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.

The full description of having a study PERC-Endorsed is provided in the PERC Governance Guidelines document.

PHASE I: PERC STUDY INTAKE FORM

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.
    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.

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 A. 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.

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. Therefore, if a supporting letter is required for a grant application a protocol must be submitted at least 8 weeks prior to a grant submission deadline. In the event of a granting opportunity with announcement and submission date less than 8 weeks apart, the PI 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.

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;
3) The site representatives signature form (upload form); and
4) If this is an RCT, a completed SPIRIT Checklist (http://www.spirit-statement.org/title/). The use of the checklist assists PIs in recognizing areas of their protocols that need improvement prior to submission to the PERC Executive.

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.

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 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 A: CONCEPT PAPER TEMPLATE

PROJECT TITLE

Principal Investigator:

Co-Investigators:

Participating Sites:

Background:

Study Aim:

Research Design:

Sample Size:

Relevance: