Bloorview
RESEARCH INSTITUTE

Consent to Participate in a Research Study
(Participant)

Summary of Informed Consent Form

Study Title: Learning from our mistakes: Exploring the tension between productive failure and demonstrating competence.

Below is a summary of information about the study. There is more information in the document (called an "informed consent form" that follows this summary. Please read the informed consent form. The research team will also talk to you about the study and you can ask any questions you may have.

Participation in research is voluntary. It is your choice whether you take part in this study.

STUDY PURPOSE
The purpose of this study is to look at Developmental Pediatrics Fellows, recently graduated Developmental Pediatricians and Experienced Developmental Pediatricians (5 or more years in practice) and their experiences with learning from failure. We seek to explore what opportunities exist to learn from failure within the Competency Based Medical Education Curriculum (CBME). We hope to better understand if there are any specific elements of CBME that promote or constraint the ability to make mistakes and learn from these experiences. This study will provide us with information to improve how we allow for these learning opportunities and how to enhance current medical education curricula. This project has been funded by the Pediatric Consultants Educational Scholarship Grant.

DURATION
It is expected that the study including recruitment and data collection will last 6 months. Although participants will only be asked to do a single interview lasting 45-60 minutes.

STUDY PROCEDURES
Developmental Pediatrics Fellows, recently graduated Developmental Pediatricians and Experienced Developmental Pediatricians (5 or more years in practice) are being invited to participate in this interview-based study. You are invited to participate in an audio-recorded interview regarding your experience learning from your mistakes in the clinical learning environment. During the interview, you will be asked questions about experiences you have had with making mistakes in the clinical learning environment and what impact this had on the overall learning experience. You will also be asked questions about how the current Competency Based Medical Education curriculum impacts your ability to learn from making mistakes. The interview will last between 45-60 minutes and will be conducted in person or virtually using the Zoom Healthcare Platform at a time convenient for you. The taped interview will be transcribed. No names will appear in the transcripts and audiotapes will be destroyed 7 years post study completion as per the research document retention protocol.

RISKS.
Participation in this study may involve risks to you. These risks are described in detail in the informed consent form.

The risks you are most likely to experience are:

- that participants may feel uncomfortable or become emotional while answering questions given their own personal experience making mistakes. Participants can choose not to answer a question and can withdraw from the study at any time.

The most serious risks are:

- There are no serious risks in participating in this study

BENEFITS.
We do not know if you will benefit from participation in this study, but researchers hope that this study will fulfil its purpose and benefit others in future.

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Principal Investigator:
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Co-Investigator(s):
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Study Sponsor or Funder:
1. Pediatric Consultants Educational Scholarship Grant.

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

Introduction
We would like to invite you to participate in our research study. This consent form explains the research study and what we will ask you to do. This consent form may have words that you do not understand. Please ask the study staff to explain anything you do not understand. You may take your time to think about the study and if you want to participate or not. Please ask any questions you may have. If you want to talk about the study with family, friends, your doctor, a health care professional, or any members of your community that you trust, this is okay. It is your choice if you want to participate or not. You do not have to be in this study.

Why am I being asked to participate?
You are being asked to participate in this study because you are a Developmental Pediatrics Fellow, recently graduated Developmental Pediatrician or an Experienced Developmental Pediatrician (5 or more years in practice).

Why is this study being done?
You are being invited to participate in a research study looking at Developmental Pediatrics Fellows, recently graduated Developmental Pediatricians and Experienced Developmental Pediatricians (5 or more years in practice) and their experiences with learning from failure. We seek to explore what opportunities exist to learn from failure within the Competency Based Medical Education Curriculum (CBME). We hope to better understand if there are any specific elements of CBME that promote or constraint the ability to make mistakes and learn from these experiences. This study will provide us with information to improve how we allow for these learning opportunities and how to enhance current medical education curricula.

How many participants will be in this study?

At Holland Bloorview, we will invite up to 22 individuals to participate in this study.

What will happen if I join this study?

You will be asked to participate in an interview. A study team member will meet with you at Holland Bloorview Kids Rehabilitation Hospital or via virtual appointment using the Zoom Healthcare Platform to ask you questions about experiences you have had with making mistakes in the clinical learning environment and what impact this had on the overall learning experience. You will also be asked questions about how the current Competency Based Medical Education curriculum impacts your ability to learn from making mistakes. The interview will take about 45-60 minutes to complete.

The interview will be audio recorded. After the interview, the audio recording will be transcribed. Transcribing means that someone listens to the audio and writes down all the words that are said. The written words will be analyzed by the research team. The transcription will be done by a professional transcription service. The audio version will be shared with the transcription agency for the purposes of transcribing the audio content to text for data collection, we will not share your name or any other identifying information. However, your voice will be heard and may be recognizable. The audio recording will be kept for the required research document retention period which is 7 years after study completion. The transcriptions and audio recordings will be destroyed 7 years post study completion.

We will send recordings to a professional transcription service. We will not send any information that could identify you. The de-identified audio recordings with be password protected and uploaded onto a secure server, Moutain Duck. The transcriptionist will have access to the server and therefore can access the de-identified audio recordings. The transcriptionist will only have access to this service and the de-identified audio recordings until all the transcription process is completed.

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

Interviews:
During the interview, some of the questions we ask you may make you feel worried, stressed and/or sad or upset. If this happens, you may skip questions, take a break or stop answering at any time.

If your answers show us that there is a serious risk of harm to yourself or other people, we have to tell somebody about it. We will do this to protect you or another person. If we feel that you need help right away because you took part in this research study we will work with trained staff to get you the help you need.

Audio Recording:
Your name will not be part of the audio recording. Even though we won't use your name, your voice may still be recognizable as your voice. If anyone talks about things specific to you during the recording (like your name, or where you live), these will be removed from the written version.

Inconvenience of time:
Being in this study will take up your time. This study involves one interview session that will last approximately 45-60 minutes.

Confidentiality risk:
The study team will work to protect your information, but there is still a chance that your information may be released by accident. The study team may be legally required to disclose certain information in

some circumstances, such as (among others): if we learn of child abuse, if someone discloses suicidal intentions (killing themselves), if someone discloses that they suffer from a communicable disease, or if the court orders production of the study papers.

Are there any benefits from being in the study?

You will not benefit directly by participating in this research study. However, we hope information gained from this research will help us to better understand opportunities to learn from making mistakes, and this could help to design future medical education curricula.

Can I choose to leave the study?
It is your choice to take part in this research study, you do not have to participate. If you agree now, you may change your mind at any time during the research study. The study team may ask why you decided to leave the study, but you do not need to give them a reason if you do not want to. Leaving the study will not have any effect on your education or career at Holland Bloorview. If you decide to leave the study, you can tell the Principal Investigator or a member of the study team to let them know.

Will I be paid and/or reimbursed if I join this study?

As a thank you, you will be given $ 30 gift card to Starbucks for being a part of this study.

How will my privacy be protected?

We will respect your privacy. No information about you will be given to anyone or be made public without asking you first, unless it is required by the law.

If you agree to participate this study, the Holland Bloorview research team (study investigators) will collect personal health information about you. “Personal health information” is information about you and your health that can be directly linked to you. They will collect only the information they need for this study. The research team will also ask for some personal information about you (name and email) so that they can contact you. This information will not be shared outside of the Holland Bloorview research team.

All information the study team has about you will be “de-identified”. This means that your personal information (like your name) will be replaced with a number or code. Only the team at Holland Bloorview will have the list that can link your name with the code. This list will be safely stored and only available to the Holland Bloorview research team. It will not be made available to the funding agency. If someone who is not part of the research team were to see the study data, the chance of connecting you to the data is very small but it is still possible. The risk of being able to identify you can never be removed completely.

Holland Bloorview guidelines include the following:

- All information that identifies you, 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 institutionally approved networks or securely on any hospital or institutionally approved portable electronic devices.
- All information identifying you will be stored in a location that is secure and private. Examples include your audio recordings.

De-identified study data, that does not have your name attached, will be sent to an outside transcription service. Study data is being shared so that a transcriptionist can transcribe the audio interview files for the information to be used for data collection.

The following people may come to the hospital to look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

- People from the Holland Bloorview Research Ethics Board and/or other Holland Bloorview Staff who oversee the conduct of research at Holland Bloorview;

The research team will keep any personal health information about you in a location that is secure and private for 7 years post study completion and then destroy it according to Holland Bloorview policy.

How will I be informed about new information?
We may learn new information during the study that you may need to know. We may also learn about things that might make you want to stop taking part in the study. If this happens, you will be told as soon as possible and we will explain what was found. If you decide to continue in the research study, you may also be asked to sign a new consent form that describes this new information.

What are my rights when participating in a research study?
You have the right to receive all information that could help you make a decision about participating in this study. You also have the right to ask any questions about this study at any time. If you are not satisfied with the answers, you have the right to say no to participating. Your privacy rights are legally protected by federal and provincial laws that require us to protect your privacy and personal information.

By signing this form you are not giving up any of your legal rights to seek compensation from the study doctor/investigator or involved institutions if you are harmed. The study doctor/investigator or their agents have legal and professional responsibilities. If you sign this form, they are still required to meet these responsibilities.

You will be given a copy of this consent form once it is signed and dated. You should keep this copy for your records.

Will I receive study results?

Research results will be shared through presentations at academic conferences and journal article publications. When the results of this study are shared, we will not reveal your identity. You have the right to find out the results of this study once the entire study is complete.

If you would like to know the results of this study, please contact the Study Doctor/Investigator. We can share the overall study results (the results from all participants put together). This means you will not know the results as they relate to you specifically.

Who can I call if I have questions about the study?
If you have any questions during your participation in this research study you can contact the Principal Investigator, Dr. Anne Kawamura at (416) 425-6220 x 3408 or the other research team members listed at the beginning of this consent form.

Research Ethics Board Contact Information

This study has been reviewed by the Holland Bloorview Research Ethics Board (REB). The REB is a group of people who help make sure that research studies are done in a way that protects the rights and wellbeing of the research participants that take part. The REB is not part of the study team. If you have any questions about your rights as a research participant, please contact the Research Ethics Office email: researchethicsboard@hollandbloorview.ca or at 416 425-6220 x 3161 during business hours.

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

1. I have been given an opportunity to ask questions and all of my questions have been answered,
2. I understand the information in this informed consent form,
3. I do not give up any of my legal rights by signing this consent form,
4. I have been told I will be given a signed and dated copy of this consent form,
5. My care/services/employment will not be affected by my decision to participate and I am free to withdraw at anytime,
6. I agree to take part in this study.

For participant consent:
I consent to participate in this study.

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

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