

Guideline: Receipt of human data or biological samples as part of an external research collaboration – local ethical review requirements.

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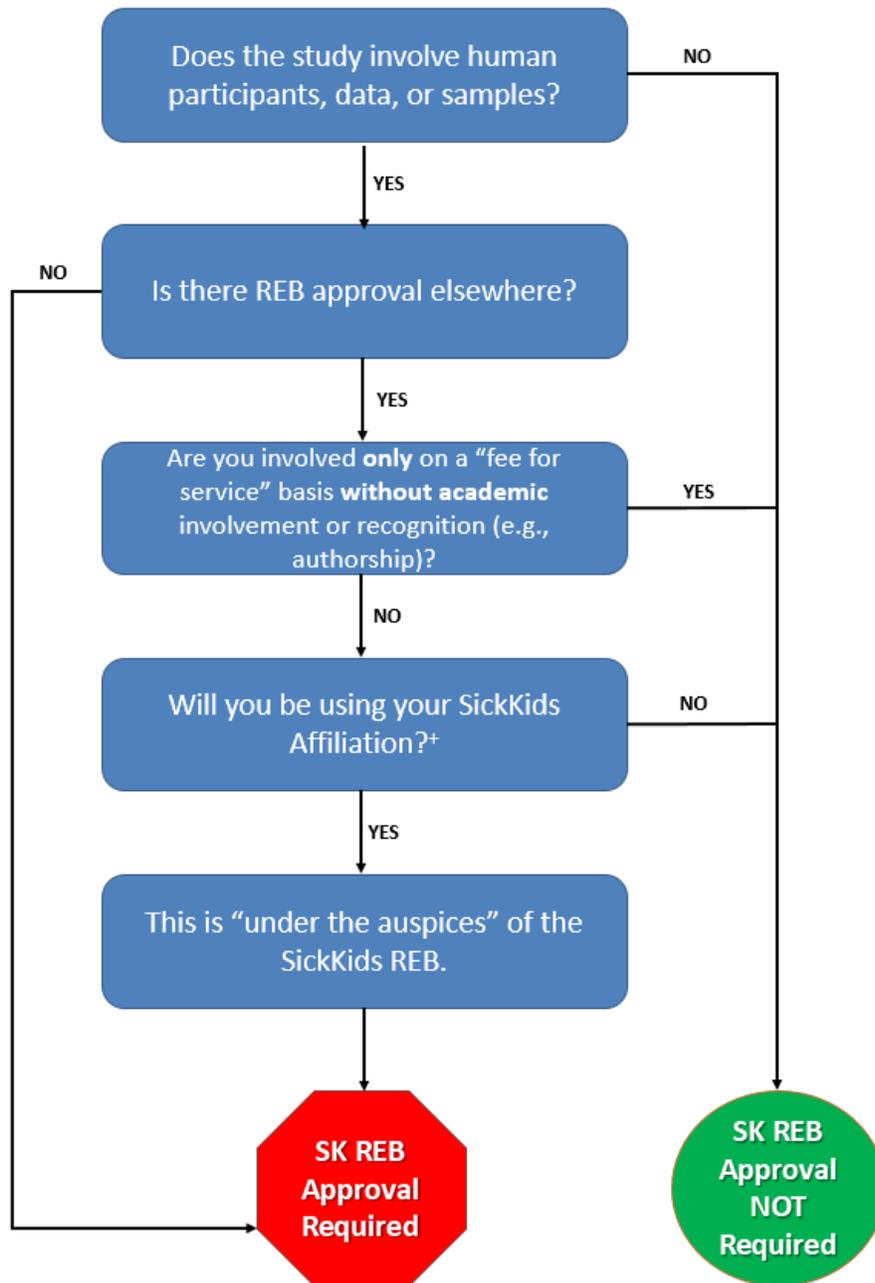
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Background

The SickKids REB is responsible for the ethical conduct of any human research undertaken within its jurisdiction or under its auspices. All research conducted by SickKids research staff involving human participants or human data/specimens must be approved by the SickKids REB. Therefore, SickKids researchers planning to receive human data or biological samples from external collaborators may be required to obtain approval from the SickKids Research Ethics Board (REB) before the transfer of material occurs. Examples of this type of research collaboration include a scientist receiving data from external sites for analysis, or accepting samples for analysis in a research laboratory. This guidance document outlines when SickKids REB approval is required, and what study teams must submit.

Note that if your study involves participants at SickKids then these guidelines do not apply; you must submit your research project to the SickKids REB.

Do I need REB approval?



*If you're not sure if you should be using your SickKids affiliation, contact the RI.

Note that if you are simply providing a service to a study team (e.g., performing analysis on samples for a fee), then an REB submission is *not* required. However, a service agreement may be required and Legal Services should be contacted. If you are not sure whether you need REB approval or not, please contact the Research Ethics Office for guidance.

What do I need to submit to the REB?

- REB Main Application
 - Your responses to the questions in the REB application should reflect the overall study design, not simply your role. For example, if the overall study is prospective interventional study, you should respond to the questions about the overall study design.
 - In order for the REB to conduct a 'proportionate' review of your study, clarify in your responses to application questions that at SickKids, you are only conducting a small aspect of the study (e.g., samples analysis, data analysis, etc.).
 - Ensure you state all institutions with which data/samples will be shared (form section 9), and explain the direction of flow of transfer.
- Study Protocol
 - You should submit the protocol for the **entire** study, *do not* create and submit a SickKids specific protocol. As mentioned above, in the eREB application, you will explain the portion of the study that you are involved in at SickKids.
- Consent Forms
 - If consent was or will be obtained at other sites, a copy of the consent form approved by the lead site should be submitted to the REB.
- Science Review
 - The rules related to scientific review still apply. A science review is required. If you would like to be considered for a waiver of the requirement of internal scientific review, you must contact the Research Ethics Manager.
- Data Collection Forms
 - If you will be analyzing data, you must include the data collection forms.
- A copy of the REB approval letter from the lead site
- Based on the nature of the activities occurring at SickKids, other documents may be required

Will my application have to go to the full board?

Risk will be assessed by the REB, and determination of level of review will be made. REB oversight at other centers will be taken into account.

What if I have questions?

If you have questions, please contact the Research Ethics Office for further guidance.