Accroître la capacité à conduire des essais cliniques avec les personnes enceintes et les enfants

Increasing capacity for Maternal and Paediatric Clinical Trials

Increasing capacity for Maternal and Paediatric Clinical Trials (IMPaCT)

Terms of Reference

September 11, 2023

1. Expectations for Mentors and Trainees

Introduction

The vision for IMPaCT is to increase clinical trial capacity in perinatal and child health, by creating a common space for training and mentorship to harness existing strengths with sustainable, accessible infrastructure. An advanced clinical trials fellowship training program (salary awards) will be developed and implemented with diverse mentorship opportunities for pediatric and perinatal clinicians and researchers. Should mentors or mentees (trainees and ECRs) have concerns about their relationship, these can be brought to the attention of the platform manager at any time.

Mentors

Mentors can be requested or will be assigned. There will be one (1) to three (3) mentors per trainee or ECR. The following sections outline key responsibilities of IMPaCT mentors, trainees and ECRs to ensure maximum experiential learning opportunities. Mentors should aim to provide a welcoming environment in which the trainees and ECRs has exposure to as many facets of clinical trials as feasible. The following checklist is provided to help the mentors ensure a successful experience.

- Discuss expectations, support onboarding and integration into your team
- Meet regularly (e.g. monthly, minimum 2x per year) to review progress on deliverables
- Coordinate experiential learning opportunities for mentees
- Attend the annual IMPaCT summit (note: travel costs will be reimbursed for mentors)
- Mentors will be invited to develop and create modules, webinars or other educational materials to be accessible on RiSE LMS
- Participate in a mock peer-review panel and elevator pitch competition
- Optional: participation in selection and review committee to review salary award applications and review 10 page proposals

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Mentees: Trainees and ECRs

Trainees (doctoral students and postdoctoral fellows) and early career researchers (ECRs) should come with a desire to learn about innovative trials methods, write a clinical trial protocol, address challenges related to clinical trials in perinatal and child health and should expect to do some hands-on work over the course of the fellowship. Mentees should be willing to dedicate time to learning about clinical trials and preparing the IMPaCT deliverables.

The following checklist outlines the expectations of the trainees and ECRs who receive salary awards:

- Discuss a realistic learning plan and schedule meetings with your mentor(s)
- Fulfill project tasks and responsibilities assigned by mentor(s)
- Attend all relevant project meetings as advised by mentor(s)
- Attend the annual IMPaCT summit (note: travel costs will be reimbursed for mentees)
- Participate in the elevator pitch competition
- Participate in immersive learning opportunities as available
- Complete the applicable training modules on RiSE LMS

2. Scope of Experiences

Mentors are expected to have a breadth of expertise across many dimensions of trials. It will be the goal for IMPaCT trainees and ECRs to be exposed to as many dimensions related to clinical trials as possible and relevant during their one-year fellowship. Examples of experiential learning opportunities could include, but are not limited to:

Trial Design: Mentors can provide opportunities to be involved in discussions about the design of new trials. Trainees and ECRs involvement can include but not limited to attending investigator deliberations about research hypothesis, framing research questions, review of the literature, intervention selection, ethical considerations, patient engagement and other.

Steering/Executive Committees: All trials have executive and steering committees that meet regularly to review the progress and conduct of the trial. These meetings will be valuable for trainees and ECRs to attend to appreciate the practical aspects of running clinical trials.

Data Safety Monitoring Boards: The presence of a Data Safety Monitoring Board (DSMB) is a common feature of many clinical trials. They will be given the opportunity to assist with the preparation of DSMB reports and attend DSMB meetings as an observer to learn the operation of these important committees.

Grant Preparation: Many trials that are not for regulatory approval are funded by public funding agencies (e.g. CIHR). Clinical trialists are responsible for grant preparation. The mentors will provide the trainees and ECRs with opportunities to contribute to the writing of grant applications as those opportunities arise.

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Pre-submission meeting with Health Canada

Patient or Parent advisory committee meeting

Global child health trials exchange

Advocacy and government relations experience

Additional funding for experiential learning opportunities is available to support mentee participation and must be pre-approved by the platform manager.

3. Funding Details

The host Institution will administer IMPaCT salary awards, for a total of $35,000 per one (1) year for PhD trainees, $50,000 per one (1) year for Postdoctoral trainees, and $70,000 per one (1) year for ECRs. There is no matching of funds required. The host institution will invoice IMPaCT once annually for this award during the funding period. There is no minimum protection time required for applicants.

Should the awardee embark on a parental/maternal leave during this award, the award shall be placed on hold for the period of the maternal/parental leave. The awardee may be eligible for a paid parental leave as per our guidelines found at https://enrichyourscience.ca/

This is a salary award, and funds should not be spent on research activities. Letters of support from mentees institutions must outline how these funds will directly support their learners to participate in the IMPaCT program.

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