CHEER Year 3 in Review

The Canadian Collaboration for Child Health: Efficiency and Excellence in the Ethics Review of Research (CHEER) is a Canada-wide initiative on a mission to improve child health by streamlining research ethics review for child health research. Led by Clinical Trials Ontario (CTO) and the Maternal Infant Child and Youth Research Network (MICYRN), the goal of the CHEER project is to streamline the research ethics review process for multi-site child health studies across Canada with the aim of a single research ethics review.

This report highlights the progress of this initiative during the third grant year (April 2022 – March 2023).

CHEER Qualification Program

The IWK in Nova Scotia has been through the qualification and we aim to qualify them very soon. The Health Research Ethics Authority (HREA), Newfoundland, received a $10,000 honorarium from the CHEER Project to start preparing for CHEER qualification. This honorarium available for any REB going through their first CHEER qualification. We hope to see the HREA CHEER qualified in the next few months. Another Ontario REB is also considering qualification. Other CHEER qualified REBs include: The Hospital for Sick Children Research Ethics Board, Children's Hospital of Eastern Ontario Research Ethics Board, Western University Health Sciences Research Ethics Board, Ontario Cancer Research Ethics Board (OCREB), Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board, Holland Bloorview Kids Rehabilitation Hospital Research Ethics Board.

As part of the CHEER qualification program, we would like to put out a call for volunteers to form a small working group to discuss Board of Record allocation and a fee structure for industry sponsored studies. As the CHEER project progresses, we would like to have input from interested parties across the country, when formalizing this process.

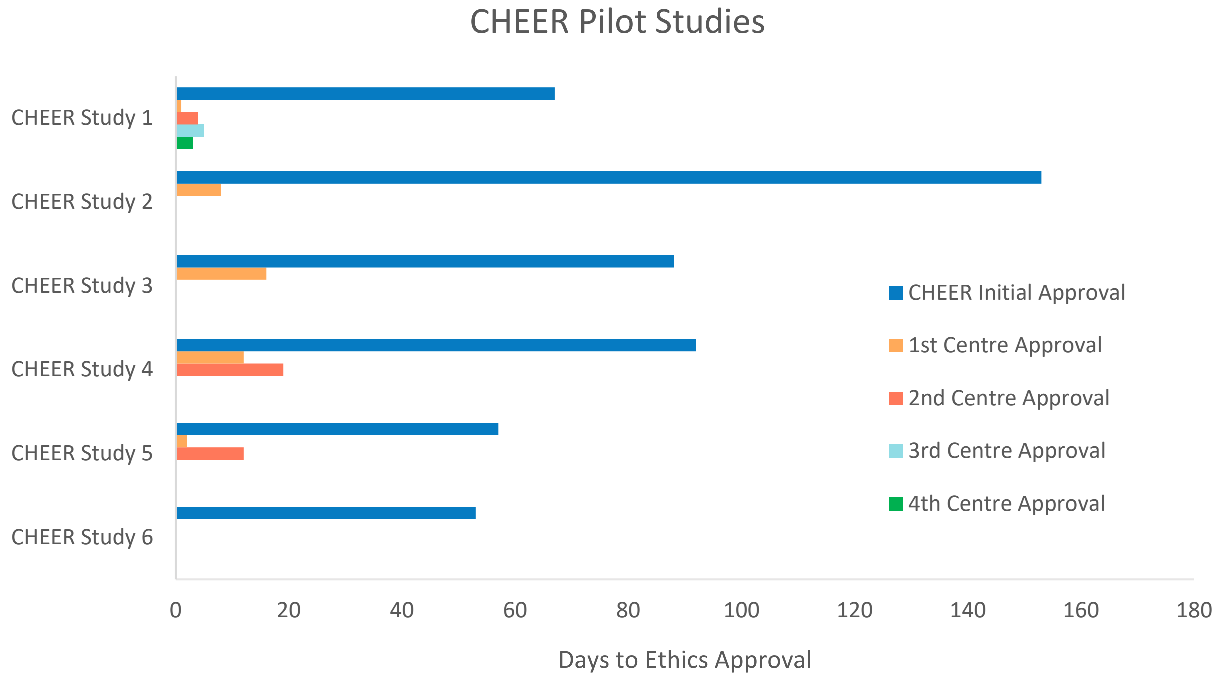
The CHEER REB qualification seal was finalized and is now part of the qualification package. This seal can be used by REBs on their websites, informing researchers that their home institution is part of the CHEER project and is an available resource.

Pilot Study Updates

Six studies are piloting the CHEER platform and 3 REBs are acting as Board of Record. The studies are mostly investigator initiated and observational in nature with two interventional studies, both of which are Health Canada and US FDA regulated.

Our hope is that when the IWK REB becomes CHEER qualified we will pilot a study that has Nova Scotia and Ontario sites. Additionally, we will pilot the CHEER Board of Record agreement at institutions across two provinces.

The graph below depicts the ethics review timelines for the CHEER studies. Single review by a CHEER Board of Record has greatly reduced the length of time to obtain ethics approval for individual study sites. Many of these studies are going into their second year and new sites are continuously being added.



Defining Pilot Studies. 'Pilot studies' refer to the first studies submitting research ethics applications through CHEER, thereby testing (piloting) the CHEER system, supports, and policies as well as informing continued development of the initiative.

CHEER Education Modules

Two of the modules have been produced and completed numerous rounds of review. One module is near to completion while work continues on the others. These education modules are intended to be interactive and provide users with a great learning experience.

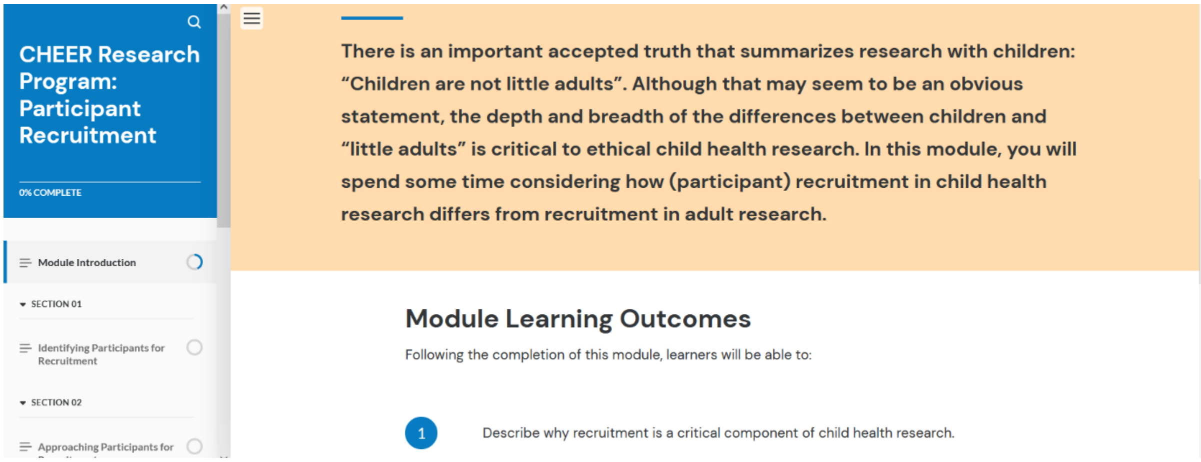
The CHEER education working group, led by CHEER Co-Investigator, Dr. Denise Stockley, is supported by the expertise of the Office for Professional Developments and Professional Scholarship at Queen's University.

We have recruited more subject matter experts for two of the modules from across the country and hope to have the remaining modules finalized in the coming months. The CHEER Patient and Family Advisory Committee (PFAC) have been instrumental in serving as subject matter experts for the modules as well as multiple rounds of review. With their help and subject matter experts across the country, these high caliber modules will create a long-lasting legacy of the CHEER project.

CHEER Education Module Topics:

- Participant Recruitment
- Patient and Public Engagement
- Participant Consent and Assent
- Study Design
- Data

CHEER Research Program: Participant Recruitment



There is an important accepted truth that summarizes research with children: “Children are not little adults”. Although that may seem to be an obvious statement, the depth and breadth of the differences between children and “little adults” is critical to ethical child health research. In this module, you will spend some time considering how (participant) recruitment in child health research differs from recruitment in adult research.

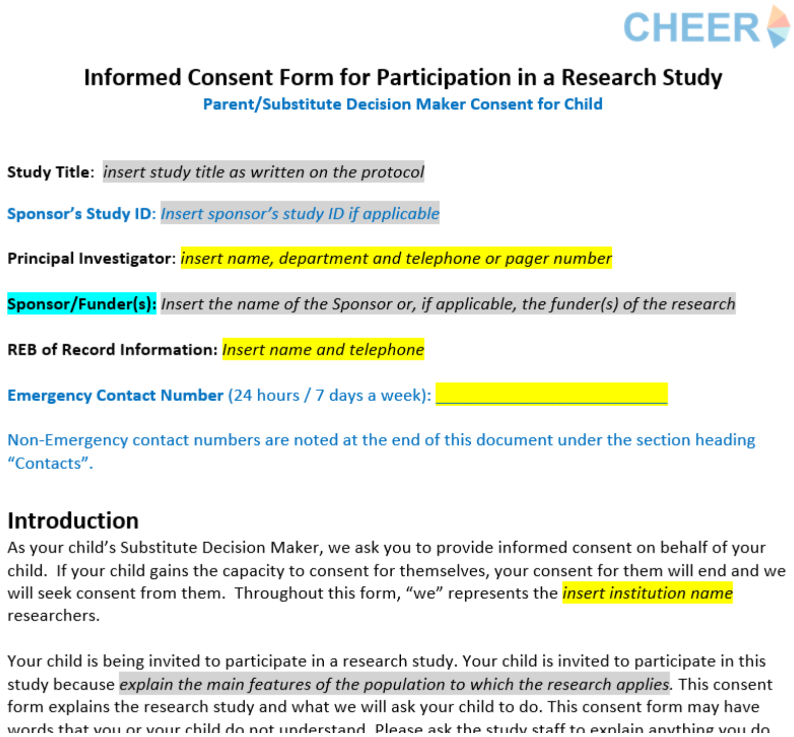
Module Learning Outcomes

Following the completion of this module, learners will be able to:

1 Describe why recruitment is a critical component of child health research.

CHEER Consent Templates

We are in the process of finalizing the CHEER consent and assent templates. These templates will be made available to CHEER researchers when submitting their ethics applications. By reviewing templates from various Research Ethics Boards across the country, we have created compliant and easy to use templates. Researchers can adapt these templates to fit their study needs while retaining the required elements from TCPS.



Informed Consent Form for Participation in a Research Study

Parent/Substitute Decision Maker Consent for Child

Study Title: *insert study title as written on the protocol*

Sponsor’s Study ID: *Insert sponsor’s study ID if applicable*

Principal Investigator: *insert name, department and telephone or pager number*

Sponsor/Funder(s): *Insert the name of the Sponsor or, if applicable, the funder(s) of the research*

REB of Record Information: *Insert name and telephone*

Emergency Contact Number (24 hours / 7 days a week): ______________________

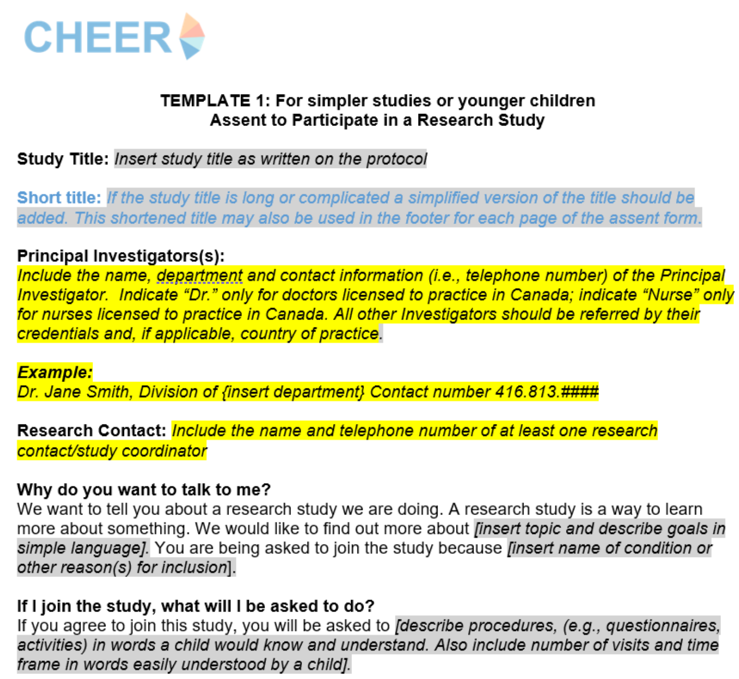
Non-Emergency contact numbers are noted at the end of this document under the section heading “Contacts”.

Introduction

As your child’s Substitute Decision Maker, we ask you to provide informed consent on behalf of your child. If your child gains the capacity to consent for themselves, your consent for them will end and we will seek consent from them. Throughout this form, “we” represents the *insert institution name* researchers.

Your child is being invited to participate in a research study. Your child is invited to participate in this study because *explain the main features of the population to which the research applies*. This consent form explains the research study and what we will ask your child to do. This consent form may have words that you or your child do not understand. Please ask the study staff to explain anything you do

The CHEER consent and assent templates have undergone multiple rounds of review by experts in paediatric research ethics and by members of the PFAC. We will have different templates for different study types, observational, interventional, sub studies or optional biobanking studies and oncology studies.



CHEER

TEMPLATE 1: For simpler studies or younger children
Assent to Participate in a Research Study

Study Title: *Insert study title as written on the protocol*

Short title: *If the study title is long or complicated a simplified version of the title should be added. This shortened title may also be used in the footer for each page of the assent form.*

Principal Investigators(s):
Include the name, department and contact information (i.e., telephone number) of the Principal Investigator. Indicate "Dr." only for doctors licensed to practice in Canada; indicate "Nurse" only for nurses licensed to practice in Canada. All other Investigators should be referred by their credentials and, if applicable, country of practice.

Example:
Dr. Jane Smith, Division of {insert department} Contact number 416.813.####

Research Contact: *Include the name and telephone number of at least one research contact/study coordinator*

Why do you want to talk to me?
We want to tell you about a research study we are doing. A research study is a way to learn more about something. We would like to find out more about *[insert topic and describe goals in simple language]*. You are being asked to join the study because *[insert name of condition or other reason(s) for inclusion*].

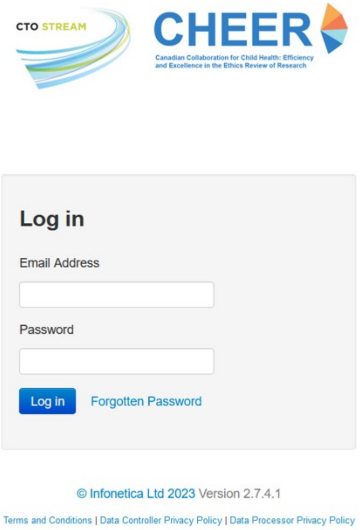
If I join the study, what will I be asked to do?
If you agree to join this study, you will be asked to *[describe procedures, (e.g., questionnaires, activities) in words a child would know and understand. Also include number of visits and time frame in words easily understood by a child*].

CHEER System

The CHEER system is fully operational now. This provides REBs and researchers a robust, regulatory compliant and auditable platform to submit applications for ethics approval of multisite studies.

The CHEER system provides a single REB review for a multisite study, improving time to ethics approval and with just one main application, researchers do not need to spend time and effort to obtain ethics approval at each local site for their CHEER study.

A goal of the CHEER project is to reduce administrative burden on child health researchers when applying for ethics approval.



Clinical Trial Navigator

In summer of 2022 MICYRN launched their clinical trial navigator program. This is jointly funded by CHEER and MICYRN and provides practical guidance and support for completing ethics applications for multi-site child health research. While we work towards a single REB review module, the clinical trial navigator is available for investigators wishing to use the CHEER platform and other REB review platforms as required.

With the help of the clinical trial navigator, one of the studies piloting the CHEER platform already has 5 sites approved through the CHEER platform and 9 other sites outside the platform.

Webinars

Importance of Data Sharing and Demystifying the Process

CHEER Webinar

CHEER
cheerchildhealth.ca

Tuesday, May 3, 2022
9-10 PDT / 12-1 EDT

Link to Register

Overview

By the end of this session, you will have a firm understanding of the importance of data sharing in pediatrics as well as some of the unique challenges faced by those doing research in this area. We will outline key considerations for Canadian researchers and present some newly produced tools aimed at addressing common barriers to data sharing.

Session Topics

Importance of Data Sharing and Demystifying the Process
Holly Longstaff and Charles Burchill

HDRN Privacy Legislation Tool
Donna Curtis Maillet

HDRN Consent Tool
Donna Curtis Maillet

Holly Longstaff, PhD

Director, Privacy and Access, PHSA Research and New Initiatives, Provincial Health Services Authority, British Columbia

Charles Burchill

Associated Director, Repository, Manitoba Centre for Health Policy, University of Manitoba

Donna Curtis Maillet, PhD

Privacy Officer, New Brunswick Institute for Research Data and Training & Research Associate, Faculty of Law, University of New Brunswick

Engagement, Consultations and Collaborations

In Fall 2022, CHEER was approached to collaborate on a textbook about research ethics. CHEER contributed a chapter outlining the project, the deliverables of the grant and why single REB review is needed. The chapter focuses on successes and barrier of the CHEER project and highlights international streamline review models. The chapter has now been received by the editors and we hope to see it published very soon.

When qualifying research ethics boards, REB managers and staff have expressed concern about reviewing multi-jurisdictional research with different provincial and territorial requirements. To address this, CHEER is engaging law students from the University of Toronto to conduct an environmental scan of the research landscape. The outcome of this will be a document that details the relevant legislation of the Canadian provinces and territories, providing REBs with a roadmap to reviewing research from outside their own jurisdiction.

In December 2022, CHEER met with a representative from the Department of Health in Australia. The conversation focused on achieving single ethics review in a multi-jurisdictional context, which Australia has achieved. The barriers and solutions to this were discussed including their preference to move from multiple systems at a jurisdictional level to a single overarching system. Overall, it was a very positive conversation. With this international success, CHEER is optimistic we can achieve the same here in Canada.

Also, in December 2022, CHEER met with a representative from the National Institute of Health Research in the U.K. The conversation focused on systems and the barriers they have overcome to achieving streamlined ethics review within the healthcare system. Integrity issues of their current multiplatform system was discussed as well as the human resources needed for data input.

Acknowledgements

CHEER Principal Investigators, Co-Investigators and Collaborators

CHEER Committees

- Operational Management Team
- REB Advisory Committee
- Patient & Family Advisory Committee
- Strategic Implementation Advisory

Supporters

- 16 paediatric hospitals/research institutes
- 23 research intensive networks
- Health Canada
- Children's Healthcare Canada

Knowledge Users:

Health Canada Santé Canada

Santé et Services sociaux Québec

NEWFOUNDLAND AND LABRADOR
HREA
HEALTH RESEARCH ETHICS AUTHORITY

Children's Healthcare Canada

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CIHR IRSC
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