**SickKids REB Main Application checklist – SECONDARY USE STUDIES (aka Retrospective)**

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

**SPRINT PROCESS: SCIENTIFIC, FEASIBILITY AND OPERATIONAL (SFO) REVIEW AND DIVISION HEAD SIGNOFF REQUIREMENTS**Before applying for REB approval, you must go through the SPRINT process. Fill out the SPRINT Initial Triage Form. You will receive an email with a link to your Secondary Use/Retrospective Roadmap which will guide you to the internal services and approvals required. Once you have completed Part I and Part II of your SPRINT Secondary Use/Retrospective Roadmap, upload one of the following on the REB application using "SPRINT Certificate" document type (details outlined on Document Checklist below):

1. Signed SPRINT Roadmap, or
2. Completed and signed off SFO

**REB APPLICATION REQUIREMENTS**:

[ ]  All sections of the **REB Main Application** in the eREB must be completed; each question must be answered directly and completely (i.e., answers cannot just refer to the study 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

[ ]  All applicable documents listed below must be **uploaded**

[ ]  For Retrospective studies using biological samples: 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 (SFO) Review form is attached and the application is submitted (see below for information on SFO 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.

**DOCUMENT CHECKLIST**:

[ ]  **Protocol** – must contain a background section, study objectives/hypotheses, and a methodssection

(including inclusion/exclusion criteria; estimated sample size and justification; health chart date review

range; data analysis plan; data management; retention and destruction). Please refer to Secondary Use

Protocol Template on the Clinical Research Services MySickKids page for all applicable sections.

[ ]  **Master linking log** – if direct identifiers (e.g. MRN) will be removed and a unique participant ID will be assigned. Must contain the confidentiality disclaimer “Confidential. To be kept separate from study data.” within the body of the document.

[ ]  If funded, **Budget** and **Proof of Funds** (if PI funds are used, a formal letter from the PI is required)

[ ]  **Data collection forms** – do **not** include direct identifiers; 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)”

[ ]  If data is coming from previously completed **questionnaires, surveys or interviews,** provide a copy of

these documents; ensure all PHI has been redacted **OR** confirm that only de-identified data will be used

* 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.

**SPRINT requirements:**

* ***For Retrospective - secondary data (no biological samples)***

[ ]  **Signed Secondary Use/Retrospective Roadmap –** Obtain Division/Department/Program Head or Clinical Designate signoff directly on the Secondary Use/Retrospective Roadmap.

* ***For Retrospective - biological samples***

One of the following required:

[ ]  1. **Scientific, Feasibility and Operational (SFO) Review Form**, or

[ ]  2. **External peer review from one of the exempted granting agencies** (for a list, see Clinical

Research Services MySickKids page); or

[ ]  3. **Waiver of internal science review email from Research Ethics and Regulatory Compliance manager** (with external science review report if applicable)

[ ]  **Itemized list of responses** must be provided if issues were identified as part of SFO review.

**Study signoff:**

[ ]  1. Obtain Division/Department/Program Head or Clinical Designate signoff on the **SFO Review form**, or if no SPRINT SFO Review is required as per above:

[ ]  2. **Signed Secondary Use/Retrospective Roadmap -** Obtain Division/Department/Program Head or Clinical Designate signoff directly on the Secondary Use/Retrospective Roadmap.

***If data/samples are coming from another study where participants consented to use of their data/samples in future studies:***

[ ]  Copy of the **consent form** used in other study

***If you will be seeking consent:***

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

[ ]  **Recruitment** **documents -** this may include:

 [ ]  Introduction letters

 [ ]  Phone scripts

[ ]  **Other participant materials** – any other study specific documents that participants will be given provided

**ADMINISTRATIVE REQUIREMENTS:**

Where appropriate, ensure all study documents are embedded with the following:

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

[ ]  the **study title**

[ ]  a **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.