GOVERNING PRINCIPLES

VISION

Pediatric Emergency Research Canada (PERC) aims to foster internationally recognized excellence in Canadian pediatric emergency care research.

GOALS

PERC is committed to advancing pediatric emergency medicine through the following goals for our network:

1. Creating new knowledge through collaborative, multicentre research involving clinical and epidemiological studies in pediatric emergency care.
2. Mentoring new investigators and fellows in developing research projects and programs of study.
3. Leveraging the expertise of researchers and clinicians within the network
4. Extending pediatric emergency medicine research collaboration at national and international levels.
5. Supporting the dissemination and implementation of pediatric emergency medicine discoveries through quality improvement collaboration and knowledge translation efforts.
6. Strengthening cohesiveness between centers involved in the evidence-based practice of pediatric emergency medicine (PEM).

ORGANIZATION

Individual Membership
Any healthcare provider involved in the delivery of care for children and youth in pediatric emergency medicine and researchers involved in PEM research. PERC will update its membership list and survey database list annually to ensure continued engagement and involvement of new researchers and clinicians.

Site Representatives
Each pediatric emergency department in Canada will appoint a Site Representative who serves as the primary liaison and key communication link between their site and PERC.

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. Subspecialty Trainee (Fellow) Representative
9. Research Coordinator Representative
10. PERC National Coordinator (ad hoc)

The Past-chair, Chair, and Vice-chair will each serve three-year terms. Once elected as Vice-chair, a member will progress automatically to Chair and subsequently Past-Chair. The Executive Board Members will also serve three years.

The Chair (or national coordinator on their behalf) will solicit nominations from the membership at least one month in advance of the elections. Any PERC member may nominate another PERC member (with their consent) or self-nominate for an Executive Board Member position. Both the nominator and the nominee must be in good standing. Executive terms should ideally be staggered so that two of these members turnover in a single year. When elections are held, one of the two positions will be selected by secret ballot vote and announced at the PERC Annual Meeting. The second position will be selected by random draw from the remaining executive nominees. When announcements for new PERC members are made at the annual meeting, the Executive will not disclose which member was elected by vote or draw.

Any PERC member may nominate another PERC member (with their consent) or self-nominate for the Vice-Chair position. Nominations for Vice-Chair will be reviewed and discussed by the PERC Executive Committee. The PERC Executive Committee will then vote for the Vice-Chair position and results will be announced at the PERC Annual Meeting.

The Subspecialty Trainee (Fellow) Representative will serve one year. Each year either at the PERC Annual Meeting or within three months after the meeting, all PEM fellows will elect their representative by secret ballot vote. Subspecialty Trainees can either self-nominate or be nominated by another Subspecialty Trainee, with their permission.

The Research Coordinator Representative will serve three years. Every three years at the PERC Annual Meeting, all research coordinators in attendance will convene and elect their representative by vote. Research Coordinator Representatives can either self-nominate or be nominated by another PERC Research Coordinator member, with their permission.

Responsibilities of the Executive Committee

The executive committee will be responsible for:

1. Planning and organizing the PERC Annual Scientific Meeting, including the Subspecialty Trainees' (Fellows') Research Day.
2. Maintaining regular communication with the membership about the status of current ongoing, recently completed, and potential new studies.
3. Administering any funds or other resources that are under PERC's purview.
4. Recording and retaining accurate meeting minutes, which are circulated to Executive members in a timely fashion.
5. Initiating the review of proposed collaborative studies and provide formal endorsement and letters of support/collaboration (including leading study protocol review).
6. Overseeing the administration of, and access to, the PERC Physician Survey Database.
7. Monitoring ongoing studies and addressing emerging research challenges.
8. Developing guidelines and policies that determine how PERC will conduct its business.

To foster meaningful relationships and collaborations with associated research and knowledge translation networks (e.g., TREKK, PERN, CAEP, MICYRN, etc.), PERC Executive members and Executive members of PERC's partner networks may attend each other's executive meetings, as necessary. Updates will be presented at PERC Executive Committee meetings about progress at associated research networks, as necessary.

Annual Meeting & Other Means of Communication

PERC Members will meet once per year to be updated on completed and on-going studies, and to discuss potential new studies. The Executive Committee will draft the meeting agenda with input from the PERC membership. Appendix A provides the guidelines for presentations during the PERC Annual Scientific Meeting.

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 newsletters, e-mails and a regularly updated website.

Special Interest Groups

Any PERC member or group of members can propose a special interest group (SIG) around a specific topic. The purpose of the group must be to further pediatric emergency care-related research or knowledge translation in this area, promoting scholarly activities and collaboration. A list of PERC SIGs is available in Appendix B. Once approved by the PERC Executive Committee, each SIG listed in the PERC Governance Guidelines will be allotted meeting time and space 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 the 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, those belonging to the 2SLGBTQIA+ community, etc.).

REVIEW AND ENDORSEMENT OF NEW STUDIES

A PERC-endorsed study must involve more than one PERC ED site and/or investigator. The PERC Endorsement and Review process involves two 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 letter of support for a grant application **must be submitted at least 6 weeks prior to the grant submission deadline**. In the event of a granting opportunity with announcement and submission dates less than 6 weeks apart, the principal investigator must submit a written/email 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 be unable to review or endorse the study in time for grant submission. The complete *PERC Endorsement and Review Process* can be found in Appendix C. Appendix D (Concept Paper Template) and Appendix E (Infrastructure Support and Budget Justification) outline additional items relevant to PERC endorsement process.

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 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/email 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

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. It is recommended that larger study groups create a team guideline for authorship early in their team formation.

Participation in PERC studies does not guarantee authorship. PERC principal investigators should adhere to the recommendations of *International Committee for Medical Journal Editors* which state:

"The ICMJE recommends that authorship be based on the following 4 criteria:

- *Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND*
- *Drafting the work or reviewing it critically for important intellectual content; AND*
- *Final approval of the version to be published; AND*
- *Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved."*

(Reference: https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html)

GUIDELINES FOR SELECTING REPRESENTATIVES ON PERN EXECUTIVE

In 2010 Pediatric Emergency Research Networks (PERN) 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, while the second member can either be on the PERC Executive or from the PERC membership at large.
- In order to identify the second PERN 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 general PERC membership. This would be a self-nomination process and if more than one person expressed interest the Executive would decide by vote.
- The expectations of the PERN Executive members are the following:
    - Attend 3-4 teleconference per year,
    - If attending the annual PAS meetings, attend the in-person PERN meetings, or if offered join remotely,
    - If attending ICEM (held every second year) attend in-person PERN meetings, or if offered join remotely,
    - Report back to PERC Executive.

ROLES & RESPONSIBILITIES OF SITE REPRESENTATIVES

Roles and Responsibilities of PERC Site Representatives

The PERC Site Representatives have the following expectations:

1. Representatives should attend and promote the PERC Annual Meeting.
2. The PERC Site Representative should attend both the in-person Site Representative meeting at the Annual PERC conference as well as the virtual meeting once a year.
3. Representatives should facilitate identifying ED colleagues from their site to act as a Site Local Investigator for proposed PERC projects. Ideally, the Site Representatives should not serve as the Local Investigator for every PERC project in order to promote a range of ED staff participation in PERC studies.
4. Representatives should provide an overview of all PERC projects being conducted at their site.
5. Representatives can be either elected by their colleagues or appointed by the Site's Medical Director.
6. Once chosen as a Site Representative, the individual will serve a first term of three years. Subsequently representatives may be re-elected/re-appointed in three-year blocks. Each site will be encouraged to consider selection of a new individual after a maximum of 2 re-appointments (9 years term, total).

ROLES & RESPONSIBILITIES OF PERC MEMBERS

PERC members must:

1. Agree to abide by the PERC Code of Ethical Behaviour for Multi-centered Clinical Trials (see attached Appendix F).
2. 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 should 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 major proposed revisions, once approved by the 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.

SUBSPECIALTY TRAINEE (FELLOW) EDUCATION DAY PLANNING COMMITTEE

The Subspecialty Trainees' (Fellows) Education Day at the PERC Annual Scientific Meeting is a supplemental full-day session designed to enhance the learning and professional development of PEM Subspecialty Trainees across PERC sites. This session is intended to complement their experience at the Annual Meeting by offering tailored content, networking and mentorship opportunities, and formal project-specific feedback. The agenda is developed by the Subspecialty Trainees' Education Day Planning Committee and requires final approval by the PERC Chair and, as necessary, the PERC Executive Committee.

The Subspecialty Trainees' Education Day Planning Committee is composed of five members:

1. The Subspecialty Trainee Representative of the PERC Executive Committee
2. A Program Director representative
3. A PERC member-at-large from Eastern/Central Canada
4. A PERC member-at-large from Western Canada
5. The PERC National Coordinator (ad hoc)

Members of the planning committee serve two-year terms. Terms may be extended by the Executive Committee at their discretion. New members may be recommended any PERC member; final selection of members is determined by the PERC Executive Committee.

GUIDELINES FOR PROPOSING A STUDY ACROSS MULTIPLE NETWORKS

Proposed studies involving both PERC and other networks' (*e.g.*, PERN, PECARN, PIRN, NCER, etc.) membership and collaboration are often more complex to operationalize than studies involving each network alone. Proposed studies using both the PERC and other national or international 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. There are also unique financial considerations for each involved network. The process for endorsement of studies involving the prospective recruitment of patients from Canadian pediatric EDs will follow the endorsement process for PERC multi-site studies. Other studies and proposed collaborations will be assessed by the PERC Executive on an as-needed basis.

APPENDIX A.
PERC ANNUAL MEETING PRESENTATION GUIDELINES

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

For **newly proposed 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 Submission Guidelines

- All investigators must submit their request to present their study by the annual deadline (typically the end of November to beginning of December).
- For presentation requests, the following is required to be submitted online: name of presenter; type of study; title of presentation; and a 1-page abstract/summary of the project.
- The 1-page abstract/summary should include: background, methods, results/updates, conclusion/expected outcomes/next steps.
    - **New Studies**: The summary should 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, pilot study status (e.g. protocol development, status of ethics, pilot data/ local enrollment) and planned funding sources. It is expected that presenters will prepare a list of questions and issues to pose to attendees prior to their presentation. These questions will help focus the PERC members discussion on the issues that would be most helpful to the presenter.
    - **On-going studies:** A 1-page abstract style update addressing enrollment, and any other important issues.
    - **Completed studies**: A standard, structured 'meeting' abstract outlining the study's objectives, methods, results and conclusions, plus a brief review of the manuscript's status
- Requests will then be reviewed by the PERC network coordinator and Chair to ensure presentation eligibility.
- Abstracts/summaries submitted as a part of presentation requests will be compiled to form the Annual Scientific Meeting E-Binder. Updates to these documents can be made up to 2 weeks before the PERC Annual Scientific Meeting by emailing an updated version to nationalcoordinator@perc-canada.ca.

Guidelines for Presenting New Studies

New Studies will be allotted a minimum of **30 minutes**. It is recommended to **use no more than 10-15 minutes for presenting your study**. Allow a minimum of 15 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. Identify the goals you plan to achieve before the next PERC meeting.

Guidelines for Presenting Ongoing Studies

- Investigators with ongoing PERC studies should prepare **a one-page update** to be included in the PERC meeting e-binder which will familiarize attendees with your project. This one-page update will be the same as the one submitted as a part of the presentation request unless an update is provided at least 2 weeks prior to the Annual Scientific Meeting.
- Investigators should also be prepared to give **a brief verbal update,** between 3-5 minutes in length.
- Investigators may plan **a separate Investigator meeting** for site PIs and study personnel 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 if deemed necessary.

Guidelines for Presenting Completed Studies

- 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**).
- **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 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.

- In addition to reporting your study's results, you should also discuss their implications, and what further follow-up studies might be pursued.
- 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 e-binder.

APPENDIX B.
SPECIAL INTEREST GROUPS

Active - Pain Interest Group (PIG) – formed January 2015

Active - Women in Research Interest Group – formed January 2019

Currently Inactive - Gastroenteritis Interest Group – formed January 2011

Currently Inactive - Quality Improvement Interest Group (QuIG) – formed January 2015

Currently Inactive - Mental Health Interest Group (MHIG) – formed April 2015

For copies of the Terms of Reference for each group please contact the PERC National Coordinator (nationalcoordinator@perc-canada.ca).

APPENDIX C.
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-endorsed study. A PERC-endorsed 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, database studies using external data, systematic reviews, and trials of knowledge synthesis tools. **A minimum of 2 PERC sites must be involved in recruiting participants/collecting data and/or investigators from at least 2 PERC sites must work collaboratively on the project for it to be eligible for consideration as a PERC-endorsed 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 completing 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 formal review by the PERC Executive and/or designated PERC members.

PHASE I: PERC Study Intake Form & Concept Paper Submission

The PI will complete the online PERC Study Intake Form in REDCap (Click Here to Access). The PERC Study Intake Form provides 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 Phase 1, 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 a portion of the budget to support PERC infrastructure (see PERC website for further details).

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.
    b. 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.

A brief demographic questionnaire is also included in the Study Intake Form to provide tracking information to PERC Executive members regarding EDI metrics and to facilitate reporting on the characteristics of the members who are applying for PERC endorsement and leading PERC studies.

Phase I also 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 D. 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 full protocol, specifically the detailed methodology, as well as budget, and proceed to the second phase.

PHASE II: Peer Review of Full Protocol & Budget

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

In phase II, 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 (see Appendix F

It is recommended that all RCT protocol submissions complete a SPIRIT checklist.

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.

Two members of the PERC 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

At least 75% of the (voting eligible) PERC executive must vote to accept the proposal to be approved as a PERC-endorsed study.

Note: PI's of previously endorsed proposals will be contacted to review future proposals on behalf of PERC as criteria of endorsement.

The PERC national coordinator 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 Chair (or their designate) 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: Clinical Trials

All PIs of PERC-endorsed clinical trials must register their trial prior to enrolling patients; publish the study protocol either in a peer-reviewed journal or on a publicly available 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 the PERC Executive. All clinical trials must also establish a data safety monitoring board (DSMB) and create a DSMB charter prior to commencing patient recruitment. Resources and examples can be provided upon request.

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 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.
CONCEPT PAPER TEMPLATE

PROJECT TITLE

Principal Investigator:

Co-Investigators:

Participating Sites:

Background:

Study Aim:

Research Design:

Sample Size:

Relevance:

APPENDIX E.
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 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.

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."

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

APPENDIX F.
CODE OF ETHICAL BEHAVIOUR

The 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, language, age, size, appearance, gender, sexual identity, physical ability, mental competence, etc).

All concerns or violations should be reported to a PERC Executive member. 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, clinicians, learners, and research staff who share their intellectual property and resources for the common goal of undertaking research in pediatric emergency medicine.
- 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, everyone 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 (IP) 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.
- Industry involvement and sponsorship should be explicitly stated in all presentations and written documentation that pertain to the study.

Breaches of Ethics by PERC Members or by Industry Representatives

- Allegations of breaches of ethical behavior by PERC members or industry representatives 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, which may include 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 member representatives from PERC affiliate institutions.