



ENDORSEMENT & REVIEW PROCESS

PROCESS SUMMARY

Any PERC member may bring forward a study to the PERC Executive for consideration as a formally endorsed 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 cohort studies, clinical trials, database studies using external data, systematic reviews, and trials of knowledge synthesis tools. A minimum of 2 centres must be involved in recruiting participants (if applicable) 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 two phases to assist Principal Investigators (PIs) with developing a methodologically rigorous project and to promote the likelihood of successfully obtaining grant funding from a peer-review agency. The first phase involves the PI completing a PERC Study Intake Form through REDCap. This study intake form requires the PI to provide basic study and study team information and to submit a concept paper for review by the PERC Executive. Based on the review of the information and concept paper, the PI will be contacted for additional details or asked to proceed to the second phase, providing a full study protocol and budget for review by the PERC Executive members and designated alternatives.

PERC Endorsement Letters of Partnership can be updated if PIs are unsuccessful in obtaining funding during a given application cycle and wish to re-apply. Learn more about updating PERC Endorsements [here](#).

All inquiries should be directed to the PERC National Coordinator by email at nationalcoordinator@perc-canada.ca.

PHASE ONE

To begin the PERC Endorsement process, principal investigators and their study teams will progress through the following steps of phase one.

1. Confirm Study Eligibility

To be considered for PERC Endorsement, the following criteria must be met:

1. The principal investigator must hold an active PERC membership and maintain that membership throughout the duration of the PERC endorsement.
2. The study must involve more than one PERC ED site or investigators from more than one PERC ED site ([view all PERC sites here](#)). *Please note, participating ED sites must be identified and agree to participation before a study will proceed to Phase II of the endorsement process.*
3. Eligible studies for PERC Endorsement include:
 - i. Prospective and retrospective cohort studies
 - ii. Clinical trials
 - iii. Database studies utilizing external data
 - iv. Systematic reviews
 - v. Trials of knowledge synthesis tools
4. The study topic must be relevant to pediatric emergency medicine and align with the goals of PERC ([view goals of PERC here](#)).
5. If applicable, a minimum of two centres must be involved in the recruitment of participants.

2. Complete Study Intake Form

The PI must complete the online PERC Study Intake Form using the REDCap database ([Access the Study Intake Form here](#)).

The PERC Study Intake Form can be completed at any time during the planning stages of a study, but it must be submitted a minimum of 8 weeks before a PI's specified deadline for PERC Endorsement. It is requested that study intake forms be submitted as early as possible.

Submission of a 2-page concept paper is required as a part of the study intake process. The PI should use the template provided in Appendix A for reference.

As a part of the study intake process for PERC Endorsement, the PI must review and attest that they understand the following **Conditions of PERC Endorsement:**

1. PERC must be listed as an author (see exemplar wording in Appendix B) for all publications resulting from a research study that is PERC-endorsed
2. If a funding application is successful, the PI will provide funds to PERC according to Appendix C
3. It is the responsibility of the PI to confirm that all included PERC sites have:
 - i. Agreed to participate in the study
 - ii. Approved the protocol and proposed budget for their site
4. All PIs of PERC-endorsed studies may be contacted to review future proposals on behalf of PERC as a designated alternative reviewed
5. PERC endorsed study updates are to be shared at the PERC Annual Scientific Meeting while the study is active
6. Final results of the study are to be presented at the PERC Annual Scientific Meeting

The PERC Study Intake Form communicates details about the proposed study to the PERC Executive. Study details are to be provided through the following questions:

1. Principal investigator name
2. Co-principal investigator name(s)
 - a. Is the co-principal investigator a trainee? (provide name)
3. Principal investigator e-mail
4. Preferred email for study communications
5. Is the principal investigator being mentored by another PERC member? (provide name)
6. Study coordinator name (if identified)
7. Lead PERC site
8. 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?
9. Working project title
10. Type of study
 - a. Randomized controlled trial
 - b. Prospective cohort
 - c. Retrospective cohort
 - d. Qualitative
 - e. Systematic review

- f. Survey of PERC physicians Survey (not using the PERC physician list)
 - g. Other (specify)
11. Do you currently have funding to support the conduct of this study?
- a. If yes, specify funding agency and amount
12. 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?
Please 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.
13. Do you anticipate your study requiring patient/parent input or involvement?
14. Has this study been presented at a PERC meeting?
- a. If yes, specify meeting year
 - b. If no, are you planning to present?
15. 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.
 - b. If no, we suggest you contact site representative to gauge interest and feasibility of conducting this research in a multi-site setting.
16. Specify your requested deadline for receiving PERC Endorsement. *Please note, this deadline date must be a minimum of 8 weeks from the date an applicant submits the Study Intake Form through REDCap. Additionally, the applicant must be prepared to submit their full protocol and budget a minimum of 6 weeks prior to this date.*
17. Upload a 2-page concept paper or full protocol, if prepared
18. Upload the study budget, if applicable and prepared
19. Complete attestation of Conditions of PERC Endorsement as described here, on page 4 of the PERC Endorsement & Review Process Document.
20. A brief demographic survey is included as a part of the study intake form for tracking and reporting purposes within PERC for PIs of PERC-endorsed projects. Questions include:
- a. Career stage
 - b. Medical degree completion in Canada
 - c. Gender
 - d. Racial Background
 - e. Person with Disability
 - f. Visible Minority
 - g. First Language

- h. Current Practicing PEM Physician

3. Executive Review of Submission

Members of the PERC Executive Committee will review the REDCap Study Intake Form submission and study concept paper to:

1. Ensure that the study topic is relevant to pediatric emergency medicine and PERC
2. Ensure that the study meets the goals of PERC as outlined in the PERC governance document
3. Ensure that the new proposal is not competing with any existing PERC studies
4. Consider if mentorship is needed
5. Determine if site engagement has been initiated
6. Identify reviewers for concept paper and full protocol

The PERC Network National Coordinator and PERC Executive Chair or Vice-Chair or one designated PERC Executive member will lead the study intake review process; however, all members of the PERC Executive will have the opportunity to review the Study Intake form and concept submission.

The National Coordinator will share submissions with the Executive committee by email as they are received. Discussions regarding whether submissions proceed to Phase II will typically occur during monthly Executive Committee meetings but may occur via email if required for endorsement deadlines.

4. Executive Decision Point

The PERC Executive will provide written feedback by email to the PI within 4 weeks of receiving a completed Study Intake Form submission through the REDCap portal.

If the Study Intake and concept paper submission is deemed to meet criteria for PERC endorsement, the PERC Executive will request that the PI proceed to the next phase of the PERC Endorsement process by submitting the full study protocol and study budget. See process details for Phase II [here](#).

If a study is deemed to not meet the criteria required for proceeding to Phase II of the PERC Endorsement process, specific recommendations will be shared with the PI on how to address the deficiencies or conflicts.

PHASE TWO

Phase II involves a peer review of the full study protocol and study budget. The process of Phase II PERC protocol and budget review takes **a minimum of 6 weeks**. 8-12 weeks is preferred for the anticipated timeline required by the PERC Executive to provide full PERC Endorsement for a study.

A full protocol should not be submitted for review until participating PERC sites have been identified and have agreed to participate. The PI is responsible for contacting PERC site representatives to establish collaborative sites for the full protocol. In choosing participating sites, PIs should note that PERC as an organization supports the principles of equity, inclusiveness, openness, creating linkages, and the promotion and fostering of research collaborations and excellence across PERC sites. 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 Committee can assist with PERC site selection if requested by the PI.

Special Considerations: RCTs

It is advisable to submit a study protocol that adheres to CIHR's specific formatting requirements for RCTs, including page limits and document headers, to enhance the quality and value of the review.

All PIs of PERC-Endorsed RCTs must register their trial prior to enrolling patients and publish the study protocol either in a peer-review journal or on a publicly available and maintained website (e.g., clinicaltrials.gov). PERC must be explicitly named in the authorship line and in the methods section of the manuscript. These authorship requirements can be found in Appendix B. All PERC approved studies must provide the trial registry number to PERC Executive.

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 authorship line and in the methods.

Submission of Full Protocol and Budget

The PI will share the following with the PERC Executive:

1. Full study protocol including detailed study methodology
 - a. All RCT protocol submissions should use the NIH Clinical Trial Template and SPIRIT checklist for guidance
2. Study Budget
 - a. All PERC-endorsed studies must include a budget line item supporting PERC infrastructure (see Appendix C)

These documents should be submitted to the PERC Network National Coordinator by email to nationalcoordinator@perc-canada.ca.

Full Executive Review

One member of the PERC Executive will be designated as the Executive Review Lead.

Typically, a minimum of one additional PERC Executive member (or designated alternative[s]) will critically review the protocol and budget. The Coordinator Representative on the PERC Executive (or a designated alternative) may also complete a budget feasibility review for the study.

Each will provide a summary and recommendation back to the PERC Executive Committee.

All members of the PERC Executive will have the opportunity to review and provide feedback on the protocol and budget. Endorsement requests will be considered on a case-by-case by the PERC Executive.

PERC Executive Vote

PERC Executive members who are investigators on the current proposal will not be eligible to vote on the projects they are affiliated with.

After considering all completed reviews and feedback received through the full executive review (Phase II, Step 3), all eligible PERC Executive members will vote on the endorsement of the project for one of the following decisions:

- I. Accepted as a PERC-endorsed study
- II. Accepted pending minor revisions
- III. Major revisions and 2nd review required
- IV. Rejected

The majority of the voting-eligible PERC Executive must vote to accept the proposal to be approved as a PERC-endorsed study.

Decision Notification

The PERC Executive will appropriately edit feedback prior to sharing with authors.

The PERC Executive will communicate the final endorsement decision to the PI and provide detailed feedback on the protocol methodology. When a study is formally accepted, a Letter of Partnership will be provided by the PERC executive indicating that the study is endorsed by the PERC network.

The endorsement decision will be reported as one of the following:

I. **Accepted as a PERC-endorsed study**

- Study protocol and budget deemed acceptable as-is for PERC endorsement. Reviewer suggestions and comments can be implemented at the PI and study teams' discretion. Letter of Partnership to be provided to PI for inclusion in funding application(s).

II. **Accepted pending minor revisions**

- Minor revisions suggested by reviewers. PI must acknowledge all minor revisions and respond to each. PERC National Coordinator and Executive Review Lead (or designated alternative) must review responses to reviewer comments and accept the response prior to PERC Endorsement being issued.

III. **Major revisions and 2nd review required**

- Significant changes to the study methodology and/or budget are suggested. The PERC Executive Committee does not believe the current iteration of the study will be successful in any funding competition. Suggested revisions are substantial and require a re-submission of a revised protocol and budget. A second review is required before PERC Endorsement will be considered.

IV. **Rejected**

- The PERC Executive does not support the current study proposal or re-submission of a revised version.

UPDATING PERC ENDORSEMENT

PIs of studies which have received PERC Endorsement and a Letter of Partnership from the PERC Executive to support a funding application can request an updated Letter of Partnership by emailing the PERC National Coordinator at nationalcoordinator@perc-canada.ca.

PIs requesting PERC Endorsement updates can assume they will be issued without hesitation unless there have been fundamental changes to the study methodology.

Requests for updated Letters of Partnership must be accompanied by:

1. A written outline of all changes, if any, which have been made to the original endorsed versions of the study protocol and budget
2. The most current version of the study protocol
3. The most current version of the study budget

Requests for updated Letters of Partnership must follow the same timeline requirements as new endorsement submissions and must be requested a minimum of 6 weeks before the PI-specified deadline for receiving the final version of the Letter of Partnership.

The PERC Executive will re-issue Letters of Partnership up to 3 times. After 3 requests, the PI must submit the most current version of the protocol and budget for review by the PERC Executive before additional Letters of Partnership will be provided.

Appendix A. Concept Paper Template

Please provide an abstract-style concept paper of your proposed study using the following headings:

Project Title

Principal Investigator

Co-Investigators

Participating Sites

Background

Study Aim

Research Design

Sample Size

Relevance

Appendix B. Authorship - Exemplar Language

Authorship

PERC must be named in the authorship, either in isolation or as a part of the larger team name. See exemplars below:

Example 1: Ware, A. L., Yeates, K. O., Geeraert, B., Long, X., Beauchamp, M. H., Craig, W., Doan, Q., Freedman, S. B., Goodyear, B. G., Zemek, R., Lebel, C., & Pediatric Emergency Research Canada A-CAP Study Team (2022). Structural connectome differences in pediatric mild traumatic brain and orthopedic injury. *Human Brain Mapping*, 43(3), 1032-1046. <https://doi.org/10.1002/hbm.25705>.

Example 2: Le May S, Ali S, Plint AC, Mâsse B, Neto G, Auclair MC, Drendel AL, Ballard A, Khadra C, Villeneuve E, Parent S, McGrath PJ, Leclair G, Gouin S; Pediatric Emergency

Research Canada (PERC). Oral Analgesics Utilization for Children With Musculoskeletal Injury (OUCH Trial): An RCT. *Pediatrics*. 2017 Nov;140(5):e20170186. doi: [10.1542/peds.2017-0186](https://doi.org/10.1542/peds.2017-0186). Epub 2017 Oct 11. PMID: 29021235.

Methods

PERC must be named in the methods section of the manuscript, either in isolation or as a part of the larger team name. See exemplars below:

*Example 1: **Study Design:*** This study was a 3-arm, double-blinded, randomized, placebo-controlled trial. It was conducted in the ED of 3 pediatric hospitals who are members of the Pediatric Emergency Research Canada network: CHU Sainte-Justine (Montreal, Quebec), Stollery Children's Hospital (Edmonton, Alberta), and Children's Hospital of Eastern Ontario (Ottawa, Ontario). The study was approved by each institutional review board.

*Example 2: **Study Design:*** This is a preplanned secondary analysis of 2 parallel, multicentre, pediatric ED-based studies conducted in the United States (Pediatric Emergency Care Applied Research Network [PECARN] probiotic study)^{16,17} and Canada (Pediatric Emergency Research Canada [PERC] Probiotic Regimen for Outpatient Gastroenteritis Utility of Treatment study).^{15,18} Children enrolled in the PECARN study presented for care in 1 of 10 US-based EDs between July 2014 and June 2017. The PERC study was performed at 6 Canadian EDs between November 2013 and April 2017. These prospective, randomized, trials enrolled 971 and 886 children, respectively, with ethical review board approval.

Appendix C. Infrastructure Support & 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. See below a description of the fee structure and examples.

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; *i.e.*, 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.

This fee structure is applicable to all PERC studies except in extenuating circumstances which must be pre-approved by PERC Executive.

Sample Budget Justification:

“PERC (Pediatric Emergency Research Canada) 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.”

Example A - If you have a 5-year study with a total funding of \$1,000,000, the following invoicing will take place:

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:

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:

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:

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



Executive Process Document
EXTERNAL STUDY REQUESTS

Purpose

This document outlines the approach to study endorsement requests and other study-related task requests from groups or principal investigators who are external to Pediatric Emergency Research Canada (PERC) and/or Canadian pediatric emergency departments (EDs).

Specifically, this process document applies to requests to endorse and/or support multi-site projects and studies involving pediatric ED resources. The purpose of this process document is to establish a clear and consistent approach to the evaluation and endorsement of such requests and to set expectations for communication with PERC regarding these requests.

Background

Each year, PERC receives several requests from external groups seeking the assistance of pediatric ED research teams in conducting research or other related work. To ensure a consistent and fair approach to these requests—whether the project is funded or not—this process document supports fair evaluation and adjudication of such requests. Further, it allows us to align all activities and engagements with our collective goals as a national research network, strengthen PERC’s viability, and uphold our commitment to supporting PERC members.

Recent discussions have highlighted the need for a standardized procedure on how the PERC Executive and individual sites evaluate external requests. Establishing clear guidelines and communicating them effectively to PERC membership is crucial for maintaining a unified approach across the network. While individual sites retain the autonomy to choose their course of action, consistent application of principles—such as seeking PERC endorsement and paying associated fees—bolsters our collective strength and supports the sustainability of our research organization. In situations where projects are unfunded or underfunded, the PERC Executive may choose to waive/lower fees and still provide endorsement, allowing sites to participate based on available resources. This policy underscores our ongoing commitment to the integrity and viability of the PERC network.

Key Considerations

1. PERC Endorsement

Studies involving two or more EDs that are part of the PERC research network require PERC review and endorsement. This endorsement is crucial to maintain the quality and coordination of research efforts across sites. If a study involves only one pediatric ED/ PERC site, PERC endorsement is not necessary.

External groups are still required to pay the necessary PERC infrastructure support fees associated with PERC Endorsement. These fees are a standard requirement for engaging PERC resources and help to ensure the financial sustainability of our network. Information on the current fee structure can be found [here](#), on the PERC website.

2. Unfunded or Under-Funded Projects

In cases where a project is unfunded or under-funded, PERC may choose to endorse the project and waive/lower the associated fees. Following this decision, sites can independently decide whether to participate based on the available funding. PERC may endorse unfunded

or under-funded projects, but sites are not obligated to participate if initiated by external groups.

3. Consent to Contact and Recruitment

External groups may request consent to contact only, with recruitment occurring later. For such studies contacting families after an ED visit, where the PERC-affiliated ED research team would manage the 'consent to contact' process, it is expected that a fee will be charged by each ED site to provide this service. Further, PERC maintains that accessing 2 or more pediatric ED's patients and associated resources to accomplish this goal would be considered a study requiring PERC review and endorsement.

4. Site Autonomy

If an external group does not secure PERC endorsement or pay the required fees, individual sites continue to have the autonomy to decide whether to participate. Sites may choose not to engage in the project even if the requirements are not met. PERC highly recommends that any site approached to participate in a study involving two or more pediatric emergency departments advise the PI to contact PERC for endorsement and guidance at nationalcoordinator@perc-canada.ca.