**SickKids REB Main Application checklist – PROSPECTIVE STUDIES**

*This checklist is a guideline to help you ensure you have all the necessary documents for your REB Main Application for a prospective study. Note that depending on what your study involves, the REB may request additional documents.*

**APPLICATION REQUIREMENTS**:

All sections of the **REB Main Application** must be completed; each question must be answered directly and completely (i.e., answers cannot just refer to the study protocol. Avoid direct copy and paste from protocol, rather explain in simple language the details from protocol.)

Please remember to complete the following sections:

**5. Project Funding**: add each source of funds by clicking on the “Add new funding source” button

**9. Sites, Agreements and Contracts**: add each external site by clicking on the “Add site” button and explain the direction of flow of data/samples between SickKids and each site

In addition to the REB Main Application, you must create and submit an **SRB Application** — this is an eREB system requirement and your study cannot be approved without it

**SRB Application (Upload)**

* Scientific, Feasibility, and Operational Review form is attached and the application is submitted (see below for information on Scientific, Feasibility, and Operational Review)

**SRB Application (Electronic) -** for Haematology/Oncology study population:

1) Haem/Onc is selected in section 1 of REB Main Application

2) SRB Application (Electronic) is created and submitted. For Haematology/Oncology Science Reviews submitted using the eSRB, only the Feasibility and Operational sections need to be completed. Upload this review on the REB Main application.

3) REB Main Application can only be submitted after the SRB Application is approved in eREB.

All applicable documents listed below must be **uploaded** in eREB for your REB application to be considered complete:

**DOCUMENT CHECKLIST**:

**Protocol** – must contain a background section, study objectives/hypotheses, and a methodssection (including inclusion/exclusion criteria; estimated sample size and justification; data analysis)

**Consent and assent forms** – must follow the SickKids REB templates, found on the Clinical Research Services MySickKids page.

* Assent Forms must be submitted with Parent Consent Form.

**TIP: Always** check the Clinical Research Services MySickKids page to ensure the use of the most up to date templates.

**Master linking log** (must contain the disclaimer “Confidential. To be kept separate from study data.”)

* Only collect direct identifiers that are required for your study. If you require partial date of birth (mmm/yyyy) as a data variable, it should be collected on the data collection form and not the Master linking log.

**Budget** and **Proof of Funds** (if PI funds are used, a formal letter from the PI is required), grant acceptance

**Scientific, Feasibility and Operational Review** –the following must be uploaded:

* Scientific, Feasibility, and Operational Review Form (After you send your SPRINT Approvals Roadmap and copies of all hospital approvals to [go.sprint@sickkids.ca](mailto:go.sprint@sickkids.ca), the SPRINT team will send you the Scientific, Feasibility, and Operational Review Form and Instructions. Instructions are also available [here](http://my.sickkids.ca/research/clinical-research-services/Documents/Science%2c%20Feasiblity%20and%20Operations%20Process_2018_04_03%20%282%29.pdf).)
  + If issues were identified as part of the SPRINT review, an itemized list of responses **must** be provided.
* To request a waiver for the SickKids science review, please contact the manager of Research Ethics and Regulatory Compliance ​​prior to submitting to the REB. You will still need to complete the Feasibility and Operational Review sections. See [Scientific, Feasibility and Operational Review heading](http://my.sickkids.ca/research/clinical-research-services/clinical-trials-roadmap/Pages/Feasibility.aspx) for waiver requirements.
* If the waiver is granted, you **must** upload the waiver of internal science review email from Research Ethics and Regulatory Compliance manager
* If a waiver was granted because you have a SickKids-approved external science review, please upload the complete external science report.

□ **Pre-REB SPRINT Certificate of Completion –** This will be emailed to you after you email your completed Scientific, Feasibility, and Operational Review Form and itemized responses (if applicable) to [go.sprint@sickkids.ca](mailto:go.sprint@sickkids.ca).

**Data collection forms** - Do **not** include direct identifiers, if direct identifiers are collected, you must provide justification in eREB application form section 24; include a “Participant ID” field; and where dates are collected, specify date format, e.g., “Date of birth (mm-yyyy),” “Date of diagnosis (dd-mm-yyyy)”

**Health Canada NOL/ITA** – applicable when the study is regulated and the sponsor is external

* Note that a study may require regulation if it involves the investigation of a new drug, a drug that is being used off-label, or a device (e.g., medical device, pedometer, exercise bike). If you’re not sure if your study requires regulation, please contact Research Ethics and Regulatory Compliance at [ask.crs@sickkids.ca](mailto:ask.crs@sickkids.ca) prior to submitting.

**Questionnaires, surveys, interview grids**

* If your study uses validated questionnaires that collect direct identifiers such as name, initial and exact DOB (dd/mmm/yyyy) ensure all these identifiers have been redacted **OR** confirm that that these identifier fields will be redacted before it is given to the participants to complete and how this will be done.
* Note that REB Main Application form section 13 indicates that **validated instruments** do not need to be uploaded but **this is not the case.** They **must** be uploaded with the application. **All** data collection forms, including surveys and questionnaires must be uploaded in eREB for REB review and approval.

**Recruitment** **documents** – this may include:

Study advertisements, including recruitment posters/flyers, pamphlets, social media posts etc.

Introduction letters

Phone scripts

**TIP: Always check the Clinical Research Services MySickKids page to ensure the use of the most up-to-date templates.**

**Other participant-facing materials** – any other study-specific documents that participants will be given will need to be uploaded in eREB for REB review.

**ADMINISTRATIVE REQUIREMENTS:**

Ensure all study documents contain:

a **document** **title** (e.g., “Data collection form”)

the **study title**

a full **version date (dd-mm-yyyy)**

**page numbers** (page X of Y)

*suggested:* **file names** should contain **document type and version date** (e.g., “Data collection form 2017\_10\_12”

Not having these administrative requirements may delay the review and approval process of your study.