CHEER

The Canadian Collaboration for Child Health:
Efficiency and Excellence in the Ethics Review of Research (CHEER)

Queen's University
HEALTH SCIENCES

CHEER Research Program:
Participant Recruitment

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TABLE OF CONTENTS

MODULE INTRODUCTION

Please see the online learning module for the full experience of interactions within this document.

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.
2. Recognize how potential participants can be identified in clinical and non-clinical settings.
3. Discuss potential implications of undue influence and incentives in the recruitment of vulnerable populations.
4. Identify ethically sound strategies for recruiting children and adolescents.
5. Assess recruitment strategies in clinical and non-clinical settings.
6. Describe how to follow-up with participants and families in child health research.

Note that activities within this module, such as short answer questions and other interactions, will not be graded. These questions are included to help you consolidate your learning, so it is in your best interest to take full advantage of them.

End of Section 00

SECTION 01: IDENTIFYING PARTICIPANTS FOR RECRUITMENT

Children and adolescents are generally considered a vulnerable population in research. In this section, you will learn about the methods and settings used to identify potential participants for child health research. You will learn about the impacts of federal and provincial/territorial legislation on researcher access to children's personal information, the different approaches suitable for identifying participants from First Nations, Inuit, or Métis communities, and the benefits and pitfalls of random and convenience sampling.

Children and Adolescents as a Vulnerable Population

All children and adolescents, with or without health conditions, are considered a vulnerable population in regards to research. The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) defines vulnerability as "A diminished ability to fully safeguard one's own interests in the context of a specific research project. This may be caused by limited decision-making capacity or limited access to social goods, such as rights, opportunities and power. Individuals or groups may experience vulnerability to different degrees and at different times, depending on their circumstances."[1]

All children are inherently considered a vulnerable population based on their developing capacity for decision making. Their "vulnerable" status requires that researchers engage in more extensive discussions and consultations with potential participants and their decision makers if the child is unable to independently provide informed consent.

The term "children" includes infants, toddlers, preschoolers, and adolescents. The term "youth" is often used in government to categorize 16-25 year olds (i.e., younger adults). Throughout the module, the term "child" or "children" will be predominantly used.

A 'decision maker' can include parent(s), guardian(s), caregiver(s), a representative from a child protective service, social worker, legally acceptable substitute/alternative decision maker, sibling(s), or any other relative(s). The decision maker refers to an authorized third party who holds the legal right to make decisions on behalf of a child. Researchers should be aware of applicable legal and regulatory requirements with respect to legal decision makers; these may vary among jurisdictions.

Children: A Vulnerable Population in Research

Answer the question using what you know about child health research.

Question: Why are children considered a vulnerable population in research?

Feedback:

Children and adolescents are growing and developing. Their body proportions are changing as neurological connections are being formed and refined. They gradually learn to understand abstract concepts and they are learning to interact with peers who are also growing and developing at different rates. All of these aspects must be considered and incorporated into recruitment strategies for child health research. By **vulnerable**, we are referring to "a diminished ability to fully safeguard one's own

interests in the context of a specific research project. This may be caused by limited decision-making capacity or limited access to social goods, such as rights, opportunities and power. Individuals or groups may experience vulnerability to different degrees and at different times, depending on their circumstances."[1] Recall that a child's "vulnerable" status requires that researchers engage in more extensive discussions and consultations with potential participants and their decision makers (if the child is unable to independently provide informed consent).

Aside from mandatory additional consent, children are also vulnerable in other aspects:

- **Growth and Development:** Children are growing both physically and neurologically. A young child's daily experiences determine which brain connections develop and which will last for a lifetime.
- **Attraction to Rewards/Incentives:** Children may be more easily enticed to participate in research (e.g., the promise of extra screen time at home, or time away from school).
- **Desire to Please:** They may agree to participate in order to please someone (e.g., the investigator, a parent or family member, or a teacher), even when the results will be of limited benefit to them.
- **Naive to Long-Term Effects:** They may not understand the larger ramifications of taking part in research (e.g., their potential labeling as having a condition, or the inability to participate in something else at a later date as a result of participation now).

Understanding that children are a vulnerable population, you will learn about the different settings in which you may identify children as participants in research.

Identifying Participants in Clinical and Non-Clinical Settings

Clinical is defined as involving or relating to the direct medical treatment or testing of patients. Various settings can be used to identify potential participants in child health research, including both **clinical** and **non-clinical** settings.

Using your preexisting knowledge, complete the sorting activity by determining whether the settings are clinical (i.e., medical or laboratory) or non-clinical (i.e., community).

Choices: Healthcare provider offices, Emergency/Urgent Care Centres, Outpatient treatment centres, Hospital, Clinics, Camps, Childcare centres, Online surveys, Schools, Recreation centres, Daycares, Social media

Clinical Settings

- Healthcare provider offices
- Emergency/Urgent Care Centres
- Outpatient treatment centres
- Hospital
- Clinics

Non- Clinical Settings

- Camps

- Childcare centres
- Online surveys
- Schools
- Recreation centres
- Daycares
- Social media

Although there are a variety of settings researchers can use to potentially recruit participants for child health research, it is important to understand that recruitment differs between clinical and non-clinical settings. For instance, provincial privacy legislation impacts the differentiation between clinical (i.e., healthcare setting) and non-clinical (i.e., school) settings, as well as how the privacy of participants is protected.

Next, you will learn about child recruitment under federal and provincial/territorial legislation.

Federal and Provincial Legislation

Both federal and provincial/territorial legislation can impact researchers' access to children's personal information in several ways, including their medical records and contact information. Federal statutes, ethical conduct in research standards, and First Nations, Métis, and Inuit Initiatives (FNMI) considerations all speak to the importance of respect for all communities and their ways of being. FNMI considerations recognize the need for community engagement or consultation prior to approaching participants. You must have a strong understanding of your local provincial/territorial legislation, as well as of the specific jurisdictional rules that apply in each of the places your study will be conducted.

Provincial/Territorial Legislation: Consent to Screen and Contact

It is often the case that researchers wish to access clinical populations with whom they do not have an ongoing clinical relationship. Medical records can be used for screening of potential participants if a waiver of consent is granted by the Research Ethics Board (REB). This allows research-related staff to access the records and identify eligible participants. However, when using medical records researchers must adhere to provincial/territorial health information privacy legislation with respect to who can access medical records for screening, and, after identification, who can approach eligible participants or their families.

While it may be permissible to screen the clinic's records for eligible participants, provincial health privacy legislation and the REB govern who can make the first approach to the family.

Provincial/territorial privacy legislation is clear that patient contact information, which meets the definition of health information, cannot be passed on to a third party, (i.e., a researcher), without the expressed consent of the patient or their decision maker. If participants will be approached in person in the clinic, this must be done by someone who would normally have access to their clinical information. If the patient provides consent to be approached, then a research team member can approach to tell them more about the study. If the participant will be notified of the study by telephone or email, then the approach is done by someone in the circle of care or an intermediary, on behalf of the research team.

Permission to Contact (PTC) is an alternative process for initial research contact that is widely used in adult healthcare facilities and is gradually being adopted for children as well. If the institution's Research Ethics Board has approved a "Permission to Contact" procedure, then the health record of each patient will indicate whether or not there is permission for direct contact by a research team. Where PTC procedures are in place, the child/family is asked at every visit to the institution whether or not they consent to being contacted directly by a research team for studies that their healthcare provider deems relevant. If they provide permission, the research team can contact them directly without the initial involvement of someone in the circle of care until the next clinic visit or until permission to contact is revoked. The PTC procedure is designed to establish a research recruitment process that is independent of the clinical care team. Children with health conditions requiring on-going medical care and their decision makers often feel dependent on maintaining a good relationship with their healthcare providers, and may be hesitant to decline research participation when approached by a member of their healthcare team. The PTC procedure enables the research team to approach the decision makers in confidence so that the healthcare team is not aware of their decision makers decision.

You will learn more about approaching participants for recruitment in Section 02.

Continue to view information regarding Alberta's Provincial legislation: consent to screen and contact.

Consent to Screen and Contact: Alberta

In Alberta, a waiver of consent may be granted by the Research Ethics Board (REB) for screening potential participants. This allows research-related staff to access the records and identify eligible participants. However, provincial/territorial privacy legislation is clear that patient contact information, which meets the definition of health information, cannot be passed on to a third party, (i.e., a researcher, without the expressed consent of the patient or their representative). If participants will be approached in person in the clinic, this must be done by someone who would normally have access to their clinical information. If the patient provides consent to be approached, then the research assistant can approach to tell them more about the study. If the participant will be notified of the study by telephone or email, then the approach is done by someone in the circle of care or intermediary, on behalf of the research team. Permission to contact from within a circle of care is intended to mitigate coercion as it creates a 2 step process.

The same process is used in the majority of other provinces. A REB or equivalent is required to approve the waiver of consent for screening for each study (i.e., it is not automatic). Always check with your REB or Health Authority for what is acceptable locally.

Considerations for Yielding High-Quality Child Health Research

High-quality child health research relies on the recruitment of a study sample that is representative of the target population. Researchers need to carefully consider and plan for the impact of the recruitment setting and procedures and whether these allow for the equal recruitment of children from all income strata and who have diverse abilities. Cultural, ethnic, and gender diversity should also be considered.

Note: Just as it is important to consider who you are including in a study, it is important to consider who you may be inadvertently excluding by preventing them from engaging with your research due to unintended barriers pertaining to access, availability, and/or resources.

You have learned that jurisdictional privacy regulations must be considered when identifying potential participants in clinical and non-clinical settings.

Answer the question using the resources "A Guide to the Personal Health Information Protection Act" and "Manitoba Health: The Personal Health Information Act."

A Guide to the Personal Health Information Protection Act

Manitoba Health: The Personal Health Information Act

Question 1 of 1: Using the resources, reflect on your provincial/territorial privacy legislation.

Feedback:

Researchers must adhere to jurisdictional privacy legislation with respect to who can access medical records for screening, and, after identification, who can approach eligible participants or their decision makers.

Sampling Methods

Convenience sampling and random sampling are two of the most common methods that can be used when selecting the study sample. When using **convenience sampling**, the sample population is selected based on convenience and accessibility, meaning the researcher draws the sample from a part of the population close to hand. Alternatively, when using **random sampling**, every eligible member of the population has the same chance of being selected as part of the sample population.[2]

Continue to learn about the pros and cons of random sampling and convenience sampling.

RANDOM SAMPLING

Pros/Benefits:

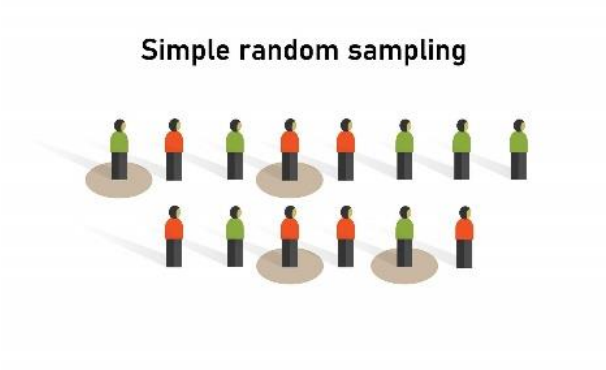
- Most likely to provide an unbiased and representative sample of the target population (reduces **sampling bias**) by providing each member of the population with the same chance of being approached to participate
- Strongest quality research design

Sampling bias occurs when some members of a population are systematically more likely to be selected in a sample than others. It is also called ascertainment bias in medical fields.

Cons/Risks:

- More time consuming to reach all randomly selected participants
- Can be difficult to identify the total population to be sampled
- May not capture groups that constitute a very small proportion of the general population
- Rarely represents all segments of a population equally (i.e., disadvantaged populations)
- May not fully represent marginalized ethnic minorities or economically disadvantaged populations

As seen in the image, individuals in the population have the same chance of being selected as part of the sample population.



Convenience Sampling

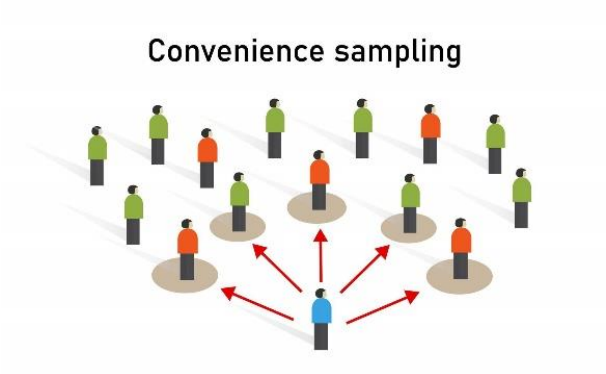
Pros/Benefits:

- Saves staff time to reach out to potential participants
- Inexpensive and quicker recruitment for meeting targets
- Ability to capture participants who have an interest in volunteering who may potentially be more motivated to follow through with activities

Cons/Risks:

- Increased risk of recruiting a biased sample (e.g., those who frequently attend, those with an inherent interest who volunteer)
- The degree of bias is often difficult or impossible to determine
- Research participants are more likely to be educated, middle class, and have higher social capital compared to non-participants

As seen in the image, convenience sampling selects a population of individuals based on convenience and accessibility.



Answer the question based on what you have learned about random sampling and convenience sampling.

Question 1 of 1: What method/s of sampling do you believe is/are **best** for child health research?

- Random sampling
- Convenience sampling
- Both random sampling and convenience sampling
- Neither random sampling nor convenience sampling

Feedback:

Correct Answer: Random sampling

Although convenience sampling is most commonly used, it is not the best option. Random sampling is the best option. Random sampling eliminates sample bias; it can be particularly challenging to implement in child health research because the recruitment settings, such as schools, child care centres, recreation programs, or hospitals, often create inherent biases. Stratified, cluster, and other more complex sampling techniques can be utilized to minimize the impact of these inherent biases. Because random sampling is often more complex, convenience sampling is a common approach used to identify participants for child health research even though it provides a lower quality of evidence. Whether it is the children who happen to be present in a school classroom or daycare facility on the day of the research assessment, the participants enrolled in a children's program, or the children who seek care at a hospital or clinic, child health research frequently relies on convenience sampling. While very "convenient", the important risks to research quality must be considered and addressed when using this approach to identifying participants.

A Closer Look at Sampling through Organizations

Particular care is required when planning recruitment through organizations such as hospitals, schools, or child care settings. While public schools are open to all children, the children attending each school will typically reflect a particular community (e.g., geographic, faith). Convenience sampling of children with medical conditions through the hospitals that provide their routine care will often create a biased sample as children with more significant medical problems are more likely to be selected simply

because they attend the hospital more frequently. Similarly, recruitment through child care settings or recreational programmes will also limit the study sample to specific sub-groups of the population.

Although convenience sampling in child health research typically creates a biased sample, if biases and potential risks are recognized and carefully considered in the analysis and interpretation of results, recruitment through these avenues can produce quality research.

Answer the reflective question using what you have learned about convenience sampling.

Question 1 of 1: How can a researcher minimize the biases and risks associated with convenience sampling?

Feedback:

To minimize the biases and risks associated with convenience sampling, researchers may:

- Track the demographics of the convenience sample compared to the target population
- Tailor the recruitment methods for each targeted subgroup
- Perform a sensitivity analysis of the key factors or sources of bias between those who are approached and those who are not approached
- Include mandatory variables that represent the potential sources of bias when performing the data analysis

In this section, you learned about the methods and settings used to identify potential participants for child health research. You began by understanding how children and adults are a vulnerable population in research. Next, you learned how to identify participants in clinical and non-clinical settings as well as recruitment under federal and provincial/territorial legislation. Considerations for yielding high-quality child health research were reviewed before introducing sampling methods for identifying potential participants. Next, you will learn about approaching participants for recruitment.

Page Links:

chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.ipc.on.ca/wp-content/uploads/Resources/hguide-e.pdf

https://www.gov.mb.ca/health/phia/trustees.html

SECTION 02: APPROACHING PARTICIPANTS FOR RECRUITMENT

In the previous section, you learned how potential participants can be identified in clinical and non-clinical settings considering provincial/territorial privacy regulations. After identifying potential participants, you must approach them. In this section, you will learn about direct and indirect recruitment strategies for approaching potential participants in child health research and the ethical considerations that apply. Keep in mind that the participants may be infants, children, or adolescents, as well as guardians, family members, or peers.

Direct Recruitment of Participants

Direct recruitment of participants is when the researcher directly connects with the participant, there is not a middle organization/individual involved with the recruitment process. It may be in-person or virtual. Examples of direct recruitment include social media, media advertisements, and/or approaching people at community locations, such as shopping areas, libraries, or recreational facilities.

When the target population is known (e.g., children with asthma, children in grade 4, children who attend overnight camp), personalized recruitment enables direct contact between the researcher and potential participant. Letters, emails, and telephone calls in addition to in-person contact are often used. When the target population cannot be specifically identified, recruitment for child health research often focuses on social or traditional media. The format of media used should reflect the desired target sample.

When recruiting, it is important to use the media platform that reflects the desired target sample. For example, guardians might be a frequent user of a social media platform that adolescents are unlikely to be found on, and vice versa.

Continue to learn about the advantages and disadvantages of personalized and media direct recruitment strategies.

Advantages to Personalized Direct Recruitment

The advantages of personalized direct recruitment strategies reflect how researchers are able to interact with potential participants directly. Personalized approaches enable the researcher to build rapport, tailor the study description to the participant's interests, and immediately respond to questions or concerns. Speaking directly with children enables the researcher to evaluate the consent/assent of the child, independent from that of the decision maker. Personalized recruitment strategies are effective when they are matched to the individual identities of potential participants.

Disadvantages to Personalized Direct Recruitment

The disadvantages of personalized direct recruitment strategies are that they typically require more staff time to arrange contact and complete discussions about the research.

Advantages to Media Direct Recruitment

The advantages of media direct recruitment strategies are that researcher time is minimized because study information is widely disseminated to potential participants.

Disadvantages to Media Direct Recruitment

The disadvantages of media direct recruitment strategies are that they typically have low rates of study enrollment relative to those approached, and researchers are unable to accurately characterize those who choose not to participate. Typically, it is expected that those who volunteer will not be a random sample, but rather reflect those with a personal interest or connection to the study topic. Assessing potential bias among those who respond to media recruitment strategies is particularly important.

Direct Recruitment through Social Media: Privacy and Confidentiality

Although methods of directly recruiting child health research participants often focus on social media, it may not always be possible or appropriate to target younger users of social media for recruitment in child health research. When recruiting on social media, it is especially important to think about the implications of privacy and confidentiality for the participant and researcher during the recruitment process.

Answer the reflective question in the space provided.

Question 1 of 1: You have been asked to use social media to directly recruit participants for an acne medication. What are some privacy and confidentiality implications to consider?

Feedback:

Social media often has commenting features. Individuals may comment on a recruitment posting on Facebook, or tag a friend or someone they think may be interested in participating in the study. Depending on the nature of the study, they could also tag someone with negative intentions (i.e., adolescents could tag someone they think might benefit from a study on acne, thereby bringing unwanted attention to another child). In this example, comments should be disabled and potential participants should be directed to contact the study team via direct message instead of publicly online.

Recruitment in private online spaces, such as a group page, chat room, or discussion board may also require specific permissions from the group or page moderators.

Design of Effective Direct Recruitment Materials

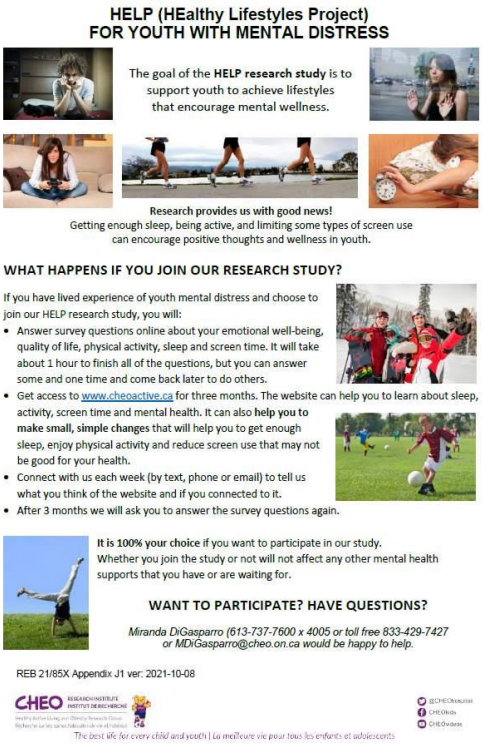
The design and content of recruitment materials are critically important because they create the initial impression of the research study among potential participants. Materials need to be interesting and eye-catching, while accurately conveying study information. Recruitment materials can include study information letters/emails, posters/flyers, social media posts, audio clips, and videos. To enhance the effectiveness of recruitment materials, it is recommended that researchers seek input from members of the target population. Ask children and decision makers what they think of materials targeting younger children. Adolescents should be consulted when developing materials that target that age group.

The tabs illustrate how a recruitment poster was changed in response to input from youth with lived experience of mental distress. The original poster (Tab 1) was developed by the research team. When youth with lived experience were consulted, most aspects of the poster were changed (Tab 2). The colour scheme was revised, messages were clarified and shortened, facts about why the research was being done were added, and the unique perspectives sought from youth were emphasized (i.e., their expertise to contribute).

Continue to view how a poster recruiting participants was adapted by youth with lived experience of mental distress.

ORIGINAL POSTER

The original poster for HELP (HEalthy Lifestyles Project) for Youth with Mental Distress shows several photographs of active individuals and a description of what participants will be required to do.



YOUTH EDITED POSTER

The altered poster for HELP (HEalthy Lifestyles Project) for Youth with Mental Distress shows some photographs of active individuals have been replaced with visually-appealing coloured blocks. Added information includes the age range of the participants as well as additional information about getting started with lifestyle changes.

Community Engagement With Indigenous Peoples

Historically Indigenous peoples and communities have not benefited from research, in fact quite the opposite. Indigenous people have the right to self-determination and autonomy; however, this has not always been the case and atrocities have been committed against them during the course of research.[3]

For example, the nutritional studies done on Indigenous children in residential schools without decision maker consent and the severe negative consequences of malnutrition being well known and documented.[4] Indigenous children died and yet these experiments continued. Recall that all children are considered vulnerable, but when children are also a member of a marginalized ethnic population such as First Nations, Inuit, and Métis peoples, this adds an additional layer of vulnerability. Due to these experiences, it is not surprising that these communities have a deep distrust of research that is conducted about them from researchers outside of their community instead of in collaboration with them.

Continue to access an article discussing Canada's shameful history of nutrition research on residential school children.

Canada's Shameful History Of Nutrition Research On Residential School Children

'Nothing about us without us' is an important phrase that researchers should remember when conducting research with Indigenous communities or any equity deserving group.

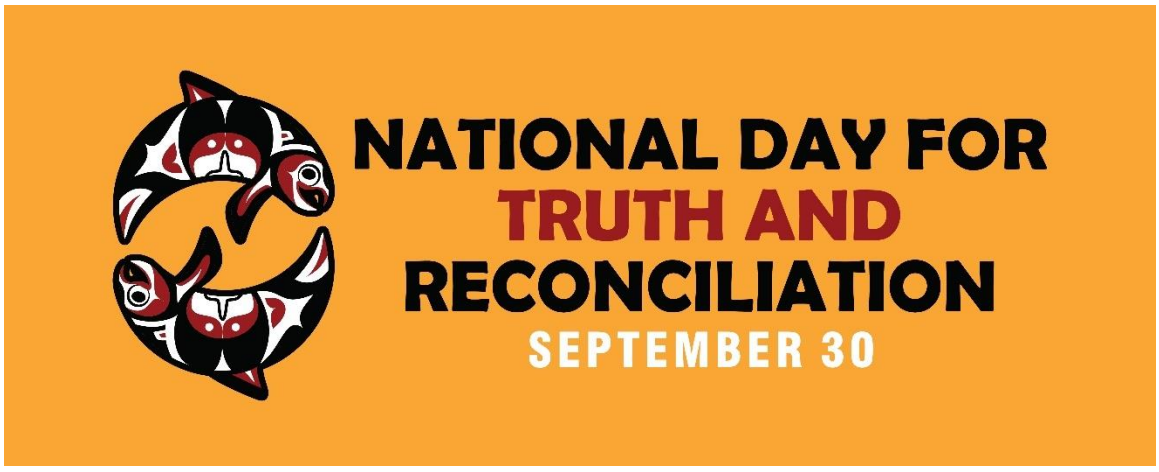
The TCPS 2 (2022) has an entire chapter that provides a framework for research with Indigenous communities.[5] Community engagement is highlighted in this chapter and is the first step a researcher should take when wishing to conduct research with First Nations, Inuit, and Métis peoples, even before starting the recruitment process.

TCPS 2 (2022) Article 9.1

As stated in article 9.1 of the TCPS 2 (2022) document, "Where the research is likely to affect the welfare of an Indigenous community, or communities, to which prospective participants belong, researchers shall seek engagement with the relevant community. The conditions under which engagement is required include, but are not limited to:

- a. Research conducted on First Nations, Inuit or Métis lands;
- b. Recruitment criteria that include Indigenous identity as a factor for the entire study or for a subgroup in the study;
- c. Research that seeks input from participants regarding a community's cultural heritage, artifacts, traditional knowledge or unique characteristics;
- d. Research in which Indigenous identity or membership in an Indigenous community is used as a variable for the purpose of analysis of the research data; and
- e. Interpretation of research results that will refer to Indigenous communities, peoples, language, history or culture."[5]

The aim of community engagement is not to be a checkbox for the ethics application to the research ethics board (REB) but to create meaningful and mutually beneficial relationships.



Some of the aims of community engagement are to create collaboration between the community and the researchers, for example ensuring the research reaches a standard that is acceptable to the community.

Community engagement not only allows for a collaborative research relationship but also an interpersonal relationship between the researcher and the community, allowing for an inclusive exchange of ideas.

Another goal of community engagement is data management and ownership for the lifecycle of the data.[6] A positive outcome of community engagement is for communities to have access to the data to use at their discretion, for example to inform decision making about future healthcare.

Research in Indigenous children is important for so many reasons, community engagement will enhance the research process and create a collective desire to improve the lives of indigenous children through research.

For example, it is believed that many Indigenous children suffer with pain that seemingly goes untreated due to the lack of receiving proper health care, as well as the lack of knowledge of clinicians to be able to treat and properly assess pain in a culturally applicable manner.[7] Without this knowledge and research, Indigenous children would have continued to not have adequate pain management, ultimately resulting in poorer health outcomes.

Community engagement can take many different forms and should be driven by collaboration between the community and the researcher. TCPS 2 (2022) provides guidance on this.

TCPS 2 (2022) Article 9.2

The nature and extent of community engagement in a project shall be determined jointly by the researcher and the relevant community and shall be appropriate to community characteristics and the nature of the research.

Of note, TCPS is "offered in a spirit of respect. It is not intended to override or replace ethical guidance offered by Indigenous peoples themselves". [5]

Each community will be different, there is no one size fits all approach. Many communities have their own protocols and processes already established for meaningful community engagement that seek to go further than initial approval to conduct research. Indigenous ethics boards, established frameworks and protocols exist across the country, researchers must be diligent in ensuring they involve the appropriate body as well as recognizing that other bodies may also be appropriate to include.

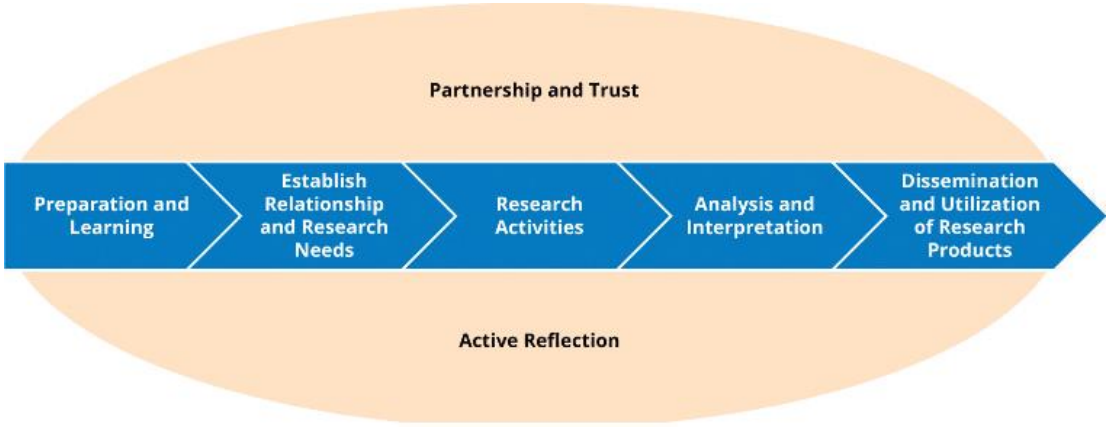
View a summary of Indigenous ethics boards, frameworks, and protocols located in Table 1 of the research article.

A New Era of Indigenous Research: Community-based Indigenous Research Ethics Protocols in Canada

Submission of an ethics application, a community engagement plan can serve as a good way to describe the activities that will occur as part of community engagement.

When undertaking research with community engagement, the theme of "partnership and trust" should be at the heart of the collaboration.[8] Indigenous peoples approach life from a different perspective compared to westernized viewpoints. Using a different lens to make sense of the world around them, this can be a challenge for researchers external to the community. This has been encapsulated in the "two-eyed seeing" framework.[9] Researchers can embark on a journey of self-reflection throughout the research to help them gain more of an appreciation of different perceptions and worldviews of Indigenous peoples.[8] Using the "two-eyed seeing" framework and self reflection can aid in the

engagement process and moving away from a historical research context where indigenous peoples were used as passive knowledge givers.



An example of how partnership and trust with active reflection can flow through the life of the research project.[8]

Community engagement for research should not encompass the research project only. Instead researchers should make efforts to become involved in other aspects of the community. This is reflective of the welcoming spirit that communities often foster when researchers start to build relationships as part of the engagement process.

The Role of Perception on Direct Recruitment

Regardless of the direct recruitment strategy used, researchers need to carefully consider the impact of who is doing the recruiting and how that person will be perceived by potential participants. Considerations might include:

- Does the researcher appear older or younger?
- Will the researcher be viewed as gender or culturally diverse?
- Will potential participants view the researcher as approachable and relatable?

When using direct recruitment strategies, decision makers may be more comfortable communicating with a researcher who appears older or more experienced, while adolescents may react more positively to a younger researcher, such as a graduate student. Researchers who wish to target populations that are often not represented in research (e.g., lower-income families, gender-diverse individuals) should be particularly careful with recruitment materials, researcher presentation, graphics, etc. when designing and using recruitment strategies. Consider who and how potential participants will be approached because direct recruitment does not allow the researcher to be represented through an organization or the study materials.

Indirect Recruitment of Participants

Indirect recruitment involves recruiting participants through recruitment agencies, preexisting organizations, and other indirect methods. Rather than the researcher contacting potential participants directly, information about the research study is disseminated by organizations, such as

recreation facilities, schools, or child care centres. Indirect recruitment methods are typically used when a sample reflective of the general population is required. However, recruitment can also occur through other condition-specific (e.g., Muscular Dystrophy Canada), interest-specific (e.g., soccer or hockey club), or child-specific (e.g., Boys and Girls Clubs) organizations.

Preparing for Research with an Organization

Regardless of the approach, it is important that researchers carefully consider the "research readiness" of the organization. Some organizations, such as hospitals and most schools, will have extensive experience with recruiting for and conducting research. However, the experience of other organizations can be highly variable. In addition to ensuring that the organization is "research ready", researchers must also ensure that both the research team and the organization adhere to the highest ethical and scientific principles of child health research. Researchers must be prepared to complete scientific and ethics reviews required by the organization (e.g, a School Board), in addition to the requirements of the researcher's own institution.

Note: Due to the increased vulnerability of children, the review of a proposed child health research project by a scientific review process or REB will necessarily be more extensive, requiring more detailed information about not only the research activities, but how those activities will be implemented. Specific methods will be evaluated not only in terms of the data provided but also by the impact of the proposed method on the child and family. Ethics reviews will also often require additional information or discussions prior to enrollment, during participation, and after study completion, beyond what would be expected for research with adults.

Tips for Successful Research Partnerships with Organizations

You have learned that "research readiness" of organizations may vary.

Continue to view three tips to consider when indirectly recruiting participants through an organization with limited research experience.

Tip 1: Include the Organization in Scientific and Ethics Reviews

It May be appropriate for the researcher to include the organization within the scientific and ethics reviews at the researcher's own institution.

Tip 2: Assign an Organization Member as a Co-investigator

Having someone from the organization as a co-investigator on the research project can be helpful on developing and maintaining an active and engaged partnership.

Tip 3: Mandate Organization Training

Requiring the organization to complete at least an introductory level of research ethics training is also recommended.

The Importance of Interaction: Examples of Negative Experiences in Research

Positive interactions between the members of the organization and the research team are imperative for successful research.

Continue to learn of two negative interactions between the members of an organization and the research team.

Teacher

"The children in our clinic are a special population so we get a lot of requests from researchers to approach patients during their clinic visit. We are very happy to collaborate with researchers who know that the clinic visit is top priority and we will try to fit the research in when we can. However, some researchers seem to think that the clinic is there to provide them with study participants. Rather than working within the clinic routine, they demand space and time to do all of the research assessments with seemingly little thought to the health needs of the child. One day, our clinic work finished 2.5 hours later than scheduled because of the disruption caused by researchers who were approaching participants when they arrived for their clinic visit. It was extremely frustrating and seemed that the researchers did not respect the needs of the family or clinic staff."

Nurse

"The research team explained the study and said that my students simply needed to complete a short, online questionnaire that would take about ten minutes. However, the survey had links that made it difficult for students to answer all of the questions independently and the research team spent 30 minutes talking to the students about their research before even providing the survey link. All-in-all the research took all morning and I probably wouldn't have agreed if I had known the real time required and disruption it would cause."

You have learned about the correlation between preparation and successful research outcomes.

Answer the question using your knowledge on child health research.

Question 1 of 1: What are some ethical and logistical considerations you should remember when approaching patients in settings of interest such as hospitals and schools?

Feedback:

In hospitals, approaching patients will require the cooperation of healthcare personnel, as well as administrative and other staff. In schools, the cooperation of the principal and teachers is required, and similar collaborations are required at other institutions. Researchers have an obligation not only to conduct research using the highest ethical standards, but to do it in such a way as to avoid negative impacts on the primary services of the organization as well as on future research recruitment opportunities. Following proper recruitment etiquette can help to ensure these goals are met.

Recruitment Etiquette

Following appropriate etiquette during the recruitment process will help build on the principles of concern for welfare, justice, and respect for persons. Practical etiquette considerations include:

- Sensitive demeanor,
- Astute observation,
- Cultural and ethnic awareness,
- Consideration of the research and recruitment environment,
- A polite manner in approach,
- Ensure staff have been introduced to the research team and preferred methods of communication are established,
- Provide researcher contact information to everyone who is approached.

Researchers need to have proper and ongoing recruitment training, as well as advanced and continuous communication with the staff of the recruitment setting. Specifically, staff should be aware of how the recruitment strategies and processes may affect their workplace.

Learn more about considerations in research recruitment etiquette.

Practical Considerations for Implementing Research Recruitment Etiquette

Next, you will learn about recruitment etiquette methods in:

- Hospitals and healthcare organizations,
- Schools,
- Children's organizations, and
- Community organizations

Tip: Always contact the hospital/healthcare research department, school, and/or organization for specific protocols and etiquette to ensure proper recruitment procedures are followed.

Recruitment Etiquette in Hospitals and Healthcare Organizations

When approaching participants for recruitment through hospitals and/or healthcare organizations, there are several steps researchers should take to follow proper etiquette.

Continue to learn about the steps researchers should take when approaching participants in hospitals and healthcare organizations.

Consideration of the Research Environment: Initial Approval

Prior to recruiting in a healthcare facility, researchers need to be sure to have applied to the organization for access so that they can assess the impact at the healthcare facility. This often includes providing an overview of the recruitment plan. Having a conversation with the head administrator of the site in advance of the application will also provide some guidance for developing a preliminary plan of approach.

Consideration of the Research Environment: Collaboration and Communication

Once operational approval is obtained, ask all staff (doctors, nurses, administrative personnel, technicians) for their input on the best way to incorporate the research approach so that it does not

impact the delivery of health services (consideration of the research environment). Explain the research study and requirements for approaching patients to all staff in the clinic or health service.

Once a plan for approaching participants has been developed, review it with all clinic staff for additional input or suggestions. Connect regularly with clinic staff throughout the time that the research team is present to confirm that the research activities are not negatively impacting care.

Sensitive Demeanor: Comply with Applicable Legislations and Policies

Applicable legislation and policies may have requirements on how patients or their families can be approached for recruitment. Ensure compliance with all applicable health information protection legislation and policies.

Sensitive Demeanor: Be Mindful of the Context

While an initial diagnosis is still recent or new, decision makers and/or children may not be emotionally ready to be approached about research participation. It is important to be mindful of the prospective participants' circumstances while they are at the hospital and/or health organization.

Sensitive Demeanor: Ensure Understanding of Clinical Care versus Research

Participants and their decision makers should clearly understand the separation of clinical services and the research activity and the differences between how each of these may impact their care.

Research staff should be explaining the research study, and clinical staff should be explaining the clinical treatment, ensuring that there is as little overlap as possible. This should also be specified in the consent and assent materials. In some cases, the research activity is a direct part of participants' clinical care, in this case, this integration should be made very clear. Participants should be approached after receipt of clinical services to ensure that there is no undue influence or confusion between clinical and research activities.

Manner in Approach: Use Visual Aids

Consider the use of visual aids to enhance the recruitment process. Visual aids can inform patients about the presence of research, provide access to a contact number if they wish, and remind clinical staff of the presence of researchers. Examples of visual aids that can be used in hospitals and/or health organizations include study posters, television screen advertisements, and a visible sign and/or placard for clinical staff on days when research staff are actively recruiting.

Be Flexible

Be flexible to change the plan or approach if clinical considerations suddenly require adaptations or a different strategy. Note that the REB must approve all recruitment strategies before they are implemented.

Recruitment Etiquette in Schools

When approaching participants for recruitment through schools, there are several actions researchers should take to follow proper etiquette.

Learn about actions researchers should take when approaching participants in schools.

Meet with the Principal

Meet with the principal (and vice-principal(s) if possible) to explain the purpose of the study, learn about the organizing and movement of students within the school, and ensure that all required approvals are in place.

Meet with Teachers

To understand their scheduling and student learning practices, meet with teachers whose students will be approached.

Develop a Strategy

Develop a proposed strategy for approaching students and discuss it with the teachers and school administration, listening to their feedback and concerns, and adjusting the plan as needed to create a collaborative, agreed-upon plan.

Introduce Research Team

Ask someone familiar to the children (e.g., teacher) to introduce the research team.

Explain the Research

Explain the research study to all children in the same class, and allow them to ask questions about the research, even if only some children will be approached to participate.

Note: In most school settings, decision maker consent will be required prior to approaching children.

Recruitment Etiquette in Children's Organizations

These settings typically include recreation facilities, camps, and formed children's organizations. When approaching participants for recruitment through children's organizations, there are several steps researchers should take to follow proper etiquette:

- Meet with all teachers, leaders, and/or administrators to explain the study purpose and activities and learn about the organizing and movement of children within the facility and programmes.
- Collaboratively develop plans to share study information with the decision makers of all children, including those who will not be approached to participate and those who decline study participation.
- Provide opportunities for decision makers to ask questions and to clarify how their children may be involved even if they have not consented (e.g., some children may be in the background of recordings; or may be asked to do the research tasks with their regular group).
- Use developmentally appropriate materials and explanations to help children understand the research study and view it in a positive light (e.g., it might help other children; what you tell us is important to us; you don't have to do anything you don't want to).

Recruitment Etiquette in Community Organizations

Children's organizations have an 'active child care/teaching' component, while community organizations are a more passive involvement with the child.

When approaching participants for recruitment through community organizations, there are several actions researchers should take to follow proper etiquette:

- **Determine the Best Approach:** Work collaboratively with program managers to determine whether the approach for research is best arranged using direct or indirect methods.
- **Learn Pre-existing Organization Frameworks and Opportunities:** Learn from the organization about the opportunities that can be provided to approach potential research participants and work within the available framework so that the research activities do not engender onerous additional demands.
- **Disseminate Material:** Have the organization specify exactly what materials will be disseminated through their newsletter, social media, etc. so that the research team can provide camera/computer-ready materials that can be used immediately with little time or effort from organization staff.

- **Develop a Plan:** If the approach for research will occur at one of the organization's programs or events, work with organization staff to collaboratively design and implement a plan that does not negatively impact on program/event participation.

Answer the question using what you have learned about approaching participants for recruitment in different settings.

Question 1 of 1: What considerations should be made when approaching participants for recruitment? *Select all that apply.*

- Recruitment setting
- Recruitment material
- Mode of recruitment
- Fixed approach

Correct Answers: Recruitment setting, Recruitment material and Mode of recruitment

Whether you are recruiting through schools, community or condition-specific organizations, it is important to be research ready and understand the different styles and processes suited to different contexts. It is also important to be aware of the ethical considerations of different modalities of recruitment (e.g., agencies that do recruitment, online recruitment, recruitment through social media). Don't forget to consider accessibility and methods of sharing recruitment materials. Finally, tailoring your approach to participants' capacity to comprehend and assent/consent to the study is a vital ethical consideration.

Pediatric Recruitment: What Works and What Does Not Work

Building Rapport with Children: Assent

Building rapport with children as well as their decision makers is critically important. Having a decision maker consent for research participation has no value if the child is not a willing participant in the research activities. At the very least, the researcher should receive consent from the decision maker (or from the mature minor), and receive agreement from the child (assent). Both are key parts of ethical recruitment.

Assent to participate is critical, regardless of the child's age or stage of development. Even infants can negate the purpose of the research assessment if they are fearful or uncooperative. Even though a fearful child may perform requested tasks, the researcher cannot ascertain whether the child's involvement during the research study is truly representative, unless the child is engaging freely and without reservation. Building rapport with the child begins with the first contact with the child or decision maker and should continue throughout all research interactions. Consent and Assent will be explored in more detail in Section 03 of this module.

For more information on Assent, view the CHEER Consent and Assent Module.

Initiating Conversation with Children

Researchers should become experts in the lives of children at the same age and developmental stage as their study participants. To get to know the child better, talk to the child directly and ask them questions to initiate and facilitate further conversations. Ask the child:

1. What do you like to do?
2. What do you know about research?
3. What other experiences or places do you know that are similar to what will happen during the research study (e.g., sleeping at a friend's house instead of at home if the study involves an overnight stay in a sleep lab)?
4. Do you have any questions?
5. Do you want to participate?

Initiate the conversation by asking questions about the child's favourite imaginary characters, what they like to do with their friends and/or family, or what games they like to play. Being able to respond to these interests with familiarity will quickly help to develop rapport. Asking the child what they think about the most popular characters or shows for children their age, or other characters that are familiar and of interest to the child, will more likely elicit an engaging response. By comparison, asking broad questions, such as what books they like to read, will often be met by silence from a shy or fearful child. Researchers are also encouraged to bring developmentally appropriate play into the research discussion.

Tip: When talking to young children about research, it is often helpful to provide the child with a choice of pictures to colour during the conversation. Allow the child to choose their preferred picture, and then build information about the research study into the conversation about the picture they are working on. Colouring with a child can also be an important icebreaker even while you are talking to the child's decision makers.

Building Rapport with Childrens' Decision Makers

Building rapport with the child's guardian(s) is equally important. Adults are naturally very cautious and protective of the children in their care. They will be thinking carefully about the child's experience during research participation, as well as the potential ramifications of that experience for other areas of their life.

Continue to view questions that are often top of mind.

"What will my child think of this experience?"

"Will my child experience pain or other negative stimuli or experiences?"

"If they have a negative experience will they "blame" me, our family, or other people who are important in their lives (e.g., doctors)?"

"Will my child miss school or will the study impact their learning?"

"Will this experience impact my child's willingness to interact with others in unfamiliar settings?"

Challenges of Building Rapport with Decision Makers

Building rapport with the child's decision maker(s) can be particularly challenging when research is conducted in school, child care, or other settings where decision makers are not always physically present. Researchers should carefully consider not only what information is conveyed to decision makers via these settings, but also the format and presentation of the information. Sending decision makers a lengthy, formal research consent form to sign is an approach that is often used, but one that should be discouraged as the initial contact with decision makers. Building rapport remotely takes time and multiple contacts.

Continue to learn steps to take when building rapport with the child's decision maker(s).

Building Rapport with Childrens' Decision Maker(s)

Although it can be challenging, building rapport with the child's decision maker(s) is essential for child health research. There are several steps that should be taken to help develop rapport with the child's decision maker(s).

Step 1:

Build Interest in Research

When possible, build interest for the research study among the children that you would like to enroll. Meet the children in their class, child care centre, or other program space. Explain the study activities and explain what it means to participate. Having children tell their decision makers about the great time they had meeting the researcher and share information about the project is a way to help build rapport with decision makers.

Step 2:

Provide an Infographic

Initially, provide an infographic or short graphical summary about the study purpose, what participants will be required to do, that participation is voluntary, and contact details for additional information.

Step 3:

Host Times for Discussion and Questions

Host times for answering questions or discussing the study in more detail. Provide information about a virtual and/or in-person meeting time in the initial study package. In some settings, you can make yourself available during child pick up and drop off times. However, recognize that at these times, adults will often be in a hurry and unable to chat. Planning to be present for pick up and drop off every day of the week allows decision makers to engage at a time suitable to them.

Step 4:

Provide Consent Form

Recall that sending decision makers a lengthy, formal research consent form to sign is an approach that is often used, but one that should be discouraged as the initial contact with decision makers.

Provide a concise study consent form after decision makers have had sufficient time (one to two weeks) to consider the initial information you provided and to follow up with questions.

Building Rapport with Decision Maker(s)

Providing the child's decision maker(s) with an infographic about the research, hosting times for discussions and/or questions, allowing sufficient time to review the consent form, and getting the children interested in the research, are all ways to help build rapport with decision maker(s).

In this section, you learned about approaching potential participants in child health research, specifically direct and indirect recruitment and the ethical considerations that apply. Recruitment etiquette methods in various settings including hospitals and healthcare organizations, schools, children's organizations, and community organizations were presented before concluding with the importance of building rapport. Next, you will learn about incentives and undue influence.

Page Links:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3941673/

https://journals-sagepub-com.proxy.queensu.ca/doi/10.1177/15562646211023705

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4324645/

https://www.socra.org/blog/pediatric-recruitment-what-works-and-what-does-not-work/

SECTION 03: INCENTIVES AND UNDUE INFLUENCE

In this section, you will learn about how to ethically encourage participation in research. First, you will be provided with an overview of incentives and undue influence in general, followed by specific considerations for children, adolescents, and decision makers. Second, you will learn about encouraging participation in community settings versus treatment settings, followed by additional considerations for using incentives appropriately. Finally, you will learn about the ethical considerations for obtaining consent/assent.

Incentives/Compensation

Incentives are designed to encourage research participation. Incentives can include anything offered to participants, monetary or otherwise, to entice and encourage them to participate in research. This is distinct from **compensation**, which is reimbursing participants for expenses they incur by participating in the research (e.g., transportation costs, parking) which is not problematic from an ethical perspective. It should not be assumed that people must be compensated to participate in research studies. However, compensation can improve participation rates particularly if the research requires multiple visits, travel, or a significant time commitment.

Unequal Incentives/Compensation

Incentives should be provided fairly to all participants, with equal payment for equal participation being the norm; however, unequal payment can arise in several ways.

Continue to learn about the ways unequal compensation can arise.

DESIGN

A study design may require a greater time commitment or more effort from some participants than others who may be compensated accordingly.

CUSTOMS

Customs may dictate a differing level of compensation (e.g., First Nations may have a different compensation model).

COMPLETION

Unequal compensation can arise when compensation is tied to participation (e.g., when incentives are tied to completion of study visits.)

CHANCE

Participants may perform slightly different tasks (by chance, or random assignment into different experimental conditions). Although every participant has an equal expected compensation before the study begins, they may not once they are assigned to an experimental group, and sizable differences in payment among participants arise which are not under their control. This chance element should be explained to participants as part of the informed consent process.

It is important to consider whether the incentive or compensation offered to participants is ethical to offer or not.

Complete the sorting activity by determining whether the incentive to participate is likely ethical or unethical to offer to the participant.

Choices: Volunteer hours, Offer compensation of an hourly wage commensurate with the expertise contributed, Reimbursement of time, Reimbursement of costs, Promises of getting out of school or other "make a wish" scale incentives, High-value gift for a short involvement (e.g., an iPad), Improved treatment efficacy, $500 gift card for an hour's participation

Likely Ethical to Offer

- Volunteer hours
- Offer compensation of an hourly wage commensurate with the expertise contributed
- Reimbursement of time
- Reimbursement of costs

Likely Unethical to Offer

- Promises of getting out of school or other "make a wish" scale incentives
- High-value gift for a short involvement (e.g., an iPad)
- Improved treatment efficacy
- $500 gift card for an hour's participation

Next, you will learn about the complexities of undue influence and the use of incentives in two sub-groups:

- Children and Adolescents
- Decision Makers

Incentives and Undue Influence: Children and Adolescents

Perhaps more than any other group of research participants, children and adolescents present the most complexities when thinking about undue influence and the use of incentives. It is important that you consider whether the individuals you are wishing to study truly understand the risks and benefits associated with participation.

Many of the decisions in the lives of children and adolescents are essentially made by the adults around them. For this reason, it is important to consider that children and adolescents may:

- Feel they need to participate in something because their decision makers or teachers will be disappointed if they do not.
- Think they have no other option but to participate, even if they are feeling apprehensive or uneasy.
- Think that participating shows they are "grown up" and capable of making scary or difficult decisions.

Note: None of these are good reasons to participate in research.

Adolescents may have an entirely different set of enticements that might motivate them to participate in research, including having time away from school or other obligations. While there is nothing necessarily wrong with this, they should be made to understand any potential risks or drawbacks that come with taking part. At the very least, adolescents should be asked to sign consent or assent forms, indicating that they understand the risks and benefits of participation.

For more information on Assent, view the CHEER Consent and Assent Module.

Incentives and Undue Influence: Decision Makers

Incentives are not limited to the child or adolescent themselves, but may extend to their parents or decision makers. For example, the decision makers of a sick child may have the impression that while participation is "voluntary", agreeing to take part in a research study may give them greater access to medical resources or a higher level of care. Their agreement to participate in that case clearly cannot be described as voluntary in the truest sense of the word.

Decision makers should not receive incentives for arranging the individual they represent to be involved in research. However, they may accept reasonable incentives or compensation on behalf of that individual, as long as these are suitable to the circumstances.[10]

Continue to learn about where compensation should be directed.

Research Focus: Children

When children are the focus of the research, compensation should be directed towards the child but also recognize the contribution of decision makers to the child's participation.

Research Focus: Children and Decision Maker

When decision makers also contribute data to the study in addition to the child, it may be more appropriate to compensate each separately.

Sometimes the family unit as a whole is compensated (i.e., grocery gift cards that can be used by the whole family). However, it's important to consider how this may impact the child's voluntariness. They may feel they have to continue participation so that their family can benefit.

You have learned about incentives and undue influence regarding children, adolescents, and decision makers. Next, you will learn about issues to consider when recruiting for treatment studies.

Incentives and Undue Influence: Treatment Studies

There are issues to consider when recruiting for qualitative research versus clinical research or treatment studies. Vulnerable populations in particular may be pinning their hopes on clinical treatment studies, and may be more willing to engage in research that could potentially help them.

It is important for the researcher to recognize that treatment studies, in particular, may be viewed through this lens, and so extra care must be taken to ensure that participants clearly understand all of

the risks and benefits of participation. Sometimes this means that a particular study may be unlikely to help them directly, but may help the next cohort of children and adolescents receiving treatment. There is nothing wrong with this necessarily, but it must be made explicit and detailed in the consent/assent forms. On the other hand, if there is some chance that the participant will benefit, the likelihood and magnitude of the benefit should be made clear so that the individual is not induced with false hope.

Even potentially innocuous variables, such as the research setting, should be considered. For instance, receiving information about a study from clinical team members wearing lab coats in a hospital or university setting can carry implied promises ("it's better to be in the study") or threats ("we won't look kindly upon those who say no").

Using Incentives Appropriately

When considering the possibility of undue influence in research involving financial or other incentives, researchers and REBs should be sensitive to issues, such as the economic circumstances of those in the pool of prospective participants, the age and decision-making capacity of participants, the customs and practices of the community, and the magnitude and probability of harms.[10]

The onus is on the researcher to justify to the REB the use of a particular model and the level of incentives.[10]

All this being said, there are several ways to use incentives appropriately. This involves:

- Informing the parent or decision maker that taking part in the study will not influence the services to which their child has access.
- Designing incentives to reflect compensation for the time and effort of participating in the research rather than to encourage participation.
- Ensuring that all participants have access to the same incentives and that control group participants have access to intervention benefits after their study participation has been completed.

Answer the true/false question using your knowledge from Section 02: Approaching Participants for Recruitment.

Question 1 of 1: In general, researchers without a clinical relationship should directly approach the potential participants.

- True
- False

Feedback:

False

In general, researchers without a clinical relationship should not directly approach the potential participants. The clinician should introduce and/or inform the family that there is a study and they can be referred to the study team for more information or provision of consent.

Consent and Assent

Free and informed consent, or assent in the case of children unable to consent for themselves, is the cornerstone of the ethical conduct of research. Because children are continually developing physically, emotionally, and cognitively, researchers are encouraged to determine the capacity of the child or decision maker(s) to understand the foundational principles of informed consent for research at the time of study enrollment and participation. The child or decision maker(s) should understand what the participant will be required to do, and that participation is voluntary and confidential, and should be aware of any potential future implications of research participation. In the same way, the approach to potential research participants should be tailored to the child and decision makers ability to understand study information.

Historically, research institutions often set rules regarding the age of children who were able to consent to research participation. No matter what age was designated, researchers would always encounter a younger child who was more able to provide consent than many older children or an older child who could not understand the implications of research participation. Therefore, current practice is to determine consent by the ability to understand the implications of participating in research and what is required for participation (refer to Mature Minor content). Children unable to provide consent can give their assent to research participation if consent is provided by an adult responsible for their care. Most often, it is the child's legal decision makers who can provide consent which may or may not be a parent (see "Children in Care" tab). Researchers should check with the organizations involved in recruitment and research to determine whether there are additional criteria (e.g., specific age limits) that need to be applied.

Continue to learn about special conditions of consent as defined for "mature minors" and "children in care".

MATURE MINOR

A mature minor is a child who has the demonstrated capacity to act on their own behalf. They are generally understood to be a child who meets specific requirements demonstrating their emotional and cognitive maturity. Who is able to determine capacity for a potential participant (or decision maker), will depend on multiple factors such as the type of study, the risk level, who is involved, how the study is being conducted and potential legal, and regulatory factors. A capacity assessment may be completed by a range of persons – physician, clinician, professional practitioner (e.g., nurse, psychologist, physiotherapist), principal investigator, research coordinator or assistant, etc. The process will be reviewed and approved by the research ethics board who will consider the factors outlined above to come to a mutually agreeable and ethical approach.

Note: The exact definition of a mature minor varies from jurisdiction to jurisdiction; please investigate the definition relevant to your practice and context.

CHILDREN CARE

Children in care are those for whom an appointed person or organization is legally allowed to consent on their behalf. Children living in institutions or for whom the government is responsible will have a care worker appointed to act on their behalf. If a child in care is able to provide informed consent, they participate in research as a mature minor. If they are unable to provide informed consent, the

appointed decision maker must consent on their behalf and the child must agree to study participation (assent).

Participants' Decision-Making Capacity

In most cases, where the child or youth is under the age of majority, parents or decision makers should be approached about the research prior to involving the minor. Alternatively, they can be approached together as a family. However, there are some instances in which the child could be approached individually, such as when the child has demonstrated **decision-making capacity** and when the research is of minimal risk.

Decision-making capacity is defined as:

"The ability of prospective or actual participants to understand relevant information presented about a research project and to appreciate the potential consequences of their decision to participate or not participate. This ability may vary according to the complexity of the choice being made, the circumstances surrounding the decision, or the point in time at which consent is sought. Assessing decision-making capacity is a question of determining, at a particular point in time, whether a participant (or prospective participant) sufficiently understands the nature of a particular research project, and the risks, consequences, and potential benefits associated with it."

Tri-Council Policy Statement (TCPS 2 (2022))

The determination of capacity should be made by someone who is trained. Someone with intimate knowledge of the child would be a conflict of interest. Capacity may also vary by province, but in general, youth aged 14 years and up may have demonstrated capacity and this should be respected. Where the research is of greater risk, it may not be possible for the child to understand the magnitude of that risk.

"In keeping with the principle of Justice, those who lack the capacity to decide on their own behalf must neither be unfairly excluded from the potential benefits of research participation, nor may their lack of decision-making capacity be used to inappropriately include them in research. REBs and researchers should be aware of these ethical considerations and seek to find a balance between them for the benefit of prospective participants who lack decision-making capacity."

Tri-Council Policy Statement (TCPS 2 (2022))

The following scenario will explore the ways in which researchers can tailor their language to best fit the needs of children when conducting child health research.

Proceed through the scenario block, selecting the best response when conversing about assent with children involved in child health research.

Having a Conversation about Consent

You are conversing with a potential child participant, requesting their assent to participate in a child health research study.

"What is going to happen?"

1. We will have you complete a standardized questionnaire.
2. We will ask you some questions.

Correct Answer: 2) We will ask you some questions.

It is important to use clear, simple language when speaking with a participant.

What is this study about?

1. We will play games, like the ones you play in gym class.
2. We will evaluate your motor skills relative to peers.

Correct Answer: 1) We will play games, like the ones you play in gym class.

Use familiar anecdotes to help the child understand the research study they are participating in.

Can I decide if I want to participate or not?

1. You can join the research or decide you don't want to. No one will be mad at you if you say no. Your decision maker can choose and you can choose.
2. I have explained the research to your decision makers and they have agreed that you can participate. Do you have any questions for me?

Correct Answer: 1) It is important to explain that it is a separate choice for the decision maker and child.

It is important to explain that it is a separate choice for the decision maker and child.

Will people know that I am in the study?

1. We will not tell anyone you are in the study. You can tell people if you wish, but they won't find out from us.
2. Your participation in the study is confidential. We will not share your personal information.

Correct Answer: 1) We will not tell anyone you are in the study. You can tell people if you wish, but they won't find out from us.

It is important to tailor your language to best fit the needs of the children. Terminology such as "confidentiality" can be simplified to " we will not tell anyone you are in the study.

You have successfully received assent from the participant.

You have completed the exercise on having a conversation about consent with your child participant. Remember to consider these responses any time you are having a conversation about consent!

When conversing about consent with children involved in child health research, use anecdotes that the child/youth will understand and explain the key points of the study in age-appropriate language. This may include:

- The question being answered
- What the child will have to do
- That their information will be kept private by the researcher even though the child can tell anyone if they wish
- That they can change their mind at any time even after the study starts
- That they can contact the researcher if they or their decision maker have questions

It is important that children understand the study because just having the decision maker agree is not enough; there are two separate parts needed to be in the study:

1. The decision maker has to agree that it is okay for the child to be in the study.
2. Equally important is the second part - that the child also has to agree. For younger children emphasize that the decision maker can say yes or no, and the child can say yes or no.

Both need to say yes, that they want to participate, in order to be in the research study.

Consent Withdrawal

To maintain the element of voluntariness, participants shall be free to withdraw their consent to participate in the research at any time, without offering any reason for doing so. In some cases, however, the physical practicalities of the project may prevent the actual withdrawal of the participant partway through. For example, this may occur if the project involves only a single intervention, or if the termination of a medical research procedure may compromise the safety of the participant.

The participant should not suffer any disadvantage or reprisal for withdrawing, nor should any payment due prior to the point of withdrawal be withheld. If the research project used a lump-sum incentive for participation, the participant is entitled to the entire amount. If a payment schedule is used, participants shall be paid in proportion to their participation.

In this section, you learned about how to ethically encourage participation in research. First, you were provided with an overview of incentives/compensation and undue influence in general, followed by specific considerations for children, adolescents, and decision makers. Second, you learned about encouraging participation in community settings versus treatment settings, followed by additional considerations for using incentives appropriately. Finally, you learned about the ethical considerations for obtaining consent/assent. Next, you will learn about participant retention and follow-up.

SECTION 04: PARTICIPANT RETENTION AND FOLLOW-UP

In this section, you will learn about keeping participants interested in your research both during and after their participation in your study. First, you will learn how to set the groundwork for an ongoing relationship with participants by developing a social and cultural understanding, establishing communication methods, and providing future updates. Then, you will learn how to maintain participant interest after the study by showing appreciation (e.g., thanking and acknowledging) and closing the loop (i.e., providing and discussing results with participants and ensuring understanding).

Participant retention refers to keeping enrolled participants in a trial for the duration of the study. There are several tips and tricks that researchers can follow throughout the study to help keep participants involved in and committed to the research.

During the Study

There are various ways to retain participant interest and involvement during the course of your research. This involves developing a social and cultural understanding of your participants, keeping in touch with them, and providing regular reminders.

Continue to learn more about the steps you may take during the study to retain participants.

Social and Cultural Understanding

Ensure that all research staff who will have contact with the participants are knowledgeable about cultural values, family dynamics, and societal issues related to the participant(s) or target population. Being able to "meet people where they are at" can significantly improve recruitment and retention.

Establish Communication Methods

When enrolling a participant in your study, ask each participant or guardian member(s) how they would prefer you to keep in touch. Using the communication method that they prefer demonstrates that you prioritize their needs and what works best for them. Keep in touch with participating families regularly throughout the project (especially for longer projects). This can be done by text, email communication, or a short phone call.

Hand outs such as fridge magnets, mirror stickers, or small calendars can be helpful for some but can also be misplaced. If participants or their decision makers keep an electronic calendar, send an email invitation with a brief list of activities that they can accept into their online calendar (preferably their phone).

Provide Future Updates

It is important that at every visit and every contact with families or participants that you reiterate what the next step, visit, or activity will be. Continuous reminders are helpful for busy families and let them prepare the children in advance for upcoming activities, such as bringing a soothing toy or snack. It also limits any "surprises" if the family has forgotten about a certain activity and/or requirement. You want them to come to the appointment ready and prepared.

After the Study

There are various ways to retain participant interest and involvement in research (this study or future studies) even after the study has been completed. This can be done using three simple actions:

- Acknowledge
- Thank
- Show appreciation

Continue to learn more about the actions you may take after the study to retain participants.

ACKNOWLEDGE

At the end of each study visit or interaction, clearly convey that the activities are complete for that day and when the next study activities will occur. A clear acknowledgement at the end of the study that this completes their involvement helps families define a start and end date. Just saying "thank you we are finished" is not always clear.

THANK

Ensure that you say "thank you" adequately. The importance of thanking participants cannot be overemphasized. Your research cannot happen without the children, youth, or families as participants.

SHOW APPRECIATION

Consider providing a small token of appreciation for the time and effort that they have contributed. A shout out to "all participants" in a clinical or community setting (without identifiers) will promote research but also may make children proud when they see their study has been completed and was a success.

Closing the Loop

Metaphorically, closing the loop means that continuous follow-up to individuals about what is going on with the project is provided. Closing the loop is particularly important for children with health conditions who are part of a very limited target population, as a negative perception of research can impact future recruitment efforts for a lifetime. Steps taken to close the loop can occur during and after the research study has been conducted.

Infographic of "Closing the Loop "

At each study visit, take the time to update the participant(s) about the study progress. Let them know how many people are enrolled, when you expect to finish data collection, or when and how they can find out the overall study results. You do not have to provide a detailed account, but families

appreciate understanding how the study is progressing and what the realistic timelines are for getting results.

After the study, close the loop by ensuring that research participants know that they will receive and understand the study results. This is important for building positive perceptions of research and supporting the willingness of the participants to engage in future studies. Sharing results with participants also respects the time and effort that they have contributed to the research. Families who never hear the results of a previous project say they are less likely to enroll in future research studies. Making the effort to share the study results lets them know that they were an important part of the project and you appreciate their contribution.

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Examples of How to Share findings with Youth

Additional “closing the loop” actions include:

- Providing each participant with their individual results from the study's assessments, as well as the overall results of the project.
- Encouraging the sponsor or lead investigator to develop a family-friendly report that is easy to read, eye catching, and provides them with the main take-aways, even if the study does not show benefit or positive results.
- Providing a mid-study update: Families may also appreciate a mid-study update to see that their efforts are appreciated. Depending on the age group involved, a child-friendly format is appreciated.

In this section, you learned about participant retention and follow-up. Specifically, you learned how to keep participants interested in your research both during and after their participation in your study. Next, you will be presented with some participant scenarios to consider.

SECTION 05: CASES TO CONSIDER

In this section, you will discuss a number of participant scenarios which present more specific and problematic challenges.

Case Study: Pregnancy Discussion

Reflect on your knowledge of participant recruitment and answer the question.

Question 1 of 1: How do you address and approach the participant and decision maker when pregnancy prevention is required for study inclusion?

Feedback:

Pregnancy prevention is often a consideration in intervention and drug trials. It is important that this conversation begins at the time of recruitment with consent review. The adolescent is given the time to consider whether they want to be involved in a study that may 'expose' a pregnancy or sexual activity.

- Discuss with both the decision maker and adolescent the general pregnancy prevention requirements of the study.
- Seek a 1:1 conversation with the adolescent about pregnancy prevention in more detail. That more private conversation with the potential participant provides them with the time to express any concerns about participating in relation to pregnancy prevention.
- Ensure the adolescent knows they can refuse participation at the end of the study consent review without indicating that it is due to the pregnancy prevention requirement.
- Make a plan with the adolescent that is acceptable to them about what process will be followed if a pregnancy is identified during the course of the study (i.e., at the time of a study pregnancy test).

Case Study: Trauma-Informed Approaches

Trauma-informed approaches include working with children with a history of sexual or emotional violence.

Reflect on your knowledge of participant recruitment and answer the question.

Question 1 of 1: How do you ensure you are taking a trauma-informed approach when recruiting participants?

Feedback:

The essential principle behind being trauma-informed is that you, as the researcher, likely do not have a realistic idea of what the child or family in front of you has experienced. This means that extra thought and care should be put into dealing with participants who have experienced trauma. The key goal is that the researcher should be thinking about how to protect the child and how to make them feel safe. This safety is important not only as a trauma-informed care principle but also for the inherent goals of the research. Safety helps to ensure that the child feels comfortable disclosing information

which may be embarrassing or otherwise difficult to share. This means establishing a safe environment to share can actually result in more accurate data.

Related to a trauma-informed approach, the researcher should consider how issues like shame and stigma factor into data collection. Asking individuals difficult questions, particularly in front of other family members, can be retraumatizing. If possible, multiple methods should be offered to the child, so that, for example, they can have a private interview, or write out their responses on a computer or iPad, or fill out a questionnaire. Thought should also be given as to how taxing each of these options will be.

It is also necessary to think through how exactly your relationship might be perceived when working with traumatized populations. Depending on the type of research, it may not be appropriate to simply "pop in", ask personal questions, and walk out, never to be seen again. On the other hand, having an ongoing relationship (e.g., where you see the child or family every month over the course of a year) may also create expectations and an intimacy which is also potentially complex. Neither of these approaches is necessarily "wrong", however, these relationships should be considered and entered into with care.

After data collection, some effort should be made to check to ensure that the child is not experiencing any ill effects potentially related to their research involvement. You may want to ask questions regarding their behaviour such as play, concentration in school, and sleep patterns. Families should also be offered some kind of contact information and/or other resources at the conclusion of the study, in case they feel the need to reach out.

Case Study: Caregivers Lacking Consensus

Caregivers are defined as a person identified and designated by the patient – a family member, friend, neighbour – who provides important personal, social, psychological, and/or physical support, assistance, and care. A caregiver does not have to be living with the person they are supporting or biologically related to the patient.

Reflect on your knowledge of caregivers lacking consensus to answer the question.

Question 1 of 1: Suppose you were in a recruitment activity taking place with one caregiver (parent-mom) and a child. The parents are co-parents, but the majority of care falls on "mom". The mother enrolled the young child into the study. At some point during the study activities, the father contacts the research group angry about enrollment of the child into the study. What are the key considerations to avoid such a scenario when enrolling children?

Feedback:

At recruitment, it is important that the researcher gains awareness of the family dynamics in order to properly prepare for and address any potential issues with consent or study participation. Consider there may be one or two and potentially more adults directly involved in the child's life.

In this case study, even if most care decisions are made by the "mother", consider the father's perspective and wishes, especially in drug/intervention trials.

Additionally, when providing the study information to the parent who has been approached, ensure you inquire about the other parent and encourage communication with that person. This is best done initially by parent #1 and if necessary the research team can follow up afterward with providing the full study information.

Similarly, if extended family members are involved in the child's care it is important to consider them when recruiting. It is a courtesy for those who are not necessarily a legal guardian but who may be present or assist with study activities as it will build a stronger potential for retention.

Finally, if you are unable to bring legal decision maker #2 (regardless of their level of involvement in the child's daily care) on board with the study, you should not enroll.

Case Study: Recruitment in Emergency/ICU

Recall recruitment for studies in the emergency department (ED) or ICU settings such as Pediatric Intensive Care Unit (PICU) is recruitment in a clinical setting. Clinical is defined as involving or relating to the direct medical treatment or testing of patients.

Reflect on your knowledge of participant recruitment and answer the question.

Question 1 of 1: What techniques or tools can be used to recruit children/ youth in the ED/PICU?

Feedback:

Time is limited for establishing trust and is difficult in this environment. Align yourself with the treatment team members who can properly introduce the idea of research to the families. In addition, add child-friendly eye-catching mini ads or videos on the emergency 'info boards' that let families know there are studies being conducted, or outline specific studies.

Lastly, it is important to seek input from Child Life Specialists prior to recruitment to get successful strategies for gaining the child's attention at recruitment time and to use during potential study treatments.

Be cognizant to the timing of the approach when both child and decision maker are in a more settled state.

Case Study: Consent and Assent

Reflect on your knowledge of consent and assent and answer the questions.

Question 1 of 2: Suppose a recruitment activity takes place initially with thedecision maker(s), either in a clinical or non-clinical setting. After the decision maker(s) consent to child/youth participation in the study, child or youth assent must be independently obtained. What are some key considerations?

Feedback:

After the decision maker(s) consent to the child/youth participation, it is important to recognize that the child may be uncomfortable speaking to the researcher or saying something different from what the decision maker(s) has said.

Question 2 of 2: How can you as a researcher quickly develop rapport with a child when discussing research?

Feedback:

Initiate a conversation with the child by asking if you can explain the research study to them. For younger children it is often helpful to have a colouring activity or simple game that they can play while listening to the explanation. Build rapport by talking about what they like to do with friends, what they like at school, lessons that they take, etc. Once the child is actively engaged in conversation with the researcher it is much more likely that they will provide their own opinion about study participation. It can also be helpful to position the child and researcher such that the child or youth cannot easily look at the decision maker for guidance or to see the decision maker reaction (i.e., have the decision maker behind the child/youth).

In this section, you consolidated your knowledge on participant recruitment by completing a number of participant scenarios with challenges.

CONCLUSION

In this module, you spent some time considering how (participant) recruitment in child health research differs from recruitment in adult research. Specifically you learned why recruitment is a critical component of child health research, recognized how potential participants can be identified in clinical and non-clinical settings considering provincial/territorial privacy regulations, discussed potential implications of undue influence and incentives in the recruitment of vulnerable populations, and identified ethical strategies for recruiting in various settings such as clinical and non-clinical settings. You concluded the module by learning approaches for participant retention and follow-up in child health research.

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Page Links:

https://cihr-irsc.gc.ca/e/8688.html

https://cihr-irsc.gc.ca/e/13147.html

https://cheerchildhealth.ca/

Continue to access the references for this module.

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