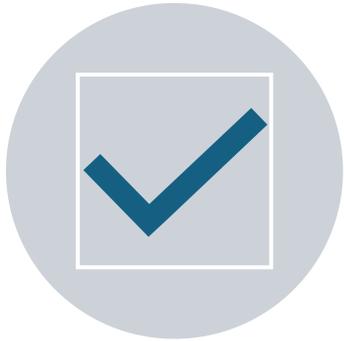


# **ASSENT IN CANADIAN PEDIATRIC INTENSIVE CARE RESEARCH**

Current Practice and Stakeholder Perspectives

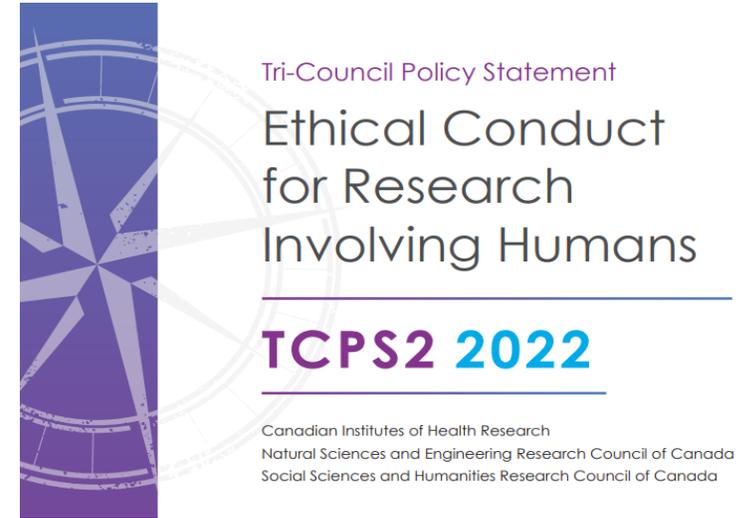
# The Problem



ASSENT IS A **REQUIRED STEP**  
IN THE PEDIATRIC RESEARCH  
PROCESS



WHILE THE PROCESS FOR  
CONSENT IS WELL  
ESTABLISHED, THE  
OPERATIONALIZATION OF  
THE ASSENT PROCESS IS  
LESS CLEAR.



# Questions around Assent Process

Which children should be asked for assent?

- Based on age and/or capacity?

How do we assess capacity?

Who should assess capacity?

Who should speak to the child?

What is the best format to provide information for assent?

What do we do when capacity changes over time?

# The Pediatric Intensive Care Unit

- Critically ill patients with acute, life-threatening disease and injuries
- **How is research in this setting different?**
  - Tight recruitment windows
  - Illness impacts capacity (sedation, active resuscitation)
  - Unplanned admissions
  - High distress
  - Unclear impact of illness on capacity post-recovery



# Additional Questions around Assent Process in PICU

If a child cannot assent at enrollment due to critical illness, should they be asked when they regain capacity?

Does this change if the study is completed vs ongoing?

When is the best time to ask them? As soon as possible? At PICU discharge?

What happens if the child refuses assent at that time?

Keep data so far? Delete all data? Ask the child what they want to do?

How long do we follow a child to try to seek “deferred” assent?  
How to deal with transfers/discharges?

# Research Program on Assent in PICU



## Current assent practices and capacity for assent in PICU

**Exploratory Environmental Scan** of assent in two Canadian PICUs (O'Hearn et al., 2018)

**Scoping Review** on how assent is defined in the current literature (Submitted for publication)

## Perspectives on assent in PICU

**Cross-sectional survey** of key stakeholder groups (research coordinators, nurses, researchers, REB Chairs)

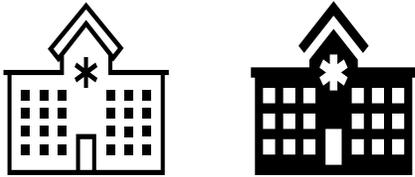
**Interview and survey study** of PICU patients and their parents/caregivers

**Guideline Development:** Development of guidelines for assent in Canadian pediatric critical care research

**Implementation study:** Evaluation of assent practices in Canadian PICUs before and after implementation of the guidelines

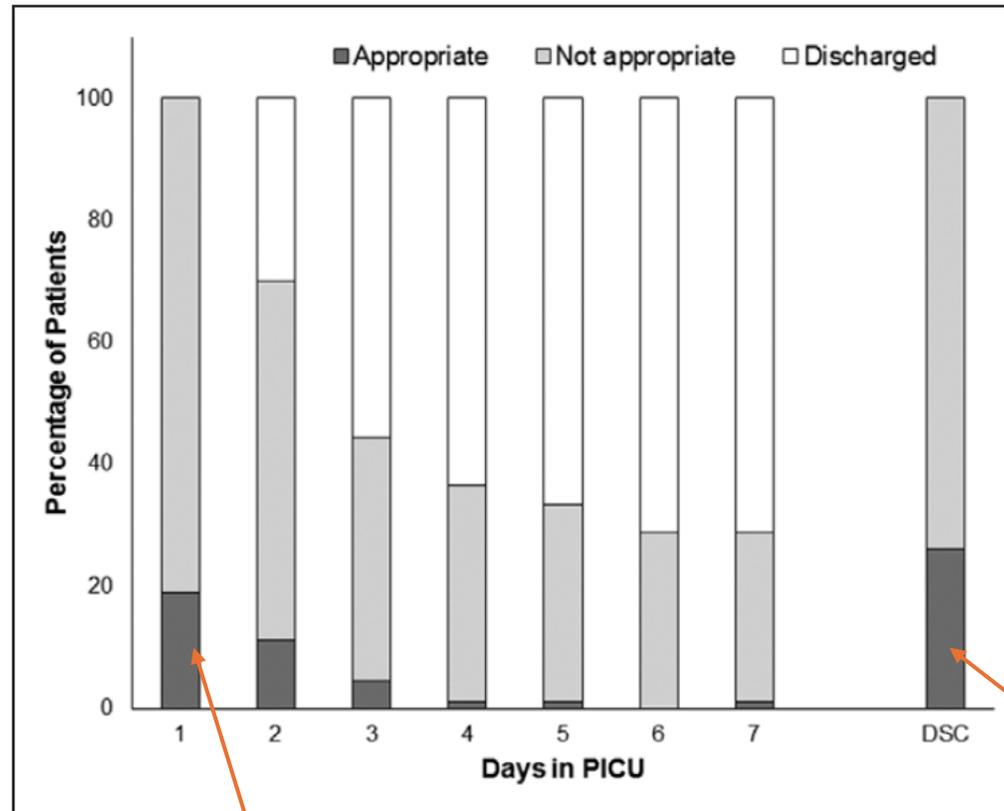
# Current Assent Practices and Capacity for Assent in PICU

# Ability to Assent in Pediatric Critical Care Research



Prospective environmental scan in two Canadian PICUs

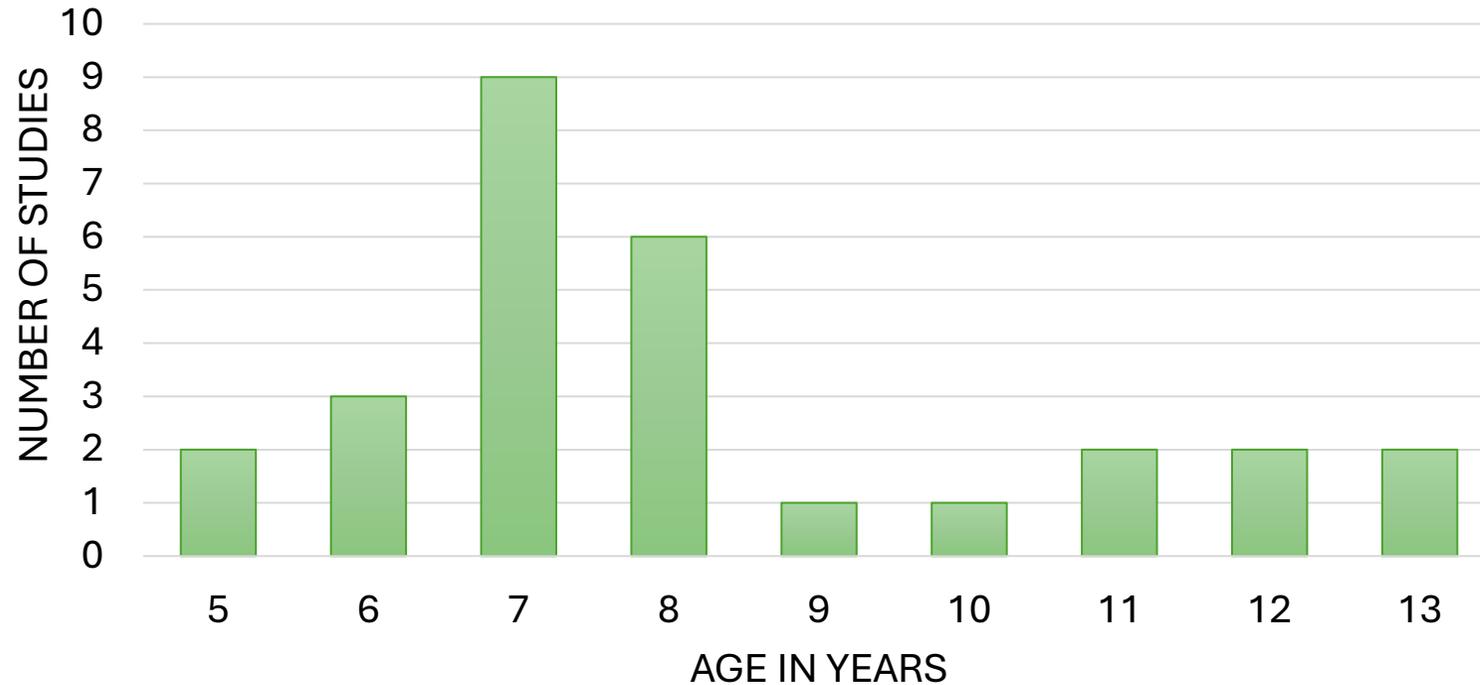
- Age < 7 yr
- Requiring invasive ventilation
- Psychotropic medication
- Developmental Delay (functional ability <7 years)
- Hemodynamically unstable
- Language barrier
- Other



- **PICU Admission:**
  - 81% not appropriate for assent

- **PICU Discharge:**
  - 74% not appropriate for assent

# Scoping Review - How is assent operationalized?



# Scoping Review - How is assent operationalized?

How was assent obtained?		
Verbal	18	22.0%
Written	33	40.2%
Other (Nonverbal, Online form, Formal acceptance)	4	4.9%
Not specified	34	41.5%

Did the authors specify what information was provided to the patient during the assent process ?		
Yes	15	18.3%
No	67	81.7%

In what format was assent information provided to the patient ?		
Verbal	20	24.4%
Written in person	14	17.1%
Written by mail	3	3.7%
Written (not further specified)	4	4.9%
Comic book	1	1.2%
Other (Cartoons, play, Written online, Using pictures, inviting child to colour)	3	3.7%
Not specified	48	58.5%
Unclear	3	3.7%

# What we learned

Capacity for assent in PICU is low

Significant variability in how assent is operationalized

# Stakeholder Perspectives

# Stakeholder Perspectives on Assent

Key stakeholder groups involved in **defining and obtaining assent for research purposes in PICUs**

**Perspectives and perceived barriers to assent.**

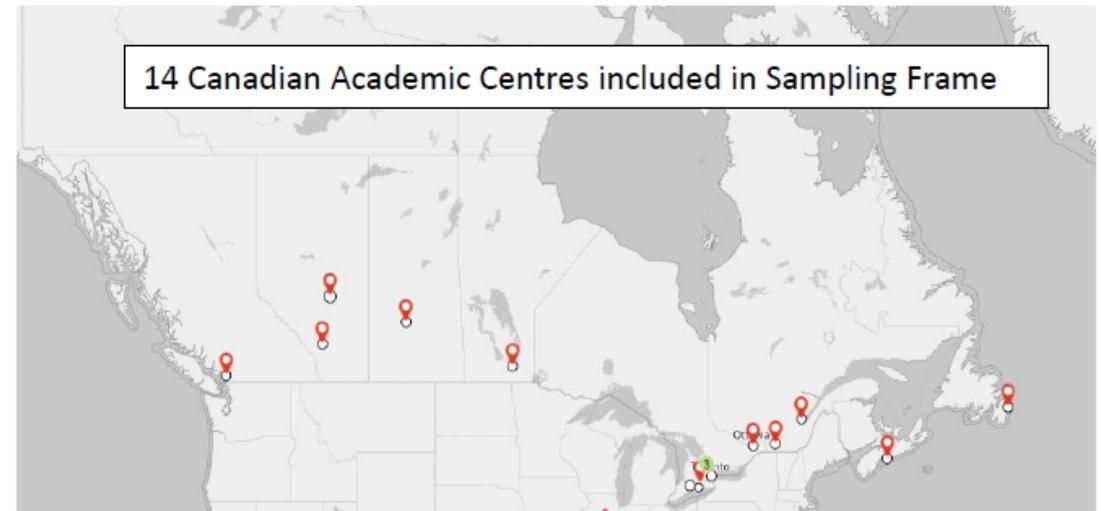
The stakeholder groups were:

- PICU nurses
- PICU research coordinators
- PICU researchers
- REB chairs

## NUMBER OF PARTICIPANTS

REB Chairs	PICU Research Coordinators	PICU Nurses	PICU Researchers	Total Participants
N = 8	N = 53	N = 87	N = 43	N = 191

## LOCATION(S)



Version 28-Oct-2022

# Stakeholder Perspectives on Assent

37% thought it was **“Never/Almost Never”** feasible to obtain assent during the first 48 hours of PICU admission

66% indicated there are **unique barriers** to assent at the time of enrollment in PICU studies.

**Assent was rated Important/Very Important :**

Interviews/focus groups with the child – 77%

Blood sample collection with a needle poke for research - 77%

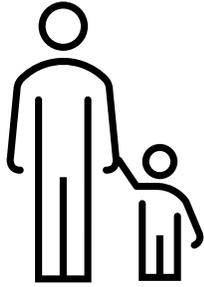
Studies involving genetic testing with results communicated to the child/legal guardian- 74%

**In two scenarios where a child and legal guardian disagreed about study participation**, most respondents indicated that whether the child should still be enrolled **would depend on the patient’s age (34-36%), and/or the risk of the study (24-28%).**

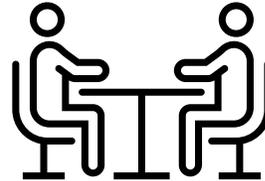
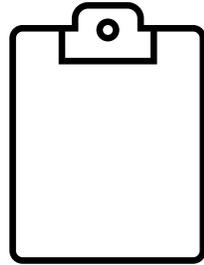
There was a **lack of consensus between stakeholder groups over when and for how long children should be followed to seek assent for ongoing study participation** in situations where the child did not have the capacity to provide assent at study enrollment.

**Most stakeholders (74%) thought that children should have the opportunity to decide if their samples could stay in a biobank** once they are old enough to do so.

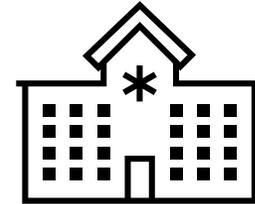
# Patient and Caregiver Perspectives



Patients and caregivers



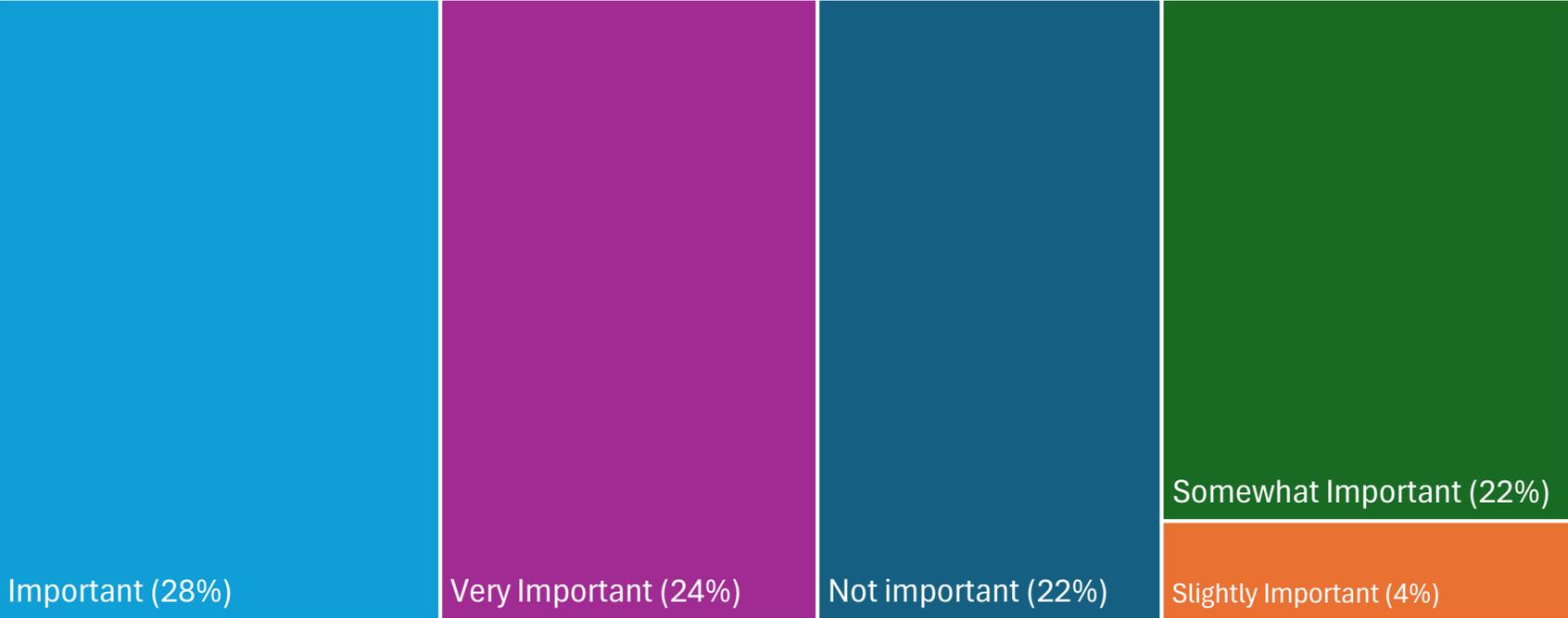
Option: Survey or interview



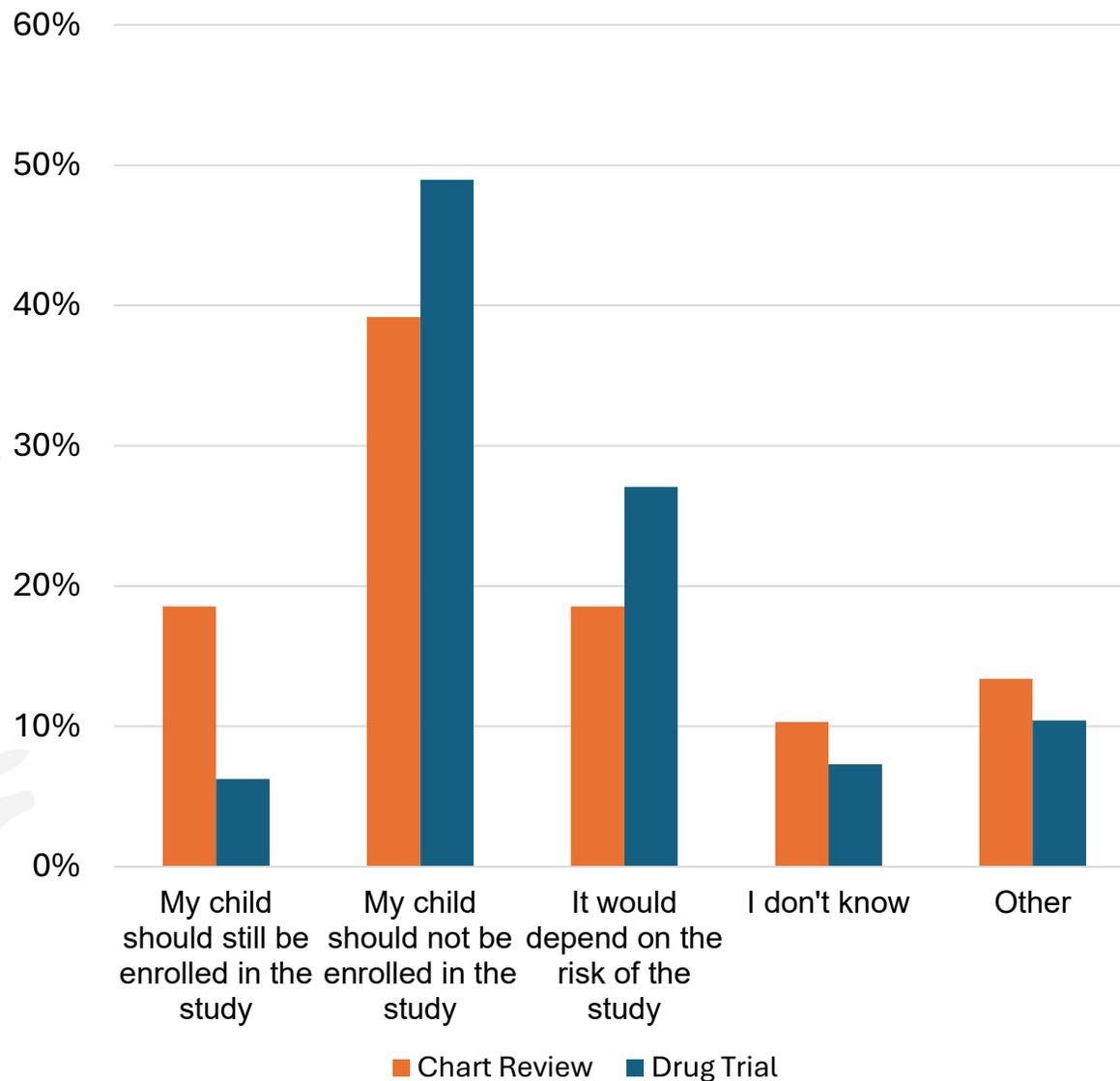
5 Canadian PICUs

Preliminary results from survey, n = 97

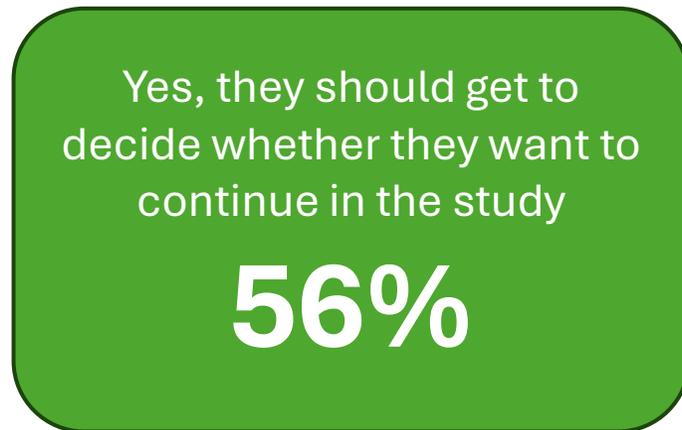
If your child was invited to be part of a research study, how important do you think it would be for your child to help decide whether or not they should be part of the study?



What should happen if the guardian provided consent, but the child does not want to participate?



Sometimes, a child is not able to say whether they want to be part of a study in the PICU because they are too sick. They can still join the study because their parent/guardian gives permission. If this happened to your child, would you want your child to decide whether they want to continue in a study once they were able to (i.e., once they were better)?



I don't know = 14%

If yes and your child did not want to continue in the study, what should happen to any data and samples collected up until that time?

All my child's information and samples should be removed from the study

**42%**

The study team should specifically ask my child to keep any information or samples

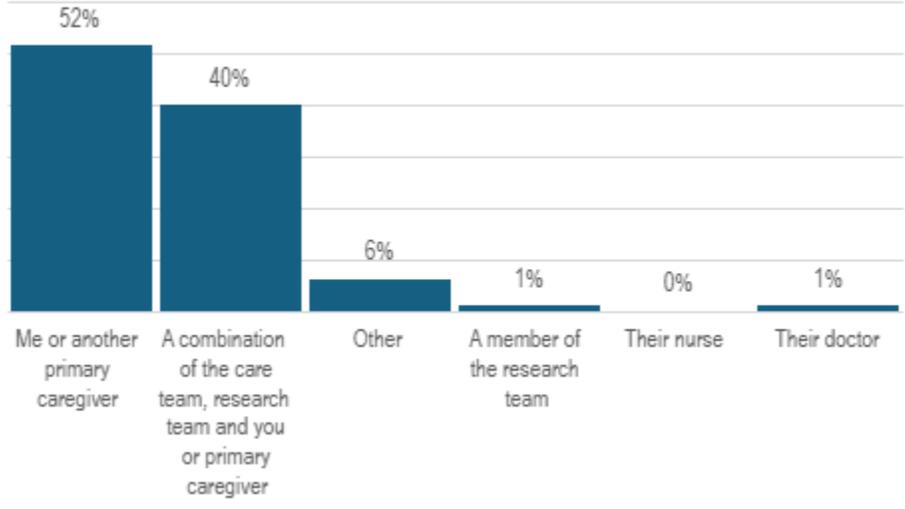
**30%**

The study team should be able to keep any information or samples they had collected so far

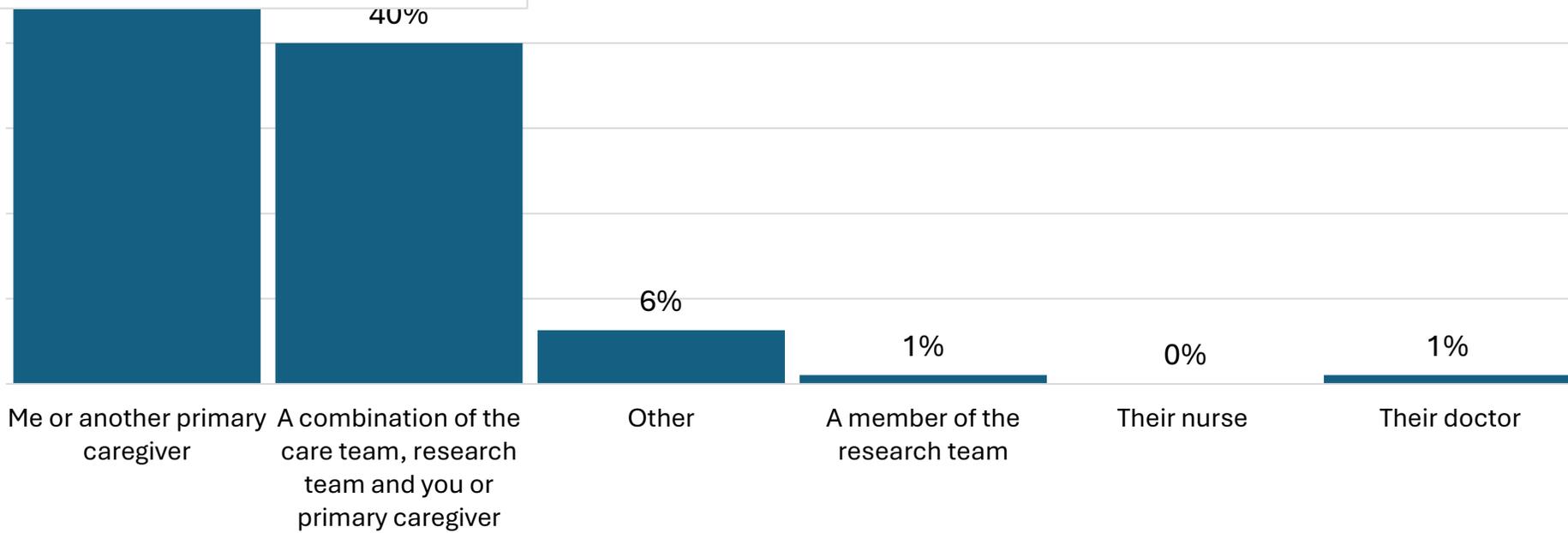
**20%**

Other= 8%

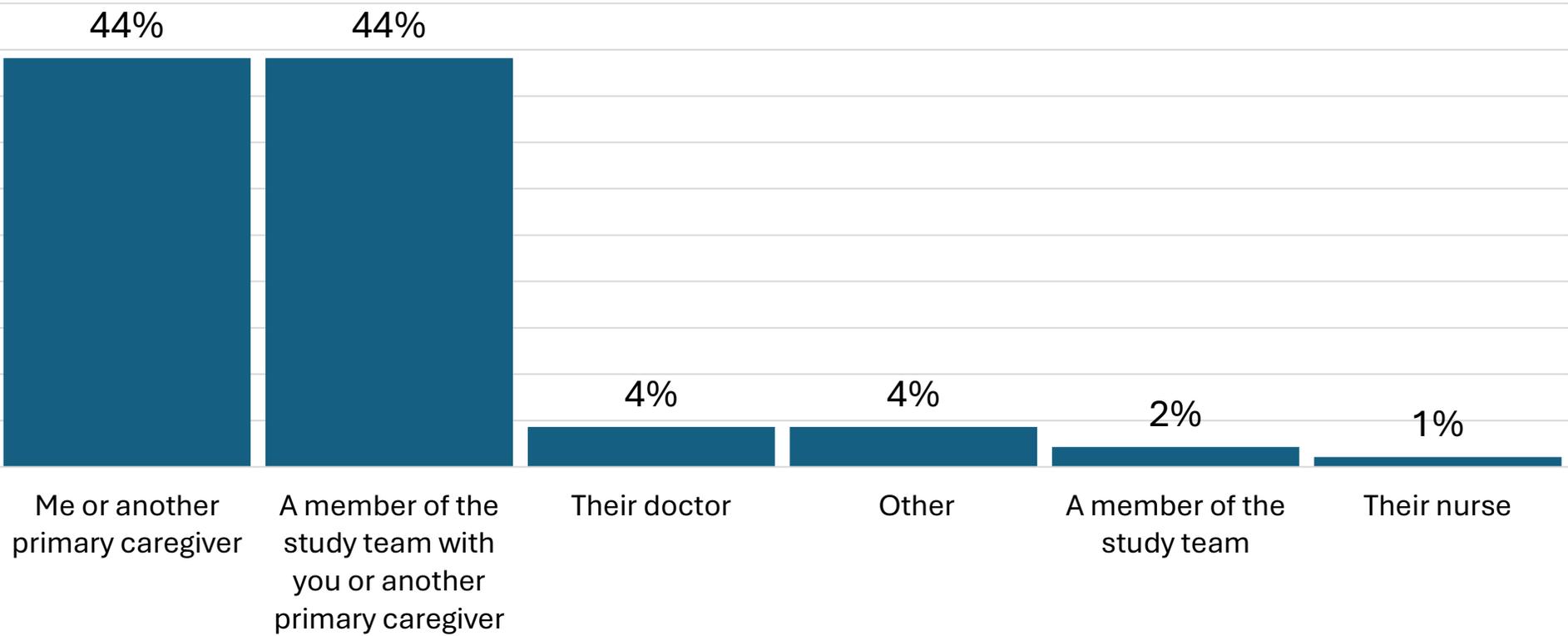
capacity



Whether your child is able to understand information about a study and make a decision about whether to be a part of a study or not?

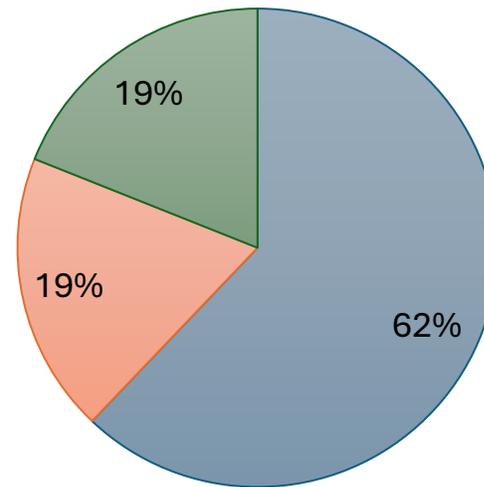


# Who would you rather speak to your child about whether they want to be part of a study?

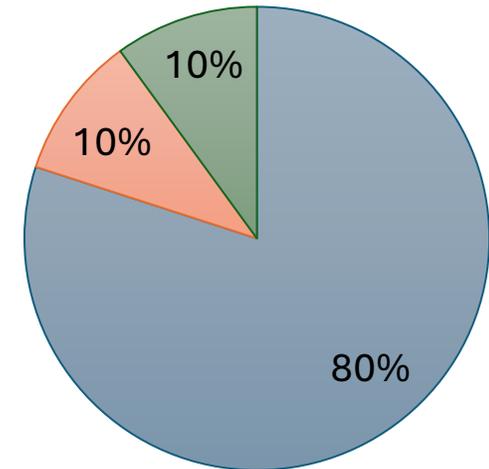


**Do you think that the way children are given information about a study and asked if they want to be in a study should be the same at all the hospitals in your province?**

Caregivers and Patients



REB, Researchers, RCs, Nurses



■ Yes ■ No ■ I don't know

# Take Home Message

There is significant variability in how assent is currently operationalized and in how stakeholders want the assent process to occur

Most stakeholders support standardization of the assent process across hospitals within their province

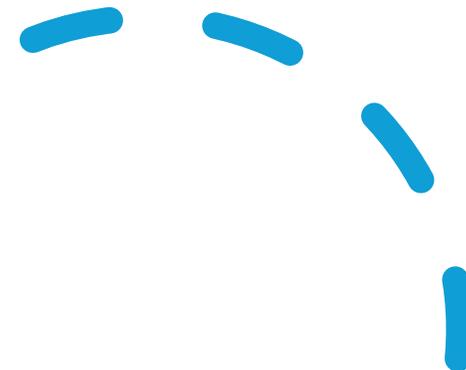
Future work should focus on developing and evaluating guidelines for assent, that are context specific and are informed by stakeholder input



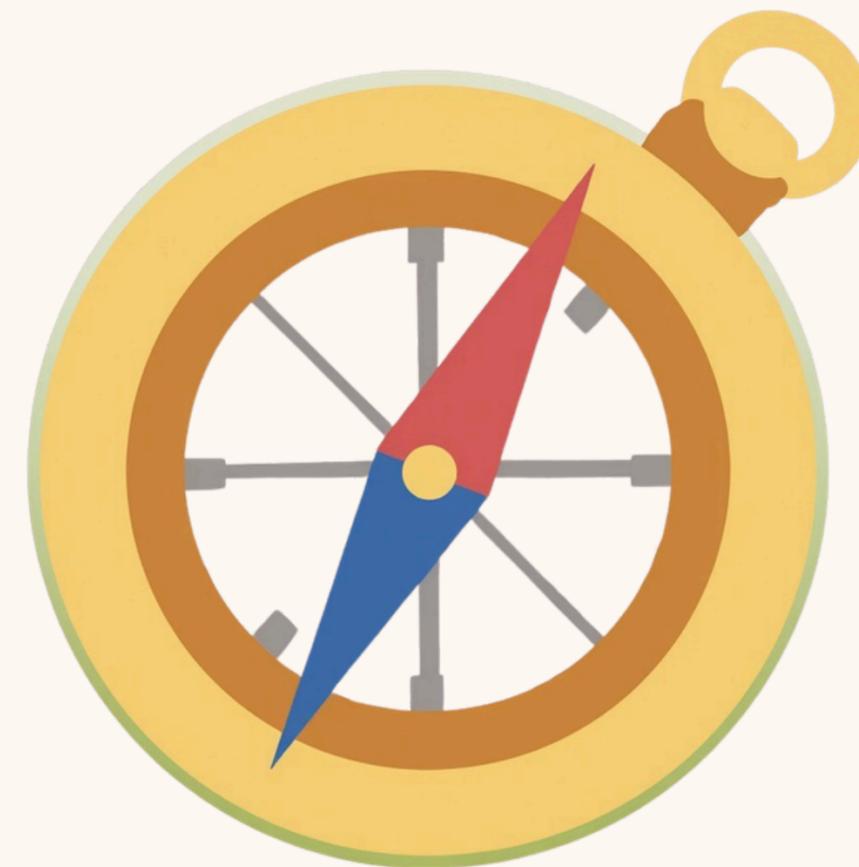
Thank you

Katie O'Hearn

- [kohearn@cheo.on.ca](mailto:kohearn@cheo.on.ca)



# Assent as Our Compass: Staying Oriented in Child-Centred Research



# What is Assent and Why does it Matter?



Assent means inviting a child to understand, ask questions, and agree to what is happening in a way that matches their age and development. It is not legal consent – parents still make the final decision – but assent ensures children feel respected, informed, and included.



TRUST— Children learn that adults will be honest with them

EMOTIONAL SAFETY – Knowing what to expect reduces fear

AGENCY – Children practice expressing preferences and asking questions

COOPERATION – Understanding increases willingness to participate

RELATIONSHIP – It strengthens the bond between child and caregiver

# Essentials of the Journey



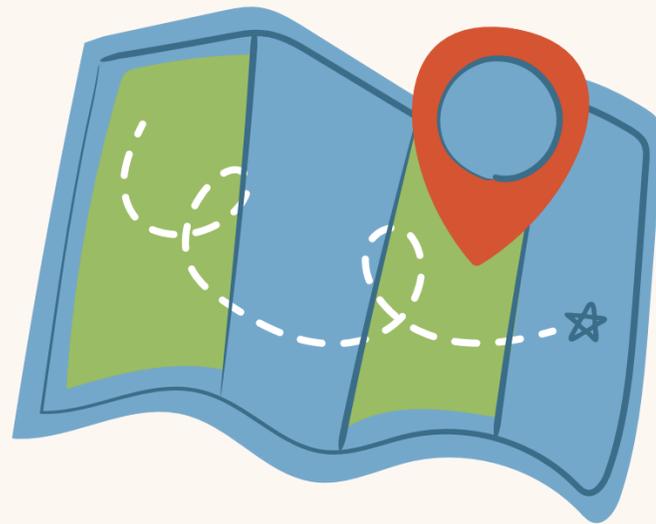
Determining whether a child is capable of giving assent is a **SHARED RESPONSIBILITY**.

It's a collaborative process that brings together the people who know the child best and the professionals responsible for their care.

**Parents**



**Researchers/Clinicians**



**Children/Youth**



# Orientation Matters: Using Assent as Our Compass



## PARENTS

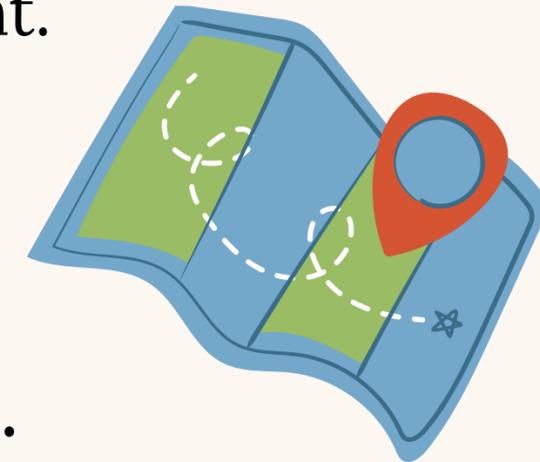
provide the DESTINATION.

CONSENT is like setting the destination on a GPS – the parent or guardian chooses the route, approves the journey, and gives the legal green light.

## RESEARCHERS

provide the MAP

(the protocol, risks, benefits, procedures).



## THE CHILD

provides the COMPASS READING – their understanding, comfort, willingness, and sense of safety.



# Helping Set the GPS

## Supporting Parents as Partners in this Journey

**Listen** with intention

Create **space** for their fears, hopes, and questions.

**Slow** the pace

Parents need **time** to process; rushing erodes trust.

**Translate** the process

**Replace jargon** with meaning so they feel informed, not overwhelmed.

**Validate** their expertise

They know their child's cues and thresholds **better than anyone**.

Offer **predictability**

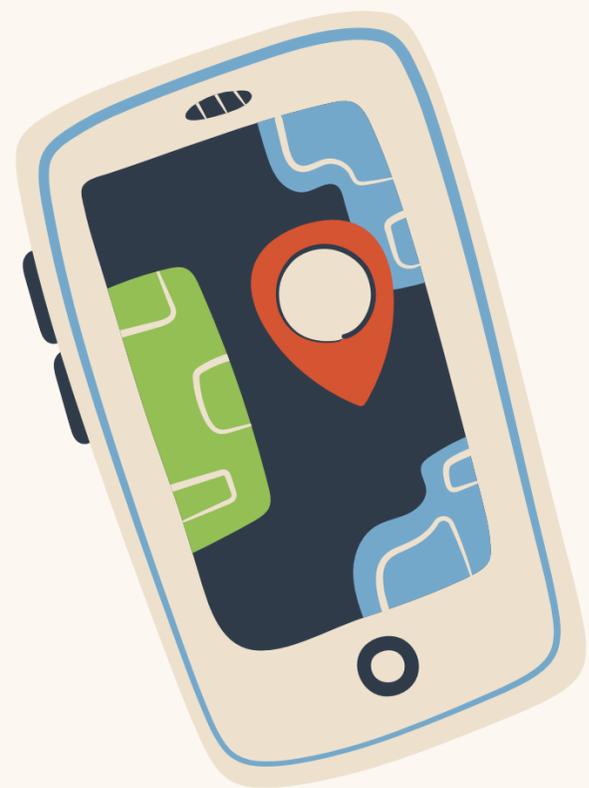
Clear **steps, visuals, and choices** reduce anxiety for both parent and child.

Normalize **pausing**

**Reassure** them that stopping or reassessing is not failure – it's **alignment**.

**Honour** their compass too

Parents give subtle signals just like children; their **orientation** matters.





# When do we set up the Compass? When should a Child be asked for Assent?

## **Age is only one part of the picture**

Consider developmental level, communication style, sensory needs, anxiety, and familiarity with adults or settings.

## **Assent is not a one-time question**

It's an ongoing check-in — especially important for children who communicate through behaviour rather than words.

## **When a child can show their compass orientation, they're already communicating assent.**

Their signals — whether steady, hesitant, or unsure — are invitations for us to notice and respond with care. Children as young as 4–6 can express comfort, curiosity, hesitation, or refusal — and these signals should be treated as assent-related data.

# What Assent Really Means

A compass doesn't choose the route — it tells us whether the child is still aligned and comfortable.

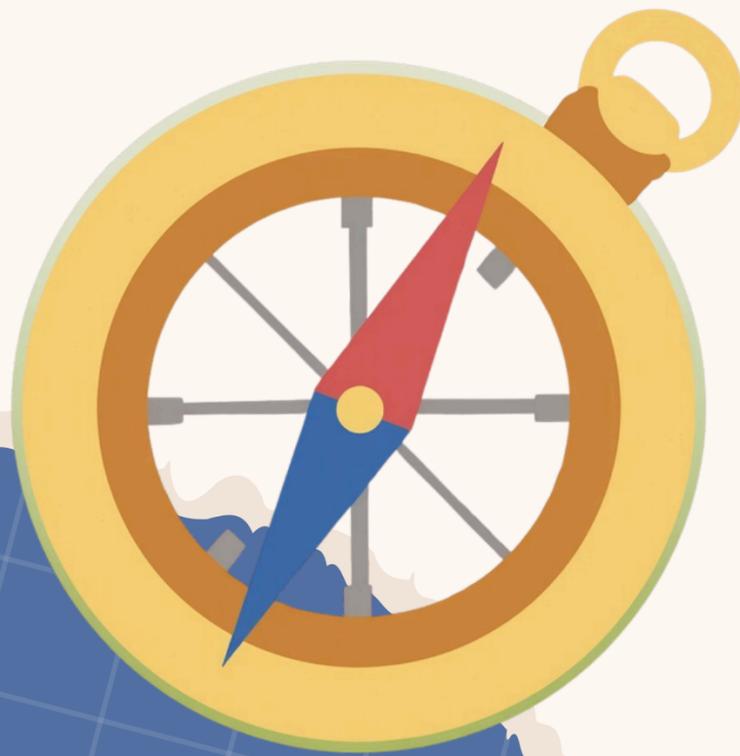
Assent is the child's compass signal that they:

Understand what's happening

Feel safe enough to continue

Can express questions or concerns

Are willing to stay on the path with us



# Who Interprets the Compass?



\* Assent capacity is a shared interpretation:

Parents

Know the child's cues and communication style

Professionals

Provide explanations and assess understanding

The Child

Gives the actual compass reading – comfort, clarity,  
willingness

We read the compass together. No one does it alone.



# Why the Compass Matters?



A compass keeps us oriented.  
Assent does the same.



When a child shows confusion or discomfort,  
that's the compass shifting.



We pause, reassess, and realign.

Ethically and methodologically,  
we can't move forward without orientation.

So assent isn't just an ethical add-on. It's a real-time check that keeps the research aligned with the child's capacity, comfort, and well-being.

# Guided by Curiosity

## What a Compass Check Sounds Like....

Simple, child-friendly prompts:



“Here’s what’s going to happen next...”

“This is why we’re doing it...”

“How does that feel to you?”

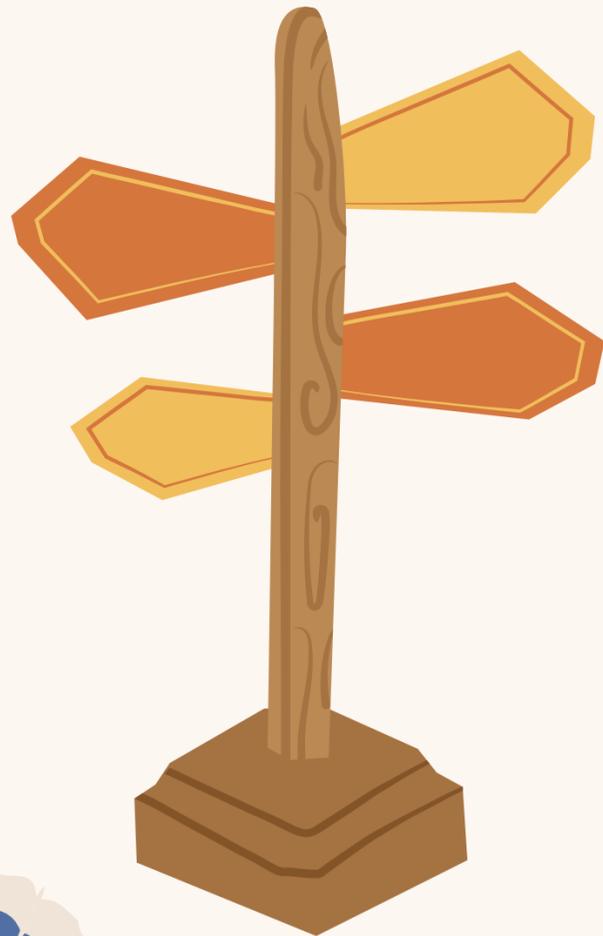
“Do you want to ask anything?”

“Would you like to choose \_\_\_\_ or \_\_\_\_?”



These are the moments where we quietly check the compass and make sure we’re still aligned.

# Orientation Over Momentum



Behind every great trip lies careful planning—maps, essentials, and an open mind ready to embrace the unexpected

Child Assent in Research is very similar.



# The Courage to Be Guided

Every child gives us a compass reading.  
Most of the time, it's **subtle** — a shift in posture, a softening, a hesitation.

We can move past it.

Many systems are built to do exactly that.

But when we do, we lose something essential:  
*the chance to reorient ourselves toward the child's experience.*

**Transformation** begins when we treat those small signals  
as **meaningful data**, not background noise.

When we let the child's orientation guide our **next step**,  
even when it complicates the plan.

**Assent** asks us to be **brave** enough  
to let the child's quiet truth **reshape** the work.



# When the Compass Leads Us Forward

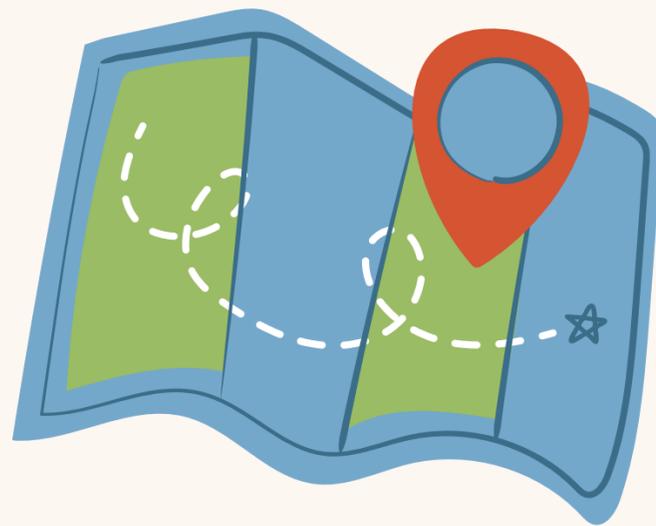
Every subtle compass reading a child offers is a chance to walk with them instead of ahead of them.

Assent is how we honor that chance and let it reshape the path with hope.

**Parents**



**Researchers/Clinicians**



**Children/Youth**



# CHEER



Canadian Collaboration for Child Health: Efficiency  
and Excellence in the Ethics Review of Research

Collaboration pancanadienne pour la santé des  
enfants: Efficacité et excellence dans la révision  
éthique de la recherche

## Launch of Assent Materials Developed by CHEER

February 18, 2025



- ▶ To view resources in real time during the presentation, either scan the QR code or visit our website

<https://cheerchildhealth.ca/cheer-resource-library/> (link in chat)



# Conception and Development



- ▶ CHEER REB community recognized a gap in current assent materials that can be challenging for younger children to use
- ▶ Request to create assent materials for child health research
  - ▶ Must be interactive, engaging and informative
  - ▶ Intention to facilitate the assent conversation and complement the consent process
  - ▶ Need to be customizable to specific studies
- ▶ Materials will be open access and housed on the CHEER website
- ▶ Legacy resources of the CHEER project – housed at MICYRN



# Conception and Development



## Literature Review

- Review of assent research to identify themes

## Environmental scan

- Current assent templates
- Published assent infographics

## Prototype development

- Aims of the materials clarified
- Interactions developed based on childrens work books

## Focus Groups

- Focus group with parents and children to review protoypes

## Finalize

- Graphic designer to finalize designs

# Examples



## Some examples from the environmental scan

I agree to take part in the research.

OR

I do not wish to take part in the research and  
below. (initialled by child/minor)

Only if child assents:

Print name of child \_\_\_\_\_

Signature of child: \_\_\_\_\_

Date: \_\_\_\_\_  
day/month/year

*If illiterate:*

A literate witness must sign (if possible, this person should be a parent, and should have no connection to the research team) and include their thumb print as well.

I have witnessed the accurate reading of the assent form to the child and provided the opportunity to ask questions. I confirm that the individual understands

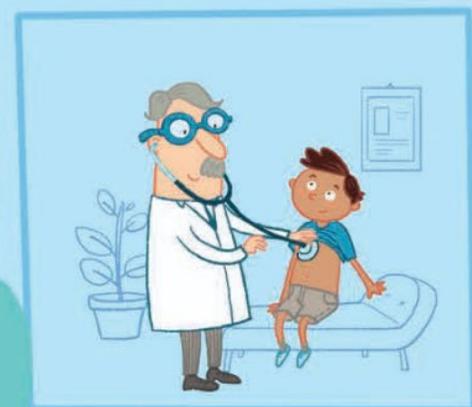
Print name of witness (not a parent) \_\_\_\_\_

Signature of witness \_\_\_\_\_

Date \_\_\_\_\_  
Day/month/year

Jack and Sarah have got anemia.  
This year they want to find out whether Doctor Ironless's new syrup works as well as the tablets do.

Once a week they go to the hospital.  
Nora the nurse takes a sample of their blood.



Once a month,  
they have an appointment  
with Doctor Ironless.



BEFORE WE START?

S!

what this trial is for ?

Yes

No

tablets to dissolve in water,

Yes

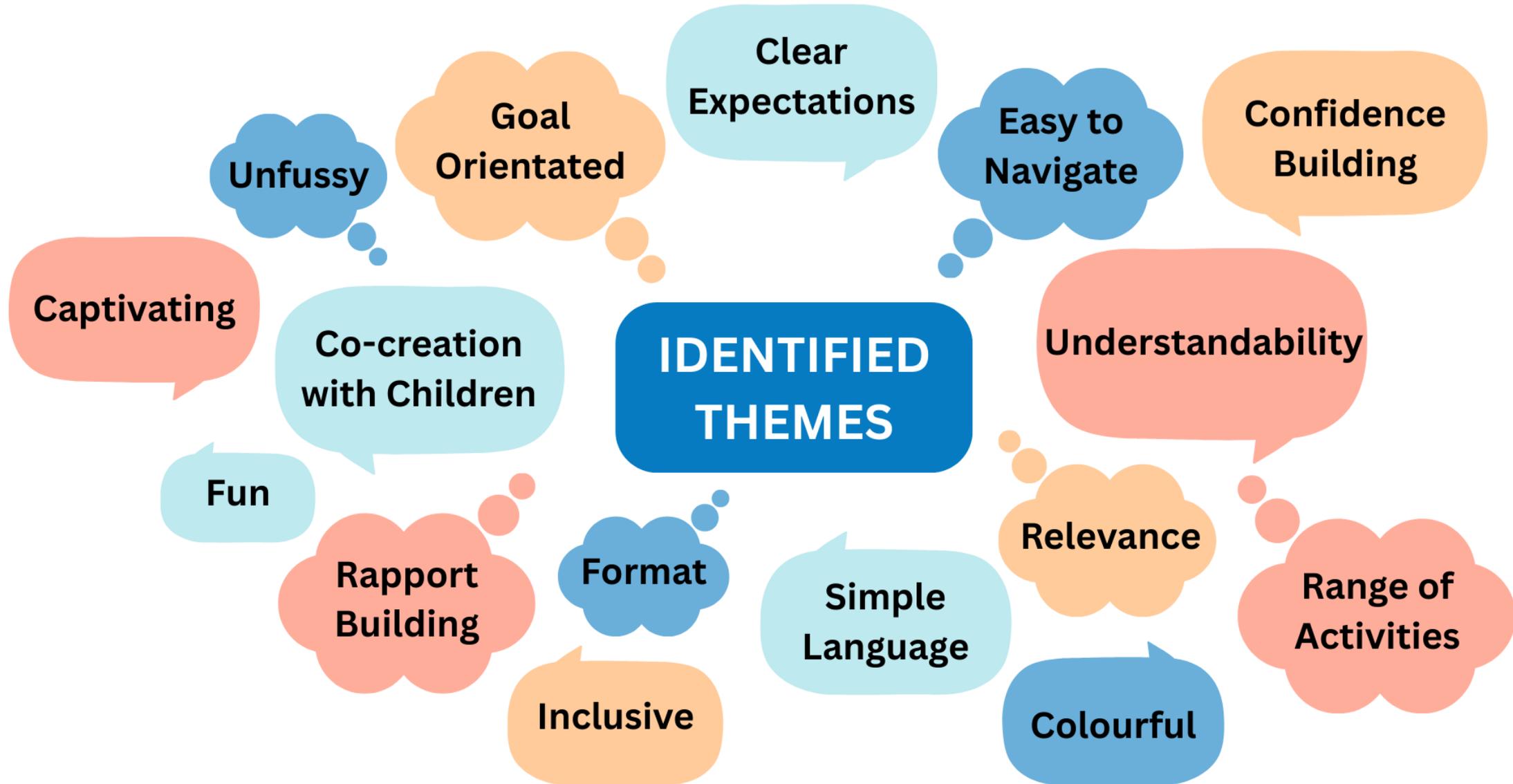
No

od sample and a

Yes

No

# Themes from Deliberative Dialogue



# Visual Study Schedule



- ▶ To be used by families and kids, can track progress
- ▶ Adapted from work the Blueprint Translational Research Group & patient partners
- ▶ Fully customizable, uses PowerPoint
- ▶ Comes with a sample picture catalogue
- ▶ Available in English and French



## VISUAL STUDY SCHEDULE EXAMPLE

What will I do as part of the study?

Week	How long will it take?	Visit details	Study activities	Notes
Week 1	 45min	You will go to the hospital and meet the study team with your parents or guardians.  	    	Hair sample is optional.
Week 4	 3hrs	We will make sure you are still well enough to be in our study.  	   	
Week 6		It's time for your surgery!  	   	The online survey can be completed at home.

What do the pictures mean?

	Doctor		Half-day		Height		Review medicine		Take photos		Diary
	Hospital		Overnight		Hair sample		Urine sample		EKG		
	Time		Weight		Listen to heart & lungs		Blood sample		Online survey		



# Unlocking Better Care



- ▶ Brochure to introduce the concept of research to families
- ▶ Adapted with permission from work by the Language Barriers Project at BC Children's Hospital
- ▶ Not specific to any research study, hospital, or jurisdiction
- ▶ Available in tri-fold, scrollable digital infographic, and TV/screen poster (large waiting room screen)
- ▶ Available in English, French, Inuktitut, Traditional Chinese and Simplified Chinese with more languages coming in collaboration with BCCHRI!

## Research: Unlocking Better Care

### Why is research important?

Research helps us better understand health and disease, **improve treatments, and find new cures**. Child health research has more impact if it is **inclusive and free of discrimination**.

**We welcome all people** from different cultures, communities, and backgrounds. When many different people take part, **research can benefit more children**.



What you should know:

### Participation is Voluntary

- ▶ Usual medical care and access to other services will continue whether you take part in the study or not.
- ▶ You do not have to participate if you do not want to and, you can withdraw from the study at any time.
- ▶ The study team will let you know how they plan to share the results with you.

### Privacy is Protected

- ▶ Rights to privacy are legally protected by federal and provincial laws.
- ▶ The research team will not reveal or share your identity unless you agree.

### Your consent is needed!



**Consent and assent** forms explain the study. If you want to take part, you must sign them. You can withdraw at any time. You do not give up **any** legal rights.

I'm ready to sign the forms.





# Recherche:

## Ouvrir la Voie à de Meilleurs Soins

### La recherche nous aide:

- ✓ À mieux comprendre la santé et la maladie.
- ✓ À améliorer les traitements et trouver de nouveaux remèdes.

### Mais, nous avons besoin de votre aide!

Lorsque les familles participent à la recherche, **cela profite aux enfants** au Canada et au-delà.

Nous **accueillons toutes les personnes** de différentes cultures, communautés et origines.



Les  
formulaires de  
consentement  
expliquent  
l'étude!



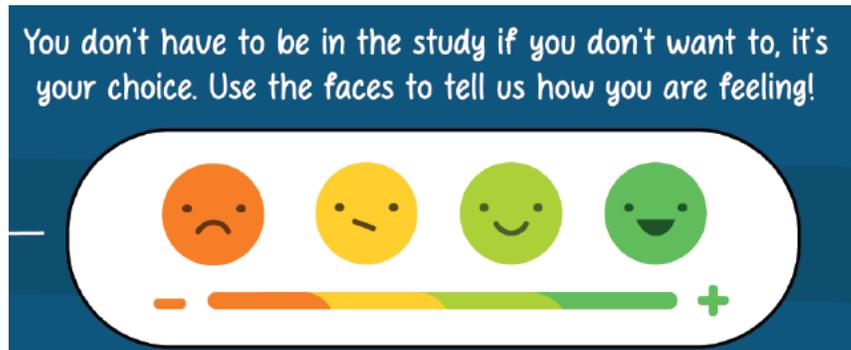
Vous pouvez poser des  
questions pour vous  
aider à décider.

- ✓ Vous ne renoncez à aucun droit légal.
- ✓ L'adhésion **est volontaire** et vous pouvez toujours **arrêter de participer**.
- ✓ Vos **droits à la vie privée** sont protégés.

# Space Mission Map Assent Activity



- ▶ Fillable space map for young explorers to learn about the mission! Children can travel from planet to planet with their trusted adult to find out what they will be asked to do
- ▶ Intended to provide high level overview about a study in child friendly language
- ▶ Visual faces check in at the end for children to express their wishes



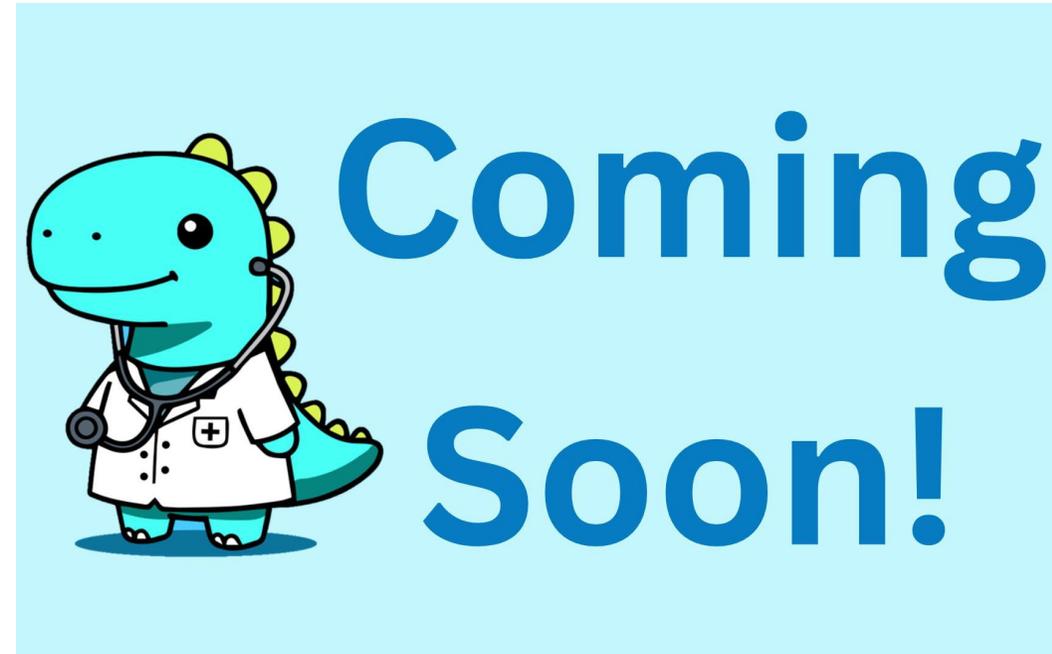




# Story Booklets



- ▶ Fillable story booklet with activities for children to do during the consent and assent conversations.
- ▶ Two versions available: puzzles and drawing activities
- ▶ Intended for older children
- ▶ Study information and activity prompts can be customized
- ▶ Visual faces check in at the end for children to express their wishes
  - ▶ Can be used to accompany any other type of assent tool



# Questions?



- ▶ Everything will be available on the CHEER website
- ▶ Everything will be available in French and English
- ▶ We welcome feedback!