

**SCIENTIFIC, FEASIBILITY, AND OPERATIONAL REVIEW**

**This section to be completed by the Principal Investigator (PI)/study team prior to review:**

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| **STUDY TITLE:****REB # (if available):****PI NAME:**

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| **THIS WILL BE GOING TO AN OUTSIDE REB:** [ ]  **OCREB** [ ]  **CTO** [ ]  **N/A****THIS HAS BEEN REVIEWED BY THE HAEMATOLOGY/ONCOLOGY SCIENTIFIC REVIEW BOARD:** [ ]  **Yes, attached** [ ]  **N/A** |

Only the feasibility and operational/financial sections need to be completed if a Haem/Onc scientific review is attached.**EXTERNAL SCIENTIFIC REVIEW COMPLETED:** [ ]  **Yes, attached** [ ]  **N/A**If the study has already undergone a grant review by an approved agency (e.g. CIHR, NIH, [see here for list of agencies approved by the REB](http://my.sickkids.ca/research/clinical-research-services/clinical-trials-roadmap/Pages/Feasibility.aspx)), the Scientific and Protocol Review may be waived and only the feasibility and operational/financial sections need to be completed. Please note, the review may not be sufficient for the REB or Department sign off and the REB reserves the right to request additional review. It is important to note that prior external science review for grants may not be adequate as the detailed clinical protocol may not have been reviewed at that time.Date Science Review completed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Please attach all feedback such as comments, reviews or scientific officer notes.****Please indicate (in the relevant sections below), if there have been any changes to the protocol since the attached science review occurred** |

**INSTRUCTIONS FOR REVIEWERS:**

The study team will provide you with the current version of the protocol and budget (for Operational/Financial reviewers) for your review.

Complete, sign and return the review as requested by the study team to the review chair prior to the review meeting (if applicable)

**PLEASE NOTE**: Reviewers must include all substantive issues and/or recommendations on this form, whether or not they have been provided verbally to the investigator

Each review must include a designated Chair agreed upon by the selected reviewers

* Disagreements among reviewers should be documented in the open comment field; and the review Chair should guide the process for resolution either remotely or in-person
* The review chair will collate the reviews and provide them to the PI/study team
* The review chair is responsible to ensuring that all recommended changes and significant concerns expressed by the reviewers have been addressed satisfactorily prior to providing final sign off

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| **SCIENTIFIC AND PROTOCOL REVIEW**  [ ]  N/A; Reason: [ ]  External Science Review [ ]  Reviewing Feasibility and/or Operational Only  |

**S1.** Is the attached research protocol clearly described?

 Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**S2.** Please list the primary objective:

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Are specific objectives clearly stated?

Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**S3.** Are the hypotheses reasonable?

 Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**S4.** Describe if the research design is appropriate to the goals of the study and why?

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**S5.** Are inclusion and exclusion criteria clearly delineated?

 Inclusion criteria: Yes [ ]  No [ ]

Exclusion criteria: Yes [ ]  No [ ]

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**S6.** Is the study population appropriate for the stated purpose?

 Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**S7.** List study procedures that entail significant risk: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Are specific study procedures appropriate and reasonable given any risks or burdens they may entail to the study population?

 Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**S8.** Are the proposed outcome measures appropriate for the research question?

Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**S9.** Describe the safety measures in the protocol to address potential harms: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Are the safety measures outlined appropriate to address the potential harms?

Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**S10.** Do the potential benefits outweigh the potential harms?

Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**S11.** Will a data and safety monitoring board or observational data and safety monitoring board be appointed for this study?

 Yes [ ]  No [ ]

* If yes, is it appropriate and is there a documented plan with regular reporting to the REB?

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* If no, is one required? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**S12.** Have blood volume guidelines been taken into account? ([See Intranet, section REB Guidelines](http://my.sickkids.ca/research/clinical-research-services/Pages/FAQ.aspx))

 Yes [ ]  No [ ]  No blood sampling in protocol [ ]

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**S13.** Describe potential incidental findings: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Is there an incidental findings plan (for any type of tests, procedures, imaging, etc)? Yes [ ]  No [ ]

Comments:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**S14.** Are the study numbers sufficient to provide likelihood of an interpretable result?

 Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**S15.** Is the statistical analysis section adequate based on the study design?

 Yes [ ]  No [ ]  Don’t have enough expertise [ ]

* If yes, is there a discussion of statistical methods and are they appropriate? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* If no, what is missing? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**S16.** Will the study findings be impactful?

Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **FEASIBILITY REVIEW** [ ]  N/A; Reviewing Scientific and/or Operational Sections Only  |

**F1.** Is this study feasible in terms of recruiting and retaining the study population?

 Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**F2.** Does the investigator have access to the required population (specific unit, ward, clinic, physician practice groups, etc, and globally if global study)?

 Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**F3.** Has the impact on the affected clinical areas been accounted for and approved?

 Yes [ ]  No [ ]  Not Applicable [ ]

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**F4.** Is there an adequate patient population at SickKids and/or enough external sites to recruit the required number of participants?

 Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**F5.** Are the aims of the study achievable in the proposed timeline?

 Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**F6.** Does the study involve disruption of schedules (including school) for participants/parents?

 Yes [ ]  No [ ]

* If yes, is the disruption justified?

 Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**F7.** Are the participants likely to be enrolled in other studies?

 Yes [ ]  No [ ]

If yes:

* Will overlapping studies pose an unacceptable burden on the participant and their family?

Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* Is there a plan to manage study prioritization?

Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**F8.** For an investigational drug trial, is the method (oral, IV, etc) of administration possible for the age of the population?

Yes [ ]  No [ ]  Not Applicable [ ]
Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**F9.** For an investigational drug trial, are there any drug-drug interactions that need to be considered in this population?

Yes [ ]  No [ ]  Not Applicable [ ]
Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **OPERATIONAL/FINANCIAL REVIEW** [ ]  N/A; Reviewing Scientific and/or Feasibility Only  |

**PROCEDURE REVIEW**

**OP1.** Do all aspects of the protocol make sense – is everything logical, sensible and possible?

 Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**OP2.** Is the timing of study procedures and visits feasible? (Does the protocol allow for a window of time for each time point?)

 Yes [ ]  No [ ]  Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**OP3.** Are the following discussed?

* Identification of potential participants? Yes [ ]  No [ ]
* Making contact with potential participants? Yes [ ]  No [ ]
* Obtaining consent (if needed)? Yes [ ]  No [ ]

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**FINANCIAL REVIEW**

**OP4**. Are all research interventions appropriately budgeted, see budget template? ([See here for Budget template and guides](http://my.sickkids.ca/research/clinical-research-services/Pages/FAQ.aspx)). Yes [ ]  No [ ]

**OP5.** Does the study protocol include any unfunded drug treatments that are not covered by the study budget or provided by the sponsor? Yes [ ]  No [ ]

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**OP6.** Considering the number of patients and the duration of the study, is there a projected budget shortfall (i.e. there is not enough money allocated for the entirety of the study)?

Yes [ ]  This is a consortium or academic study – the shortfall will be covered by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Yes [ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Additional funding has been secured from: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 No [ ]

**OP7.** What is the cost centre number (EPIC project ID)? If not yet established, please remember that before you can start your study in EPIC, a number will be required. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **RECOMMENDATIONS**  |

This study needs the following revisions and must be resubmitted for a final Scientific, Feasibility, and Operational Review before it can be submitted to the REB for ethical review:

­­­­­­­­­­­­­­­­­­­[ ]  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **ITEMIZED RESPONSE AND REVIEWER SIGN OFF** |
| Should this study go forward? [ ]  Yes, as is [ ]  Yes, with revisions indicated [ ]  No; explain: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_I confirm that I have received and read the study protocol and provided accurate feedback for one or more of the following parts that I have been assigned to review: Scientific and Protocol, Feasibility and/or Operational/Financial and I acknowledge that my feedback is essential to the development and delivery of good quality research studies at SickKids.  |
| **REVIEWER NAME** | **SIGNATURE** | **REVIEW TYPE** | **CLINICAL OR RESEARCH DIVISION**  | **ROLE** | **DATE** |
|  |  | [ ]  S, F and O [ ]  Scientific [ ]  Feasibility[ ]  Operational |  |  |  |
|  |  | [ ]  S, F and O [ ]  Scientific [ ]  Feasibility[ ]  Operational |  |  |  |
|  |  | [ ]  S, F and O [ ]  Scientific [ ]  Feasibility[ ]  Operational |  |  |  |

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| **REVIEW CHAIR SIGN OFF** |
| The recommended changes and significant concerns expressed above have been addressed satisfactorily.  [ ]  Yes [ ]  No [ ]  NA Review Chair Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_ |

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| **SECTION HEAD/DIVISION HEAD/PROGRAM HEAD\*** |
| By signing below, I confirm the following:* I am aware of this proposal and support its submission.
* I consider it feasible and appropriate, and the principal investigator has the necessary resources to conduct this study.
* I attest that the principal investigator responsible for the conduct of this study is qualified by education, training, and experience to perform his/her role in this study, and that I do not have a conflict of interest with regard to this study.
* I do not have any concerns with this study being conducted at SickKids.

**NAME OF DIVISION HEAD/DEPARTMENT HEAD/CLINICAL DESIGNATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****SIGNATURE:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DATE:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

\* if the Section head/Division head/Program head is part of the study team, they will delegate another clinically responsible person for sign-off.