log should be limited and it must always be kept separate from study data. For an example of a master linking file/code breaking file, see [templates](#).

### Protection during data/materials transfer

If data or materials are being transferred to or from SickKids, details on how they will be adequately protected and safeguarded during the transfer with external sites should be described to the REB. No identifying information should ever leave SickKids. If you are exchanging data or materials with another site, you may require a data or materials transfer agreement. Please consult with [Legal Services](#) regarding the requirements for a transfer agreement.

### Data storage and destruction

[SickKids policy](#) requires that all study data be stored behind two of each of the following types of safeguards:

- a) **Physical safeguards** – includes locked office, locked storage unit, biometric authentication, cipher/coded locks, access cards, etc.
- b) **Administrative safeguards** - includes the development and enforcement of organizational rules about who has access to personal information about participants (e.g. computer passwords only with study team, designated individual responsible for controlling who has access to data, etc.)
- **Technical safeguards** – includes use of computer passwords, firewalls, anti-virus software, network drive, encrypted computer, encrypted USB etc.

Data must be stored by researchers for a minimum of 7 years post publication or study closure, or 25 years from end of study in the case of Health Canada regulated studies.

Details of how data will be destroyed should also be provided to the REB. Paper records can be disposed of in SickKids confidential disposal bins, electronic records can be destroyed by contacting SickKids IS help desk, and old CDs, DVDs, videos, USB keys, external hard drives and other technology can be sent to the repair centre for destruction.

## TIMELINES

### Planning for REB Approval

Investigators and study teams should plan to submit a complete application for REB review well in advance of when the research needs to start. The REB recommends that research teams use the following timelines:

- **Full Board Studies** – Submit at least 6 months in advance of anticipated start date
- **Delegated Studies** – Submit at least 3 months in advance of anticipated start date
- **Retrospective Studies** – Submit at least 1 month in advance of anticipated start date
- **Amendments** – Submit at least 6 weeks in advance of anticipated start date

Submissions to the REB are processed and reviewed on a **first-come, first-served basis**. Failure to plan for the REB review process may delay the start of your research. No research activities involving participants or identifiable data, including recruitment, may begin until final REB approval is granted.

If your study requires Full Board review, please take note of the meeting [schedule](#). A complete submission needs to be received at least three weeks prior to the scheduled meeting date in order to make the meeting agenda. The level of review (full board vs. delegated) is determined by the REO based on your protocol.

### REB Review Timelines

The current REB review timelines are posted as a **general guide only**. Submissions that are incomplete or do not adhere to REB submission guidelines may require additional time. Please submit early whenever practicable.

The exact timing of review depends several factors, including:

- the quality of the submissions submitted to the REO;
- complexity of the project;
- the volume of submissions received by the REO;
- whether or not there are conflicting demands.

**NOTE:** The REB review timeline is calculated **from the day the REB accepts** a complete submission (eREB state "Ready for Triage") **to the day the REB review letter is sent** (eREB state "Clarification Required (In screening)"). The time is *not* calculated from the day the PI submits the application in the eREB.

The REB does not respond to requests to expedite a review, unless there is an emergency that may affect participant safety.

REB approval depends on several factors that are not entirely within control of the REB (i.e., PI response time, regulatory requirements, contracts, other hospital services, etc.).

<b>Application Type</b>	<b>Target # of business days for review letters</b>
<b>REB Main Application</b>	
<i>Full-board review</i>	5-10 days after the REB meeting
<i>Delegated review</i>	20-25
<i>Delegated review of secondary use (retrospective) studies</i>	10
<b>Amendment Application</b>	
<i>Full-board review</i>	5 days after the REB meeting
<i>Delegated review</i>	15-20
<i>Delegated review of secondary use (retrospective) studies</i>	5-10
<b>Staff Change Form</b>	
<i>Staff change (study team members only)</i>	5
<i>PI change</i>	5-10
<b>Renewal/Closure Application</b>	Dependent on expiry date*

[\\*Renewal/Closure Application Review Timeline](#)

The REO receives a high volume of renewal/closure applications. As a result, review of renewal/closure applications is prioritized based on the study's expiry date and the date the completed renewal application was received.

Complete renewal applications should be submitted to the REB a **minimum** of 10 business days prior to study expiry date. Renewals that require Full Board review should be submitted 10 business days prior to the scheduled REB panel meeting preceding the study expiry date in order to have the renewal added to the meeting agenda. We encourage study teams to submit early in order to ensure their study is re-

approved. Renewal/closure applications that are received on time are typically reviewed 10-20 business days prior to the study expiry date. Renewals that require full board review will be reviewed at the board meeting prior to the study expiry. The REO makes every effort to re-approve studies before their expiry date, provided the renewal application is submitted to the REB on time. If you have a closure application that needs to be processed earlier, please contact the REB analysts.

### Response to REB reviews

Responses to the REB's requests for modifications are typically reviewed within 5-10 business days.

However, the turnaround time for responses varies significantly depending on:

- the inclusion of an itemized response to the REB concerns
- the clarity, accuracy and completeness of the response (frequently responses indicate that changes have been made that are not reflected in actual changes to the protocol, consent form or eREB application);
- the number and complexity of the requested modifications to the study; and
- the total volume of REB applications at the time of the submission

Please note that the REB retains the right to close any files relating to an ethics application that has been pending for three (3) months or more (i.e., the study team has not provided a response within 90 days). Should the research team wish to pursue with the research at SickKids, they will have to resubmit a new application for ethics approval.

## FEES

Effective Nov. 2, 2015, the following REB review fees will be implemented. These fees cover costs of initial and ongoing review of all new applications for industry-funded research studies.

Please note that research supported by public funds (i.e., CIHR) is not subject to these fees. All funds are in Canadian currency.

Initial REB Review: \$3,000

Study Renewals: \$500

Protocol Amendments: \$500

Initial REB Review Fee: \$3,000

For review of new ethics applications funded by a for-profit entity (i.e., pharmaceutical/medical device company).

Study Renewal Review Fee: \$500

For review of study renewal applications of ongoing research studies (annual or otherwise) funded by a for-profit entity (i.e., pharmaceutical/medical device company).

Protocol Amendment Review Fee: \$500

For review of amendments involving revisions to the study protocol and/or patient safety changes to the consent documents. Amendments that do not include changes to the study protocol and/or patient safety information will not be subject to this fee.

### Invoicing and Payment

All REB fees are charged regardless of the level of review required (full board vs. delegated) or the outcome of the review.

All invoicing and payment is handled by the SickKids Research Awards and Financial Services (RAFS). Please contact RAFS for more information regarding invoicing, billing of REB fees.

Questions or concerns respecting this Notice may be directed to the Manager of the Research Ethics Office (REO) at 416-813-7654 ext. 205718, or by email at david.kenney@sickkids.ca

## FREQUENTLY ASKED QUESTIONS

### **Do I need approval for a small, pilot research study or to pre-test a study instrument or questionnaire?**

Yes

### **What do I do if I want to make a change to a study after I obtain approval?**

All protocol changes, whether major or minor, must be submitted for approval prior to implementation. This is done via an REB Amendment Application in the eREB.

On the main study screen, click "New application" on the left side. This will generate a dropdown list, where the REB Amendment can be found. Please ensure all form sections are complete, the PI has clicked the "Submit" button.

### **Once I obtain ethics approval on my Health Records/Database application, how can I obtain the charts from Health Records?**

Present your signed REB application form to staff in the Health Records Department.

### **There has been an adverse event at another study site. Do I still have to fill out an Unexpected Problem/Adverse Event Form in the eREB?**

Yes.

### **How long does it take to get approval?**

That depends on many factors e.g., completeness of the application at the time of submission to the office, whether or not full review is required, the extent of unanswered questions raised by the Board following its review etc.

See Timelines on page 28.

### **How will I be notified about my approval?**

A notification email is automatically generated by the eREB once final sign-off from the Chair has been obtained. The approval letter is not part of this email but is found attached to the original application in the eREB.

### **If a project has been funded by an external agency, is internal science review automatically waived?**

No. Internal science review can be waived if the funder is a major granting agency and the project has undergone a competitive review and approval process. A list of granting agencies from which we accept an SRB substitution and more information on the Scientific, Feasibility and Operational Review process can be found here.

**Note:** Even if a waiver is granted, the Scientific, Feasibility and Operational Review form must still be submitted.

### **Do result reports for research need to include a research disclaimer?**

Yes, reports of results generated for research purposes must include the following statement:

"RESEARCH USE ONLY: The results contained in this report were generated in a research lab that is not an accredited or licensed clinical laboratory. The results are provided for research purposes

only. The underlying tests were not performed for the purposes of obtaining information for diagnosis, prophylaxis, or treatment."