

PERC ENDORSEMENT AND REVIEW PROCESS

OVERVIEW OF PROCESS STEPS

Any PERC member may bring forward a study to the PERC executive for consideration as a PERC study. A PERC study must involve more than one PERC ED site/investigator. Types of studies that can be put forward for PERC-Endorsement include prospective and retrospective cohorts, clinical trials, surveys using the PERC Physician list, database studies using external data, systematic reviews, and trials of knowledge synthesis tools. **A minimum of 2 centres must be involved in recruiting participants and investigators from 2 centres must work collaboratively on the project for it to be eligible for consideration as a PERC study.**

The PERC-Endorsement and review process involves three phases to assist PIs with developing a methodologically sound project and to promote the likelihood of successfully obtaining grant funding from a peer-review agency. The first phase involves the PI filling out a PERC Study Intake Form in REDCap. This form communicates details about the proposed study. Based on a review of the information provided, the PI will either be contacted for additional details or will be asked to proceed to the second phase: providing a concept paper for review by the PERC Executive. Based on the review of the concept paper, the PI will be contacted for additional details or asked to proceed to the third phase, providing a full study protocol and **budget** for review by the PERC Executive and/or designated PERC members.

PHASE I: PERC STUDY INTAKE FORM

The PI will complete the online PERC Study Intake Form in REDCap (<https://www.perc-canada.ca/pages/104-perc-project-intake-form>). The PERC Study Intake Form communicates details about the proposed study to the PERC Executive. Based on a review of the information provided, the PI will either be contacted for additional details or will be asked to proceed to the second phase.

In REDCap, the following study details are required:

- 1) Principal investigator name
- 2) Co-principal investigator name
- 3) Is the co-principal investigator a trainee (provide name)
- 4) Principal investigator e-mail
- 5) Preferred email for study communications
- 6) Is the principal investigator being mentored by another PERC member? (provide name)
- 7) Study coordinator name (if identified)
- 8) Lead PERC site
- 9) Have you previously conducted a multi-site study?
 - a. If yes, specify study name
 - b. If no, do you have a mentor who has conducted multi-site research?
 - i. If yes, provide name of mentor.
 - ii. If no, do you wish to have a mentor?

- 10) Working project title
- 11) Type of study
 - a. Randomized controlled trial
 - b. Prospective cohort
 - c. Retrospective cohort
 - d. Qualitative
 - e. Systematic review
 - f. Survey of PERC physicians
 - g. Survey (not using the PERC physician list)
 - h. Other (specify)
- 12) Do you currently have funding to support the conduct of this study?
 - a. If yes, specify funding agency and amount
- 13) Do you plan on applying for grant funding or additional funding?
 - a. If yes, specify opportunity and submission deadline
 - b. If no, how do you plan on supporting the conduct of your proposed study?

Note: If successful, all PERC-Endorsed studies will be required to include a budget line item for PERC Infrastructure support with the exception of total budgets under \$50,000.

- 14) Do you anticipate your study requiring patient/parent input or involvement?
- 15) Has this study been presented at a PERC meeting?
 - a. If yes, specify meeting year
 - b. If no, are you planning to present
- 16) Has this study been discussed with potential participating sites?
 - a. If yes, list the names of investigators/sites that have agreed participate at this stage.

If no, we suggest you contact site representative to gauge interest and feasibility of conducting this research in a multi-site setting. Note it is the responsibility of the PI to fill out the PERC intake form. The Executive will review the intake form to ensure the following: 1) if mentorship is needed; 2) if site engagement has been initiated; 3) identify reviewers for concept paper and full protocol.

PHASE II: CONCEPT PAPER SUBMISSION

Phase II involves providing a 2-page concept paper for review by the PERC Executive. The PI should use the template provided in Appendix B. It is the responsibility of the PI to develop the research question and prepare a concept paper to be submitted to the PERC Executive.

The Executive will review the intake form and concept paper to ensure the following: 1) the study topic is important and relevant to pediatric emergency medicine; 2) meets the goals of PERC as outlined in the PERC governance document; and 3) the new proposal is not competing with any existing studies (see more information about potential conflicts below). The executive will provide written feedback to the PI.

If the concept paper is deemed to meet the above criteria, the PERC executive will request that the PI submit a protocol, specifically the detailed methodology, and proceed to the third phase.

PHASE III: PEER REVIEW OF FULL PROTOCOL

Phase III involves a peer review of the full study protocol. The process of PERC protocol review takes a minimum of 6 to 8 weeks.

In phase III, the PI will upload the following to the original PERC Intake Form:

- 1) Full protocol;
- 2) Study budget. Reminder: all PERC-endorsed studies must include a budget line item supporting PERC infrastructure (as per the budget justification in Appendix A);
- 3) The site representatives signature form (upload form); and
- 4) All RCT protocol submissions must use the NIH Clinical Trial Template (<https://osp.od.nih.gov/clinical-research/clinical-trials/>). This template must be submitted along with a completed SPIRIT checklist (<http://www.spirit-statement.org/title/>) to the PERC Executive for review.

The PI is responsible for contacting PERC site representatives to establish collaborative sites for the full protocol. In choosing participating sites, PERC as an organization supports the principals of inclusiveness, openness, creating linkages and the promotion and fostering of research collaborations and excellence across PERC sites. As a result, PIs should offer the opportunity to participate in their PERC study to as many sites as possible (within the confines of their study protocol and budget). The PERC executive can help with PERC site selection if requested by the PI.

A full protocol should not be submitted for review until participating PERC sites have been identified and have agreed to participate. The PI must provide PERC with signed documentation that named PERC sites have agreed to participate in the study (see point 3 above).

Two members of the executive (or a designated alternative) will critically review the protocol and budget and provide a summary and recommendation to other PERC Executive members. Each member will then submit an anonymous vote, except for those that are investigators on the current proposal, to the PERC Coordinator for one of the following decisions:

- 1) Accepted as a PERC-endorsed study;
- 2) Accepted pending minor revisions;
- 3) Major revisions and 2nd review required;
- 4) Rejected.

Note: PI's of previously endorsed proposals will be contacted to review future proposals on behalf of PERC as criteria of endorsement. **At least 75% of the (voting eligible) PERC executive must vote to accept the proposal to be approved as a PERC-endorsed study.**

The PERC Executive members will communicate the decision to the PI and provide detailed feedback on the protocol methods. When a study is formally accepted, a letter will be provided by the PERC executive indicating that the study is endorsed by the PERC network.

It is expected that the principal investigator of all on-going PERC approved studies will provide an update at the Annual PERC Meeting.

Special Considerations: RCTs

All PIs of PERC-Endorsed RCTs must register their trial prior to enrolling patients; publish the study protocol either in a peer-review journal or on a publicly available, maintained website (e.g. Research Institute website) and must explicitly name PERC in the main author line and in the methods. These requirements will be detailed in the PERC-Endorsement letter. All PERC approved studies must provide the trial registry number to PERC executive. All RCTs must also provide the PERC executive with a list of DSMB members and their affiliations and a copy of the DSMB charter prior to commencing patient recruitment. Resources and examples provided on the PERC website.

Special Considerations: Cohort Studies

All PIs of large prospective cohort studies must publish the study protocol either in a peer-reviewed journal or on a publicly available and maintained website. This requirement will be detailed in the PERC-Endorsement letter. The study protocol must explicitly name PERC in the main author line and in the methods.

APPENDIX D: INFRASTRUCTURE SUPPORT AND BUDGET JUSTIFICATION

All PERC-Endorsed studies will be required to include a budget line item for PERC Infrastructure support with the exception of total budgets under \$50,000.

For total budgets between \$50,000 and \$1,000,000 the contribution will be 2% of the total grant for the first year of the grant and then each subsequent year will have a 0.3% contribution per year. Any grant over \$1,000,000 will be invoiced \$20,000 for the first year and then each subsequent year will have a \$5,000 contribution per year.

The budget line item will be invoiced per year of the awarded grant (unless otherwise specified and communicated to by the PI ie. to be invoiced the total contribution all at once).

These budget line items are for funding from Tri-Council and CIHR. If the grant is industry or otherwise sponsored these amounts will need to be discussed with the PERC executive for final approval.

Please see below table for examples and guidance:

TOTAL BUDGET	2%	
under \$50,000	N/A	<ul style="list-style-type: none"> • Example A - if you have a 5 year study with a total funding of \$1,000,000 the following invoicing will take place: <ul style="list-style-type: none"> ○ Year 1 contribution = \$20,000 (2% of total grant funding) ○ Year 2 contribution = \$3,000 (0.3% of total grant funding) ○ Year 3 contribution = \$3,000 (0.3% of total grant funding) ○ Year 4 contribution = \$3,000 (0.3% of total grant funding) ○ Year 5 contribution = \$3,000 (0.3% of total grant funding) - Total contribution = \$32,000 • Example B – If you have a 2 year study with a total funding of \$150,000 the following invoicing will take place: <ul style="list-style-type: none"> ○ Year 1 contribution = \$3,000 (2% of total grant funding) ○ Year 2 contribution = \$450 (0.3% of total grant funding) - Total contribution = \$3,450 • Example C – If you have a 3 year study with a total funding of \$700,000, the following invoicing will take place: <ul style="list-style-type: none"> ○ Year 1 contribution = \$14,000 (2% of total grant funding) ○ Year 2 contribution = \$2,100 (0.3% of total grant funding) ○ Year 3 contribution = \$2,100 (0.3% of total grant funding) - Total contribution = \$18,200 • Example D – If you have a 4 year study with a total funding of \$3,000,000, the following invoicing will take place: <ul style="list-style-type: none"> ○ Year 1 contribution = \$20,000 (2% of total grant funding to a max of \$20,000) ○ Year 2 contribution = \$5,000 (max of \$5000) ○ Year 3 contribution = \$5,000 (max of \$5000) ○ Year 4 contribution = \$5,000 (max of \$5000) - Total contribution = \$35,000
over \$50,000	\$1,000	
\$75,000 & under	\$1,500	
\$100,000 & under	\$2,000	
\$150,000 & under	\$3,000	
\$200,000 & under	\$4,000	
\$250,000 & under	\$5,000	
\$300,000 & under	\$6,000	
\$350,000 & under	\$7,000	
\$400,000 & under	\$8,000	
\$450,000 & under	\$9,000	
\$500,000 & under	\$10,000	
\$550,000 & under	\$11,000	
\$600,000 & under	\$12,000	
\$650,000 & under	\$13,000	
\$700,000 & under	\$14,000	
\$750,000 & under	\$15,000	
\$800,000 & under	\$16,000	
\$850,000 & under	\$17,000	
\$900,000 & under	\$18,000	
\$950,000 & under	\$19,000	
\$1,000,000 & over	\$20,000	

Sample Budget Justification: “PERC is a national network formed in 1995 consisting of health care researchers dedicated to improving care in pediatric emergency medicine through multi-site research. This study is a PERC specific project and as such funds are required to support network specific coordination duties as they relate to research. These funds will be used to offset costs associated with coordination of the network that includes all pediatric emergency departments across Canada to enable multi-site research, proposal development and review, and hosting project meetings at the annual PERC conference.”

APPENDIX B: CONCEPT PAPER TEMPLATE

PROJECT TITLE

Principal Investigator:

Co-Investigators:

Participating Sites:

Background:

Study Aim:

Research Design:

Sample Size:

Relevance: