COMIRB
APPROVED for
EXEMPTION
25-Oct-2013

**Study Title:** **Expanding and Studying Research Based Consent via Video Conferencing**

**Principal Investigator: Joel A Friedlander D.O., M.Be.**
**Co-Investigators: Edward Hoffenberg**
**COMIRB No:** 12-0314
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**Version #:3**

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

## Why is this study being done?

This study plans to learn more about the effectiveness of informed consent in a low risk research study and to improve its ability to be obtained.

You are being asked to be in this research study because you are giving informed consent for your child to participate in the Pediatric Improve Care Now Inflammatory Bowel Disease Study or other research study of the Digestive Health Institute of the Children's Hospital of Colorado.

## Other people in this study

Up to *600* people from your area will participate in the study.

Up to *0* people around the country will be in the study.

## What happens if I join this study?

If you join the study, you will be asked to take two multiple choice surveys totaling 23 questions to assess your anxiety level and preference to participate in the study before having your study coordinator obtain consent for you child to participate a study of the DHI. You will also be asked to answer some demographic information. No personal health information will be collected.

After you give consent for your child to participate in the study you will be asked to take two multiple choice surveys totaling 45 questions to assess your anxiety level and understanding of what you gave consent for. ½ of the study participants will be asked to repeat one of the surveys 20 minutes after completing the final survey.

The total time to answer these surveys involves 10-15 minutes of your time

Study participation will be complete after finishing the last survey.

**What are the possible discomforts or risks?**

Discomforts you may experience while in this study include a slight change in your level of anxiety due to answering questions about your understanding of the study or being asked about your anxiety level. If this occurs we will supply you with a name of a mental health professional, but will not provide reimbursement for care.

Other possible risks include you may feel you did not give an adequate consent, but once the study is complete you are free to ask your study coordinator additional questions.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

The study may include risks that are unknown at this time.

**What are the possible benefits of the study?**

This study is designed for the researcher to learn more about the consent process and improve the process for other research subjects. The benefit to yourself includes the satisfaction of knowing you are helping others.

This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

**Are there alternatives?**

The alternative to participating in this study is choosing not to participate. You are under no obligation to participate in this study

**Who is paying for this study?**

The Digestive Health Institute of the Children's Hospital of Colorado is paying for this study.

**Will I be paid for being in the study?**

You will not be paid to be in the study.

**Will I have to pay for anything?**

It will not cost you anything to be in the study.

**Is my participation voluntary?**

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

**Can I be removed from this study?**

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

**Who do I call if I have questions?**

The researcher carrying out this study is Dr. **Joel Friedlander.** You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Joel Friedlander at 720-777-6669. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Joel Friedlander with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

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Name of Subject recruited:_____ Date:_____

Consent form explained by:_____ Date:_____

Print Name: _____