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Consent and Authorization Form Approval

NOV 2 2012

Date: COMIRB **Valid for Use Through:** Nov. 1, 2013

Study Title: The ImproveCareNow Collaborative

Principal Investigator: Deborah Neigut, MD
COMIRB No:
Version Date:08/31/2011
Version #: 3

You are being asked to enroll your child 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?

You are being asked to enroll your child in this research study because your child has Inflammatory Bowel Disease.

There are more than 50,000 children and adolescents in the USA and Canada who have IBD, which includes Crohn's disease and ulcerative colitis. Children and adolescents with Crohn's disease and ulcerative colitis are cared for by pediatric gastroenterologists (doctors who are specially trained in both pediatrics and gastroenterology). There are about 1000 pediatric gastroenterologists in the USA and Canada, and many of them want to improve the care given to children and adolescents with IBD by being part of the ImproveCareNow Collaborative, a network for research and quality improvement. Their goal is to reduce the pain and suffering and improve the quality of life of children and adolescents with Crohn's disease and ulcerative colitis by confidentially sharing information with each other about their patients. By collaborating in ImproveCareNow, pediatric gastroenterologists can learn from each other about the approaches to diagnosis and treatment that are most likely to make their patients better.

Other people in this study

Up to 500 children and adolescents from your area will enroll in the study. Nationally, over 2000 people at 20 practice sites, where children with IBD receive care, have enrolled in the study.

What happens if I join this study?

If you join the study, your child will continue to receive medical care from your pediatric gastroenterologist. Patients will not have any additional tests or receive any additional drugs, but the doctors will keep a record of the history, physical examination, tests (blood, urine, stool, x-ray, pathology, endoscopy, biopsy and skin tests), the medications given and the response to treatment, and send this information to the ImproveCareNow Database for analysis. The study will continue indefinitely, with data collected each time you receive care.

What are the possible discomforts or risks?

There are no additional anticipated risks or discomforts associated with being in this study.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about Pediatric Inflammatory Bowel Disease. This study is not designed to treat any illness or to improve your health.

Are there alternatives to participating in the study?

Your participation in this study is voluntary. You may refuse to participate without penalty or loss of benefits. The medical care your child receives will not be affected by your decision.

Initials_____

Will I be paid for being in the study?

You will not be paid to participate 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 for any reason. If you decide to receive care from a pediatric or adult gastroenterologist that is not from Children's Hospital Colorado , you will be removed from the study.

Who do I call if I have questions?

The researcher carrying out this study is Deborah Neigut, MD. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Neigut 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. Neigut with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver and the hospitals it works with, including Children's Hospital Colorado , have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include ("participating institutions):

- University of Colorado Denver
- Children's Hospital Colorado The ImproveCareNow Collaborative Members: (Children's Hospital Boston, MA; Children's Healthcare of Atlanta, GA; Children's Hospital of Philadelphia, PA; Children's Medical Center in Dallas, TX; Cincinnati Children's Hospital Medical Center, OH; Inova Fairfax Hospital for Children, VA; MassGeneral Hospital for Children, MA; Mayo Clinic, MN; Nationwide Children's Hospital, OH; Nemours/Alfred I. DuPont Hospital for Children, DE; Oakland Children's Hospital, CA; Pediatric Gastroenterology and Nutrition Associates, NV; Texas Children's Hospital, TX; University of Michigan Medical Center, MI; University of North Carolina, NC, UW Health, University of Oklahoma, OK; University of Wisconsin Hospital, WI; Vermont Children's Hospital at Fletcher Allen Healthcare, University of Vermont, VT)
- The Center for Health Care Quality at The Cincinnati Children's Hospital Medical Center
- The National Program Office for Quality in Pediatric Subspecialty Care

The research staff of this study will make all or some of the following health care Information about your child available to the participating institutions:

- Date of birth and gender.
- Pre-existing health information pertaining to you that the researchers will need to use in connection with the performance of the study, such as, inpatient medical records, outpatient medical records, primary care physician's notes (such as internists, family practitioners, obstetrician-gynecologists), specialist's notes (such as surgeons, oncologists, cardiologists, and others as needed). We will review your records as few years back as necessary to gather the pertinent information to perform this study. We will not access mental health records or any other sensitive information such as HIV status or genetic information.
- All of the health information resulting from the procedures you will receive in the course of this research study. More specifically, the types of procedures include a record of blood, urine, stool, x-ray, pathology, endoscopy, biopsy and skin tests, medications given and responses to treatment as part of your standard of care.

The participating institutions will not receive you or your child's names, addresses, medical record number, phone numbers, email addresses, or any identifiable information not listed in this form. We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Deborah Neigut
Children's Hospital Colorado , Gasteroenterology, Heptology and Nutrition
13123 East 16th Avenue, B-290
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and his/her team of researchers.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

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Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Investigator:_____ Date:_____

_____ Date_____
Child

Consent form explained by: _____Print Name _____ Date_____

Investigator _____ Date _____

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Date: COMIRB Valid for Use Through: Nov. 1, 2013

Study Title: The ImproveCareNow Collaborative

Principal Investigator: Deborah Neigut, MD
COMIRB No: 10-1100
Version Date: 08/31/11
Version No: 2

Informed Assent for: The ImproveCareNow Collaborative

Person In Charge of the Study: Deborah Neigut, MD
Name of Organization: Children's Hospital Colorado
COMIRB # 10-1100

What is this study about?
I am being asked if I want to be in this study. The goal of this study is to learn how doctors can improve the care they give to kids with Inflammatory Bowel Disease.

Why are you asking me?
I am being asked to be in the study because I have Inflammatory Bowel Disease

What Do I Have to Do or What Will Happen to Me?
If I am in the study, I will:

- Continue to receive normal care from my doctor.
- Information about me and my health will be collected from the computer.

Will this Hurt?
This will not hurt.

Do I get anything for being in the study?
I do not get anything for being in the study.

Can I ask Questions?
I asked any questions I have now about the study. All my questions were answered.

I know that if I have a question later, I can ask and get an answer. If I want to, I can call Dr. Neigut at 720-777-6669.

Do I Have to Do This?
I know that I do not have to in this study. No one will be mad at me if I say no. My doctor will still take care of me.

I want to be in the study at this time. ☐ yes ☐ no

I will get a copy of this form to keep.

*Child's Printed Name:*_____
*Child's Signature:*_____
*Date:*_____

*Witness or Mediator:*_____
*Date:*_____

I have explained the research at a level that is understandable by the child and believe that the child understands what is expected during this study.

*Signature of Person Obtaining Assent:*_____ *Date:*_____

*Initials:*_____