GOVERNING PRINCIPLES

VISION

To be international leaders in pediatric emergency research.

GOALS

1. To create new knowledge through collaborative, multicenter research involving clinical and epidemiological studies in pediatric emergency medicine
2. To mentor new investigators and fellows in developing research projects
3. To enhance the image of pediatric emergency medicine as a credible academic discipline with its own research agenda
4. To pool the expertise of researchers and clinicians to develop cohesiveness between centers involved in the practice of pediatric emergency medicine

ORGANIZATION

Membership: Any health care provider involved in the delivery of care for children and youth in pediatric emergency medicine and researchers involved in PEM research. On an annual basis, PERC will update its membership list to include contact details.

Site Liaisons: Each pediatric emergency department in Canada will be asked to select a representative who will serve as the liaison for that site and be the key communication channel.

Executive Committee: The Executive Committee will consist of the following ten positions

1. Past Chair
2. Chair
3. Vice-Chair
4. Executive Board Member
5. Executive Board Member
6. Executive Board Member
7. Executive Board Member
8. Fellow Representative
9. Research Coordinator Representative
10. PERC National Coordinator

The past-chair, chair, and vice-chair will each serve four years. Once elected as vice-chair, a member will progress automatically to chair and subsequently past-chair. The past-chair will solicit nominations from the membership at least one month in advance of the elections. Any two PERC members in good standing may nominate another PERC member (with their consent) for vice-chair. An election for the vice-chair will be held every four years by secret ballot at the PERC Annual Meeting.

The executive board members will serve two years. The past-chair will solicit nominations from the membership at least one month in advance of the elections. Any PERC member in good standing may nominate another PERC member (with their consent) for any of these four positions. Elections for three of these positions will be held every two years by secret ballot at the PERC Annual Meeting. Elections for the fourth position, a member-at-large, will be in alternate years, also in a two-year cycle. The PERC National Coordinator will be represented by the current incumbent.

To maintain close ties with associated research networks (e.g., TREKK, PERN, MICYRN) members will be asked to attend PERC Executive Committee meetings as necessary. An update will be presented at each PERC Executive Committee meeting about progress at associated research networks.

The fellow representative will serve one year. Each year at the PERC Annual Meeting, all pediatric emergency fellows in attendance will convene and elect their representative. The research coordinator representative will serve two years. Every two years at the PERC Annual Meeting, all research coordinators in attendance will convene and elect their representative.

Responsibilities of the Executive Committee: The executive committee will be responsible for planning and setting the agenda for each annual meeting of PERC. In addition, they will:

1. Communicate regularly with the membership about the status of studies and potential new studies;
2. Administer any funds that come into PERC directly;
3. Keep accurate minutes, which are circulated in a timely fashion;
4. Initiate review of new studies and provide letters of support;
5. Monitor ongoing studies and identify issues that need addressing; and
6. Develop guidelines and policies that determine how PERC will conduct its business.

Annual Meeting & other Means of Communication: PERC Members will meet once per year to be updated on newly approved and on-going studies, and to hear about and discuss potential new studies. The Executive Committee will draw up the agenda with input from the PERC membership. (APPENDIX A – Guidelines for Presentations) As well, informal ad-hoc meetings may be arranged in association with any major North American conference that is relevant to pediatric emergency medicine. Throughout the remainder of the year communication will occur through teleconferences, e-mail and a regularly updated website.

Special Interest Groups: Any PERC member or group of members can form a special interest group around a specific topic, the purpose of the group must be to further the research in this area, promote scholarly activities and collaboration. Terms of reference for each PERC Special Interest Group are included as attachments to the PERC Governance Guidelines and listed in Appendix B. Each of the groups approved by executive and listed in the PERC Governance Guidelines will be allotted time at the PERC Annual Scientific Meeting.

EQUITY, DIVERSITY AND INCLUSION (EDI)

The PERC network is committed to excellence in research and research training. Achieving a more equitable, diverse and inclusive Canadian research network is essential to creating the outstanding,

innovative and impactful research necessary to advance knowledge and understanding, and to respond to local, national and global challenges.

What is EDI?

- **Equity** is defined as the removal of systemic barriers and biases enabling all individuals to have equal opportunity to access and benefit from the program.
- **Diversity** is defined as differences in social and ethnic background, including colour, place of origin, religion, immigrant and newcomer status, ethnic origin, ability, sex, sexual orientation, gender identity, gender expression and age.
- **Inclusion** is defined as the practice of ensuring that all individuals are valued and respected for their contributions and are equally supported.

PERC recognizes that systemic barriers and constraints have contributed to underrepresentation of Canada's diversity in pediatric emergency medicine. We welcome membership, participation, and leadership from individuals of all backgrounds, including those who identify as a member of an underrepresented group (e.g. members of visible minorities and other racialized groups, women, indigenous people, persons with disabilities and those belonging to 2SLGBTQIA+).

REVIEW OF NEW STUDIES

Endorsing a new study takes a minimum of 6 to 8 weeks. The PERC-Endorsement and review process involves three phases to assist principal investigators (PIs) with developing a methodologically sound project and to promote the likelihood of successfully obtaining grant funding from a peer-review agency. Therefore, protocols requesting a supporting letter for a grant application must be submitted at least 8 weeks prior to the grant submission deadline. In the event of a granting opportunity with announcement and submission dates less than 8 weeks apart, the principal investigator must submit a written explanation justifying to the PERC executive why the study review process is requested to be expedited in this particular circumstance. Upon receipt of that justification, the PERC executive will consider the request. **NOTE**: if insufficient time is provided the PERC Executive may **not** be unable to endorse the study in time for grant submission.

The process to have a study become “PERC-Endorsed” can be found in Appendix E.

It is expected that the principal investigator of all on-going PERC approved studies will provide an update at the Annual PERC Meeting. Additionally, all PERC approved studies **must** include the PERC logo on presentation slides and posters as well as including PERC in the main list of authors and methods section of all manuscripts.

In the event of potential study conflicts:

1. If the Executive, in the review of a new proposal, identifies a potential conflict with an existing PERC study, the Executive will notify the Principal Investigators of both the proposed new study and the existing study with which there is a potential conflict. The Executive will ask the two Principal Investigators to discuss potential conflicts and synergies with the intention of identifying ways that both the proposed and existing study can, if at all possible, be conducted and how they might enhance each other’s enrollment. Once their discussions are complete, the

two Principal Investigators will submit a written report to the Executive outlining all potential conflicts and how these might be resolved to allow for parallel conducting of both studies, and any potential synergies that have been identified that might facilitate enrollment into each other's study.

2. If an agreement on how to conduct both a new and existing study in parallel cannot be achieved, either of the Principal Investigators can ask the Executive to mediate the process.

AUTHORSHIP GUIDELINES

1. Prior to the start of any PERC study the principal and site investigators should agree upon the contribution of each member to the study and the implications this has on authorship.
2. Participation in PERC studies does not guarantee authorship. PERC principal investigators should generally adhere to the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, issued by the *International Committee for Medical Journal Editors* which is quoted below:

   "All persons designated as authors should qualify for authorship, and all those who qualify should be listed. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article."

   "Authorship credit should be based only on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Conditions 1, 2, and 3 must all be met. Acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship."

GUIDELINES FOR SELECTING REPRESENTATIVES ON PERN EXECUTIVE

In 2010 PERN (Pediatric Emergency Research Networks) was initiated with PERC as the founding network. Each of the member networks must nominate 2 members to be a part of the PERN Executive committee; this selection process for PERC will be the following:

- The first member on the PERN Executive must also be on the PERC Executive (currently Dr. Stephen Freedman), the second member can either be on the PERC Executive or from the PERC membership at large.
- For the second member the PERC Executive members will initially be approached to see if anyone is interested and if not a call for nominations will be circulated to the PERC membership. This would be a self-nomination process and if more than one person expressed interest the Executive would vote.
- The expectations of the PERN Executive members is the following:
  - Attend 3-4 teleconference per year,
  - If going to the annual PAS meetings attend the in-person PERN meetings, or if offered dial in via teleconference,

- If going to ICEM (held every second year) attend in-person PERN meetings, or if offered dial in via teleconference,
- Report back to PERC Executive.

ROLES/RESPONSIBILITIES OF SITE REPRESENTATIVES & COORDINATORS

Roles and Responsibilities of PERC Site Representatives

The PERC Executive has the following expectations:

1. Representatives should attend and promote the PERC Annual Meeting.
2. In addition to the Annual Meeting, a PERC Site Representative's Teleconference will be held twice a year. Representatives should attend these Teleconferences as well as the Annual Meeting.
3. Representatives should know which of their ED colleagues are interested in acting as a Site Local Investigator of PERC projects, facilitating Primary Investigators' identification of these individuals. Site Representatives should not serve as the Local Investigator for every PERC project. In fact, it is optimal if a range of ED staff participate in PERC studies.
4. Representatives should provide budgetary oversight of all PERC projects being conducted at their site, including the projects contained within the PERC Team Grant.
5. At each Annual Meeting, site representatives should provide a summary report of their site's budget and participation in PERC projects.
6. Representatives are encouraged to use the funding from the PERC Team Grant to match local sources of funding to expand their Site Coordinator coverage.
7. Representatives can be either elected by their colleagues, or appointed by the Site's Medical Director.
8. Once elected, representatives will serve a first term of four years. Subsequently representatives may be re-elected in two year blocks.

Use of Site Coordinators funded by the TREKK NCE-KM

With the award of the TREKK NCE-KM (TRanslating Emergency Knowledge for Kids – Networks of Centres of Excellence – Knowledge Mobilization Grant), participating PERC sites will be eligible to receive part-time funding for Site Coordinators. Note: this funding source may change over time. Site Coordinators funded by the TREKK NCE-KM may be used in the following ways:

1. To conduct activities included in the TREKK NCE-KM.
2. To carry-out surveys and small cohort studies with the intention of providing background information for grant submissions for other PERC projects.
3. To conduct small locally focused projects as long as this does not impair enrollment into on-going PERC projects. (Investigators are expected to seek additional funding to carry-out new PERC or local projects. These funds can be used to expand and supplement the funding from the TREKK NCE-KM.)

ROLES/RESPONSIBILITIES OF SITE MEMBERS

1. PERC members must agree to abide by the PERC Code of Ethical Behaviour for Multi-centered Clinical Trials (see attached APPENDIX C).
2. Members should pay PERC Annual Dues in a timely fashion.

Mentorship of Junior Investigators
The PERC network will play a supportive role in the development of projects by junior or novice researchers. If requested, members of the PERC executive and other identified members of PERC could function as mentors in the areas of study design, protocol development, and application for funding and manuscript preparation.

Revision of PERC Governing Principles & Code of Ethical Behavior
Any member of the Executive Committee may propose revisions to the PERC Governing Principles and/or Code of Ethical Behavior. Any proposed revisions, once approved by the entire Executive Committee, must be submitted to the PERC membership for ratification. A minimum of at least 20 members must be present or participate in a vote. A majority of those voting will constitute ratification.

GUIDELINES FOR PROPOSING A STUDY ACROSS MULTIPLE NETWORKS (E.G. PERN, PECARN)

1. Studies involving both the PERC and other networks within PERN are much more complicated and complex to run than studies involving each network alone.
2. Very few studies will require combined efforts between the PERC and another PERN network.
3. Those requiring collaboration will mostly be due to extremely rare outcomes or studies requiring very large sample sizes.
4. In particular, proposed studies using both the PERC and PERN networks require a unique process to assess potential collaborative proposals and standardize the method of sending this proposal on to the other network for consideration.

The process to have a study become a joint "PERC-PECARN Study" is as follows:

a. Any PERC member may bring forward a study to the PERC executive for consideration as a PERC-PECARN study.
b. A 2-page concept paper should be submitted to explain why both networks are required to complete this study. (The 2-page concept paper should include Background, Study Aims, Research Design, Sample Size and Relevance).
c. The PERC Executive will review the concept paper to ensure the new proposal is not competing with any existing studies, and that the study is relevant to pediatric emergency medicine. They will also assess the need for involvement of the PECARN network.
d. Once reviewed and approved by the PERC executive, the Chair of PERC will contact the Chair of PECARN to share the 2 page proposal. The Chair of PECARN will assess the interest of the PECARN network and feedback the results to the Chair of PERC and the PI.
e. The process to obtain PECARN approval involves presenting the 2-page proposal to a regional PECARN node to seek approval, followed by presentation to the national PECARN meeting for final approval of the concept.
f. If the concept is approved by both networks the PI will be asked to write a full protocol to be submitted for funding. Once this is approved by the PERC and PECARN executive a supporting letter will be provided to the principal investigator for grant submission from both PERC and PECARN.

g. The PERC name and/or logo should appear in presentations and manuscripts that result from PERC collaborations.
h. Studies originating from other PERN networks that wish to have PERC site involvement will come via other networks' executive through the PERC executive. PERC sites will be informed of the opportunity to collaborate with other PERN network studies through the PERC executive contacting the PERC site investigators.

APPENDIX A: GUIDELINES FOR PRESENTATIONS AT THE PERC ANNUAL MEETING

The PERC Annual Scientific Meeting gives the opportunity for investigators to present their research protocols to all PERC members as well as completed PERC studies. To be considered for presentation of a new study, an investigator should have a written completed protocol prior to the meeting. The proposed new study must be multicentre (and specifically include more than one PERC site and PERC investigator). The overall goal of these guidelines is to maximize the chance that investigators will receive **constructive and informative feedback** on their protocols, on-going, and completed studies.

All PERC members are expected to read the protocol/study summaries that are pre-circulated for each study, and to help balance the discussion of background issues with those of design and execution. For **new proposed**, **on-going and completed studies,** the presenter and PERC members together must ensure that there is **adequate time for group input on questions and issues of importance to the presenter**.

Pre-Meeting Presentation Guidelines

1) All investigators must submit their request for time to present their study by the annual deadline (typically the beginning of November). For a presentation request the following is required to be submitted online: name of presenter; type of study; title of presentation; and a brief description (100 words or less). The requests will then be reviewed by the PERC network coordinator and chair to ensure presentation eligibility.
2) Due to the number of PERC studies that are submitted each year, and in order to be committed to a meaningful discussion of all studies presented at the meeting, the following written materials must be received by email no later than 2 weeks before the PERC annual meeting:
   - <u>New Studies</u>
     - A 2-page written summary of the protocol/study progress/study results, and a 1 page list of questions and issues on which the presenter would like feedback from PERC members
     - The **2-page Protocol Summary** will help acquaint the PERC members to the study prior to the presentation. The summary should include a brief background, objectives, overall study design, study population, outcome measures, sample size calculation, anticipated time frame, state of protocol (e.g. fully developed? submitted for ethical review? local enrollment?) and planned funding sources (e.g.: Children's Hospital Foundations, CIHR Clinical Trials, etc…).
     - The **1-page list of questions and issues** should help focus the PERC members to discussion of issues that would be most helpful to the presenter.
   - <u>On-going studies</u>
     - A 1-to-2 page update addressing enrollment, and any other important issues.
   - <u>Completed studies</u>

- A standard, structured 'meeting' abstract outlining the study's objectives, methods, results and conclusions, plus a brief review of the manuscript's status

3) These written materials will be **pre-circulated to PERC members** if it is received by Becky Emerton **at least 2 weeks in advance of the PERC meeting**. These should be submitted by email to: ***rebecca.emerton@albertahealthservices.ca***

Guidelines for Presenting New Studies

All New Studies will be allotted **30 minutes**. It is recommended to **use no more than 10-15 minutes for presenting your study**. Allow 15-20 minutes for group discussion and feedback on your pre-circulated questions and issues.

- Begin with a **structured abstract** of your study, including the clinical question it addresses, the basic design features, and the population, intervention and outcomes of interest.
- Give a **brief presentation** of previous work, if any, in this area ensuring that the study designs, sample sizes, results and conclusions are clear.
- **Spend most of the presentation time on the methods of your study**. Use your judgment in focusing primarily on the study design issues that are most difficult, or debatable, and/or those for which you would most appreciate feedback. While any issue on any protocol may be reasonable fodder for discussion, it is primarily your (i.e., the presenter's) responsibility to ensure that issues of greatest importance to you are discussed.
- **Report tentative plans for your study over the next 6-12 months**, including activities such as a) systematic reviews, b) protocol revisions, c) background work such as feasibility studies, d) requests for collaboration, and e) target grant submissions. Publicly identify the goals you hope to achieve before the next PERC meeting.

Guidelines for presenting on-going Studies

- Investigators with on-going PERC studies should prepare **a one page update** to be included in the PERC meeting binder. **Also include a 1-page summary** of your project for those in attendance who are not familiar with your project.
- Investigators should also be prepared to give **a brief verbal update,** which will take place at the opening Business meeting and should last no more than 2 to 3 minutes.
- Investigators should plan **a separate study meeting** to deal with administrative details associated with the conduct of their studies.
- Investigators of on-going trials that have new significant study issues may ask to give a longer formal presentation (maximum 20 minutes with slides). Decisions on whether these requests will be granted will be based on discussion by the PERC network coordinator and chair, with involvement of the executive as deemed necessary.

Guidelines for Presenting Completed Studies

1) Investigators who have completed a PERC trial will be allotted 15 minutes to present their results **(10 minutes for presentation and 5 minutes for discussion**).
2) **Present your study in the same format that you would use for an oral presentation at a medical conference.** Begin with the study title and authors, a brief summary of why this issue is important and previously published work. Clearly state the study question. Present your methods in sufficient detail to provide listeners with a clear understanding of your study design. Succinctly present your study results focusing on the primary and secondary outcomes of interest. Mention additional findings of potential interest for follow-up studies.
3) In addition to reporting your study's results, you should also discuss their implications, and what further follow-up studies might be pursued.

4) Prior to the meeting, the investigator should submit an abstract of their study's objectives, methods, results, and discussion so that it can be pre-circulated and included in the PERC meeting binder.

APPENDIX B: SPECIAL INTEREST GROUPS

Gastroenteritis Interest Group – formed January 2011
Pain Interest Group (PIG) – formed January 2015
Quality Indicators Interest Group (QuIG) – formed January 2015
Mental Health Interest Group (MHIG) – formed April 2015
Women in Research Interest Group – formed January 2019

For copies of the Terms of Reference for each group please contact Becky Emerton (rebecca.emerton@ahs.ca).

APPENDIX C: CODE OF ETHICAL BEHAVIOUR

The Pediatric Emergency Research Canada (PERC) Network and Annual Conference strive to create a "safe space" environment, where all participants and guests feel welcome and views respected. We do not tolerate behavior or language that is hurtful to members or guests participating in any of our activities. This includes but is not limited to physical as well as verbal remarks that may be inappropriate (e.g. related to race, ethnicity, age, size, appearance, gender, sexual expression/orientation, physical ability, or mental competence).

All concerns or violations should be reported for immediate resolution to any of the PERC Executive members. The Executive retains the discretion to evaluate the concerns and to work with the appropriate authorities to resolve the issue. If needed PERC may restrict participation in future PERC activities.

Principles

- PERC is a collaborative network of investigators who share their intellectual property and resources for the common goal of undertaking research in pediatric emergency medicine.
- In order to promote the free flow of ideas among PERC members, there must be an expectation of ethical behavior among participants. Collaborative research can only flourish in an atmosphere of openness and trust.
- With membership in PERC each individual must agree to follow this code of ethical behavior.
- This expectation of ethical behavior must extend to the interactions with industry and other funding partners.

Ethical Behavior among Investigators

- The "intellectual property" of a PERC protocol belongs primarily to the principal investigator(s) and secondarily to the participating investigators.

- When a protocol is introduced to PERC by an investigator, other PERC investigators should declare any real or potential conflicts of interest and absent themselves from further discussions of the protocol. Such conflicts include, but are not limited to, developing or implementing, or intending to develop or implement, a similar protocol with the same or other funding agency outside of the PERC framework.

- Once a PERC investigator has agreed to participate in a particular study, the investigator should not undertake any conflicting study that could interfere with the capability to perform the PERC study.

- In the event that a PERC study does not get implemented, a participating investigator should not undertake a similar study without prior discussion to determine whether the study impinges on the intellectual property of the PERC study. This applies to studies with the same or other funding agencies.

- Prior to beginning a study, rules of interaction should be established between investigators. These "rules" should govern the performance of supplementary studies, additional use of clinical material derived from the study, and use of the data (presentation, publication).

Ethical Behavior in the Interactions with Industry Partners

- When an industry-generated protocol is presented to PERC for consideration, the protocol remains the intellectual property of the industry participant and confidentiality must be maintained. The protocol should not be modified or used by PERC investigators without the permission of the industry partner.

- When an investigator-generated protocol is submitted to industry for consideration, it remains the intellectual property of PERC and confidentiality should be maintained. The protocol should not be modified or used by industry without the permission of PERC.

- PERC expects that industry partners who choose not to fund a PERC study will not undertake the same or similar studies with a PERC member without the approval of PERC.

Breaches of Ethics by PERC Members or by Industry Representatives

- Allegations of breaches of ethical behavior by PERC members will be brought to the attention of the PERC executive who will serve as the review committee of PERC. This process will be strictly confidential.

- After an investigation into the circumstances of the alleged incident, including written testimony by involved parties, the PERC executive will make a judgment. The involved parties (the complainant and the alleged offender) will be informed of the decision in writing.

- Sanctions available for breaches of ethical behavior by a PERC member will include a written warning, suspension, or expulsion. Notice of the decision will also be sent to the appropriate individual responsible for the member's academic performance.

- Sanctions available for breaches of ethical behavior by industry will include, but not being limited to, a written warning and suspension of interactions (research and other) by PERC members with the offending party.

Appeals of Executive decisions can be made to an appeals committee comprised of one member representative of each PERC affiliate institution.

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
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

- 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**

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 E: 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 you will be asked to contribute 1% - 1.5% of the budget to support PERC infrastructure.

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. This concept paper is uploaded in REDCap by accessing your original PERC Intake Form. The PI should use the template provided in Appendix 1.1. 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 D);
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 publically 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 publically 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 1.1: CONCEPT PAPER TEMPLATE

PROJECT TITLE

Principal Investigator:

Co-Investigators:

Participating Sites:

Background:

Study Aim:

Research Design:

Sample Size:

Relevance: