OBSERVATIONAL INFORMED CONSENT FORM: INFORMATION AND TEMPLATE FOR PARENTS/SUBSTITUTE DECISION MAKERS
Version Date: November 25, 2025

Consent to Participate in a Research Study
Parent Consent for Child

Study Title: Neonatal ERAS Outcomes (NEO) Study
Implementing Enhanced Recovery After Surgery (ERAS) for Neonates Undergoing Major Surgery: A Prospective Multicenter Stepped-Wedge Cluster Hybrid Effectiveness-Implementation Study.

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Study Team/Research Contact: Study PI

Study Sponsor and/or Funder:
- Study Sponsor: SickKids
- Study Funder: CIHR Project Grant

Conflict of Interest:
There are no conflicts of interest to declare related to this study.

Introduction

As your child's Parent/Substitute Decision Maker, you are being asked to provide informed consent on behalf of your child. Throughout this form, "we" represents the SickKids researchers.

Your child is being invited to take part in our research study. This consent form describes the research study and what it means to participate. This consent form may have words that you do not understand. Please ask the study staff to explain anything that you do not understand. Please take as much time as you need to think about your decision to allow your child to participate or

not, and ask any questions you have. If it is helpful to you, you are encouraged to discuss the study with family, friends, your child's personal physician, other health professionals, or any members of your community that you trust.

All participation in a research study is voluntary and you are not under any obligation to allow your child to participate.

Why is my child being asked to participate?

Your child is being invited to participate in this study because your child has recently undergone or will be undergoing surgery while admitted to the Neonatal Intensive Care Unit.

The standard of care (or usual treatment) for children who require surgery at SickKids is guided by the infant's healthcare team based on clinical expertise and implementation of best practice.

Why is this study being done?

This research study is being done to measure the impact of recently developed international guidelines for best practice for infants who require surgery. We hope to find out if implementing these guidelines improves outcomes after surgery (e.g., reduces post-operative complications). We will also learn how best to support healthcare teams to use the guidelines.

How many participants will be in this study?

This is a multicenter study being done in two centers in Canada and one center in the UK. A total of ~400 children are expected to be enrolled in the study. At SickKids, up to ~300 children are expected to participate in this study.

What will happen in this research study?

As part of this study, we want to look at your child's health records. We will collect information about their health, surgery, recovery after surgery, and time spent in the NICU (Neonatal Intensive Care Unit). We will also check on your child's brain and development over time during special follow-up visits at the neonatal clinic, which are part of your child's care.

Your child's participation in this study will not involve any additional study visits nor any study-specific tests.

Despite protections being in place, there is a risk of unintentional release of information.

What are the risks, harms or discomforts of the study?

Your child may experience side effects while participating in this study. Some side effects are known and are listed below, but there may be other side effects that are not known or expected. You should tell the study doctor if your child has any complaints, behavior changes, changes to

their health, or had other doctor visits or hospitalizations outside of the study visits. It is important that you discuss these with the study doctor.

We don't know of any risks or harms associated with participating in this study.

Despite protections being in place, there is a risk of unintentional release of information. Even though the risk of identifying your child from the study data is very small, it can never be completely eliminated.

Are there benefits from being in the study?
Your child may not benefit from being in this study. However, the information we learn from this study may be used to develop better guidelines and better implementation toolkits for healthcare providers to increase the use of evidence-based care for infants undergoing surgery.

We hope that the information learned from this study can be used in the future to benefit other people with a similar disease and/or health condition.

What are my responsibilities in this study?
If you choose to participate in this study, you will be expected to:

- Tell the study doctor if you are thinking about your child participating in another research study.
- Ask your study team about anything that worries you.
- Tell the study staff if you change your mind about your child being in this study.

What are the optional parts to this study?

The sponsor, the researchers at SickKids doing this study are interested in doing additional optional research. This optional study is to understand your experience as a parent/legal guardian whose child underwent surgery while in the NICU.

<u>You do not have to take part in the optional study/studies to take part in the main study.</u>

Please initial next to your preference:

Options	**Initial**
Yes, you **can** contact me to complete a survey and/or participate in a focus group discussion to share my experiences as a parent/legal guardian. If you agree, please share your preferred email contact information with the study team.	_____
No, you **cannot** contact me to complete a survey and/or participate in a focus group discussion to share my experiences as a parent/legal guardian.	_____

Can I choose to have my child leave the study?

It is your choice to decide to take part in this study, and participation is voluntary. You can change your mind at any time during the research study. You do not have to come to SickKids for a 'withdrawal visit' assessment.

The study team may ask why you are withdrawing your child for reporting purposes, but you do not need to give a reason to withdraw your child from the study if you do not want to. Withdrawal from the study will not have any effect on the care your child or your family will receive at SickKids. If you decide to have your child leave the study, you can contact a member of the study team to let them know.

Can I withdraw my child's research data from the research study?
If you no longer want your child's study information to be used in this research, you can request your child's data to be withdrawn and destroyed. Please note that any study data that has been included as part of the analysis or that has been shared cannot be withdrawn.

If you want your child to leave the study and want to withdraw your child's de-identified information collected for the research study, let a member of the study team know.

Will it cost me or my child anything to be in this study?

Taking part in this study will not result in added costs to you or your child.

Will my child be paid and/or reimbursed if they join this study?

You and your child will not be paid to be part of this study. We do not anticipate any additional costs to you for participating in this research study because there are no study-visits required.

It is possible that a commercial product may be developed as a result of this study. You and your child will have no rights to any products that may be created as a result of this study or any future research studies using this research study data. You and your child will not receive royalties from any products that may be created as a result of this study or any future research studies.

What personal health information will be collected about my child as part of this study?
Personal health information (PHI) is any information that is collected about your child from their medical records. PHI also includes any information collected from/about your child during the study.

If you decide to allow your child to participate in this study, the SickKids study team (study investigators, coordinators, nurses and delegates) will collect personal health information about your child. This includes things learned from the study procedures described in this consent form and/or information from your child's medical records. The study team will only collect the information they need for this study.

Some of the data collected for this study includes identifiable information about your child, including: MRN, procedural, consent and enrollment dates, and all indirect identifiable information (i.e. partial date of birth, gender, gestational age at birth, birth weight, hospital/NICU admission and disposition dates, participant identification codes, etc.). This information is needed to accurately identify the eligible participants and answer the study questions. We may also collect your email address should you choose to complete questionnaires remotely, and in order to share study documents, or coordinate scheduling.

Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your child's race or ethnic origin is not required. If race/ethnicity is provided on their electronic medical record, then it will be recorded.

How will my child's privacy be protected?

Your child's rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your child's privacy is respected.

We will respect your child's privacy. The SickKids researchers are also committed to respecting your child's privacy. No information about your child will be given to anyone or be published without your permission, unless the law requires us to do this.

Information collected about your child will be "de-identified" by replacing your child's name with a unique participant code. Records identifying your child at SickKids (including the link between your child's identity and your child's participant code) will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

The SickKids study team is in control of the study code key, which is needed to connect your child's personal health information/personal information to them. The link between the study number and your child's identity will be safeguarded by the SickKids study staff and will not be available to the the funding agency or other study sites. SickKids guidelines include the following:

- All information that identifies your child, both paper copy and electronic information, will be kept confidential and stored and locked in a secure place that only the study staff will be able to access.
- Electronic files will be stored securely on hospital or institutional networks or securely on any portable electronic devices.
- No information identifying your child will be allowed off site in any form without your consent. Examples include your child's hospital or clinic charts, copies of any part of your child's charts, or notes made from your child's charts.

The following people may look at your child's original (identifiable) medical/study records to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

- Representatives of SickKids Research Ethics Board and other SickKids staff who oversee the conduct of research at SickKids;

Access to your child's personal health information will take place under the supervision of the Study Doctor. You and your child have the right to access, review and request changes to your child's personal health information.

The study staff and the others listed above will keep the information they see or receive about your child confidential, to the extent permitted by applicable laws. Even though the risk of identifying your child from the study data is very small, it can never be completely eliminated.

The study staff will keep any personal health information about your child in a secure and confidential location for 7 years as per SickKids guidelines and then destroy it according to SickKids policy.

When the results of this study are published, your child's identity will not be disclosed. You and your child have the right to be informed of the results of this study once the entire study is complete.

Data will not be shared outside of SickKids as this is the coordinating center.

Your child's participation in this study will be noted in their hospital or clinic chart. This is done to ensure your child's safety so that all their treating physician(s) will know that your child is participating in a research study.

You also have the right to request for your child's study information to be sent to you and/or another person such as your child's treating doctor, a member of your child's health care team, or a family member. You can choose the way by which this information is requested. For example, you can have the information sent to you or any person you wish to have this information sent in paper or electronic format.

In some cases, your rights to your child's information may be limited by current rules and laws related to the use and storage of information collected as part of a research study. This will be explained to you as needed.

If you have any concerns about the way your child's information is being kept private, you can contact the SickKids Research Ethics Board or the SickKids Privacy Office.

How will my child be informed about new information?
We may learn new information during the study that you and your child may need to know. We may also learn about things that might make your child want to stop participating in the study. If this happens, you and your child will be notified about any new information in a timely manner. You and your child may also be asked to sign a new consent form that describes these new findings if you decide to continue in the research study.

Will I receive study results?
Research results will be shared through journal publications and academic conferences. When the results of this study are shared, your child's identity will not be disclosed. You have the right to be informed of the results of this study once the entire study is complete.

If you and your child would like to be informed of the results of this study, please let the study doctor know.

The results of this study will be available on the clinical trial registry website.

You and your child will only be provided with overall study results (aggregate results from all participants). This means you will not know the results as they relate to your child specifically.

What are my child's rights when participating in a research study?
You and your child have the right to receive all information that could help you make a decision about participating in this study. You and your child also have the right to ask questions about this study at any time and to have them answered to your satisfaction. Your child's rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your child's privacy is respected.

By signing this form, you do not give up any of your child's legal rights against the study doctor, SickKids or involved institutions for compensation, nor does this form relieve the study doctor, SickKids or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to your child's participating in this study. If your child is able to read, they will be given information about the study in a different form, called an assent form. If you agree to have your child take part in this study, and your child agrees to be in the study, your child will be asked to provide their assent to show that they understand what will happen in the study.

We may do future related research studies and want to know <u>if we can contact you and your child</u> about these studies in the future. Please initial next to your preference:

Initial	Options:
_____	**Yes**, you can contact my child regarding future related research studies.
_____	**No**, I do not want you to contact my child regarding future related research studies.

Who can I call if I have questions about the study?
If you have any questions during your child's participation in this research study you can contact the Study Doctor, Dr. Mercedes Pilkington at 416-813-1937.

Research Ethics Board Contact Information

The study protocol and consent form have been reviewed by the SickKids Research Ethics Board (REB). If you have any questions regarding your child's rights as a research participant, you may contact the Office of the Research Ethics Board at 416-813-8279 during business hours.

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By signing this research consent form, I understand and confirm that:

1. All of my questions have been answered,
2. I understand the information within this informed consent form,
3. I allow access to my child's medical records and/or biological samples as explained in this consent form,
4. I do not give up any of my child's legal rights by signing this consent form,
5. I understand that my child's family doctor/health care provider(s) will/may be informed of my participation in this study
6. I have been told I will be given a signed and dated copy of this consent form.

I consent on behalf of ______ to participate in this study.

Printed Name of Parent/SDM	Parent/SDM signature & date (DD/MMM/YYYY)

Printed Name of person who obtained consent	Role of person obtaining consent	Signature & date (DD/MMM/YYYY)

Printed Name of person who obtained consent	Role of person obtaining consent	Signature & date (DD/MMM/YYYY)

If the parent/substitute decision maker (SDM) was assisted during the consent process:
Please check the relevant box and complete the signature space below:

☐ The consent form was read to the parent/SDM. The person signing below attests that the study as set out in this form was accurately explained to, and appeared to be understood by the parent/SDM.
☐ The person signing below acted as a translator for the parent/SDM during the consent process. Language: _____

Name (print)	Signature	Date (DD/MMM/YY)