Guidelines for Application to the Neonatal Research Committee

The Neonatal Research Committee (NRC) provides scientific review of all research projects proposed to take place within the Neonatal Intensive Care Unit at McMaster Children's Hospital or involving resources on the unit. In this way, the unit's limited resources can be optimally allocated to support research, while ensuring that staff, patients, and families are informed and not overwhelmed.

Investigators must receive written approval from the NRC prior to submitting an application to the Hamilton Integrated Research Ethics Board.

Committee membership

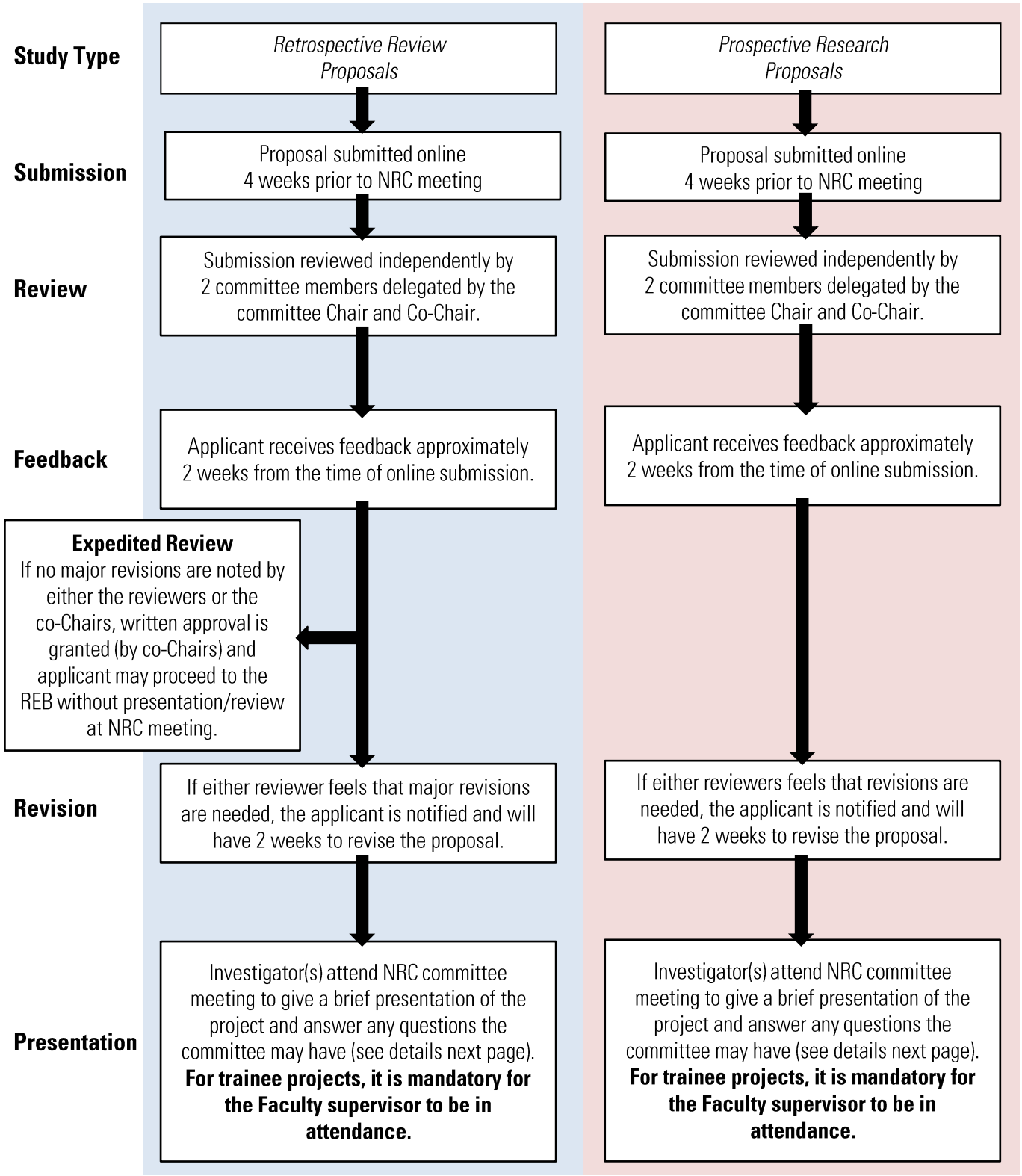
The NRC is composed of faculty, staff, and learners from neonatology, the Department of Pediatrics, and the Department of Obstetrics and Gynecology. The diverse membership of the committee allows for informed review of research applications. The following roles are represented on the committee: program fellow, OB/MFM representative, Jack Sinclair Chair, research coordinator, clinical manager, nurse practitioner, research associate, fellowship program director, clinical fellow, medical director, associate member, neonatologist, nurse specialist.

Submitting a project to the NRC

For consideration of a project by the NRC, investigators must prepare and electronically submit the documentation listed on page 3. Submission and review processes are illustrated on the following page. All reviewed studies will be reported at the monthly meeting.

- **Submission deadline** is noon on the Tuesday four weeks prior to the next NRC meeting. The NRC typically meets the third Tuesday of every month (meeting dates can be confirmed with Osiris Lopez-Chevez, assistant to Dr. Connie Williams).
- **Retrospective reviews** of medical records/data are eligible for expedited review and, if successful, they proceed to the REB without full committee review or presentation at an NRC meeting.
- **Prospective studies** undergo full committee review and investigators are invited to present at an NRC meeting.
- **Presentation to the NRC** is required for retrospective reviews not granted expedited review and all prospective studies. Investigators are invited to give a brief 10-minute presentation outlining their proposed project. It is advisable to prepare ten or fewer PowerPoint slides to support the key aspects of the proposal including – background, objectives, methods, data to be collected, statistical plan, and relevance. For trainee projects, it is mandatory for the Faculty supervisor to be in attendance.
- **Notice of decision**
  - Investigators who submit an application for a retrospective review will be notified of the status approximately two weeks post-submission. Those not requiring revision will proceed to the REB without presentation at the next committee meeting, while those requiring revision will be invited to edit the proposal and present at the next committee meeting.
  - Decision regarding a submission that proceeds to full committee review (e.g., retrospective reviews not granted expedited review and all prospective studies) will be made during the meeting at which it is reviewed.

Review Process



Submission Format

Proposal submission is online: https://fhspeds.mcmaster.ca/pedsCapOne/surveys/?s=Tvyerren8R
Please do not access the link until such time that you are prepared to **submit** your proposal.

Note: For trainee projects, supervisors must review and approve all materials submitted to the NRC. As part of the online submission, trainees will be required to indicate the date on which approval was received.

You will be asked to upload the following as separate documents:

1) A **three page** summary of the proposed study addressing the following points:
    a. *Study Title**
    b. *Funding source and amount**
    c. *Name of Principal Investigator and Local Principal Investigator (if different from PI)**
    d. *Co-Investigators and their roles**
    e. *Study staff and their responsibilities**
    f. What is the rationale for the study (i.e., why are you doing this study)?
    g. What are the objectives of this study (i.e., what do you hope to show)?
    h. Study design (e.g., RCT, cohort)
    i. Study population (e.g., diagnosis, age, gender)
    j. Study procedures
    k. Primary outcome and how will it be measured
    l. Secondary outcomes and how they will they be measured
    m. Sample size
        a. Local
        b. Total (for multi-site studies)
    n. How you determined your sample size
    o. How you plan to analyze your data
    p. For clinical trials: registry name and registry number

    *You will be asked to copy and paste the first 5 items (noted in italics above) of the summary into an online form.

2) The full study protocol developed according to the appropriate reporting guidelines (up to but not including results/discussion sections), addressing each criterion separately. For easy access, links to protocol development checklists for common study types are listed below:
    a. clinical trials (modify as needed for non-randomized trials),
    b. quality improvement studies, and
    c. observational studies (modified as necessary for retrospective chart reviews)

    For other study types, see the Equator Network http://www.equator-network.org/ for a searchable library of additional reporting guidelines.

3) Study consent and information forms, as appropriate.