Research Study:
Using patient data to improve outcomes for children and adolescents with Inflammatory Bowel Disease

Key Information:

We hope this consent form will help you decide if you would like to join a study to improve care for children and adolescents with Crohn's Disease or ulcerative colitis (Both Crohn's Disease and ulcerative colitis are types of Inflammatory Bowel Disease or IBD). It is important that you talk about this study with your doctor and/or the research team. We can answer any questions you have.

Consenting to participate: By signing this form and giving your consent, you are agreeing to participate in the ImproveCareNow research study. When we say "you" in this form, we mean you or your child; "we" means the study doctor and other staff.

If you are 18 years and older: This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of it for your records.

COMBINED Parental Permission/Assent: The permission of parents or legal guardians is required for a child who is less than 18 years old. Your child may also be asked to "assent" (agree) if they are old enough to do so.

Investigator:
Benjamin Gold, MD FAAP, FACG

Contact Info:

404-257-0799

Reason for the study:

The main reason for this research study is to improve the care and health of children, adolescents and young adults with IBD. Your participation in this study will allow researchers to use some of the information from your regular treatment visits to improve care for patients with IBD. This study is conducted by the ImproveCareNow Network (ICN). Your doctor, as well as more than 100 other pediatric gastroenterology centers across the US, Europe and the Middle East participate in ICN. In ICN, doctors, patients, families, dietitians, nurses, and other caregivers all work together to improve the care of children with IBD. One way they do this is to study what treatments work best for which patients. For example, using information from patients like you to learn which IBD medications work best for different types of patients. Your information may also be used as part of applications to the FDA or other regulatory agencies to approve new drugs for children and youth with IBD.

In addition to this research study, ICN offers many resources to patients and families. There is more information on other ICN research projects as well as resources like toolkits for managing IBD on the ImproveCareNow Network website, improvecarenow.org. There are other patients and families like you that work together to improve care within ICN. You can learn more about how to get involved in ICN by asking your healthcare team or visiting our website.

Procedures:

We are asking your permission to use information about your health and medical status, tests, treatment, and response to treatment, as well as information about your daily experiences with IBD and your overall well-being for research. We are also asking to use dates related to your IBD care, like dates of your office visits, tests, treatments, and your birth date. In order to understand differences in IBD care that might be related to the neighborhood in which you live we are also asking for your zip code. Last, we are asking for your email address to contact you to

obtain consent should you be interested in participating in additional research studies. We will NOT use your name, medical record number, or any other personal information about you as part of this research.

If you agree, researchers may continue to use your information for research purposes until you decide that you no longer want to have your information used for research. Your information may be shared with other researchers in ImproveCareNow and possibly with outside collaborators.

Will I receive any direct benefits from participating? Your participation might benefit you and other patients by helping doctors learn what treatments work best to improve care for children with IBD. To date, medical information has been used to create new drugs, treatments and tools for doctors to provide the best care for young people with IBD, and to develop tools for patients and families to understand and manage their own condition.

Are there any risks to sharing your information for this research? The only risk to sharing your information is the very small possibility that your personal information could be seen by someone who is not part of the research team. Careful steps are taken to reduce this risk.

How is my information protected? Protecting the security and privacy of your information is extremely important to us. To protect your privacy, all records used for research are given a special code number. They are stored on secure computer systems that can only be viewed by approved researchers. All researchers must agree to follow specific ICN rules that make sure information is only used for research that may help patients. Your information may be shared with collaborating researchers across the network and others who have their studies approved by the ICN research committee.

How long will my information be used? If you agree, researchers may continue to use your information in future research unless you decide that you do not want to have your information used for research anymore.

Are there any EXTRA costs to participate? No.

Can I choose NOT to participate? Yes. We will not use your information for research without your permission.

Alternatives to participating: Your alternative to participating in this research study is not to participate. Participation in research is completely voluntary.

Will participating or NOT participating in this study negatively affect my clinical care? No. Please be assured that your doctor will continue to provide the best IBD care to you whether or not you agree to participate in the research.

Can I choose to stop having my information used for research at any time in the future? Yes. You can stop having your information used for research at any time by writing or calling your/your child's doctor, Benjamin Gold, MD. There are no consequences for stopping your participation in the study. If you decide to stop participating, all information already shared will continue to be used. None of your new information will be added or used for research.

Will I be paid or given anything extra for participating? No. You will not receive payment for taking part in this study.

Additional Study Information:
The following is more detailed information about this study in addition to the Key Information.

Your doctor is a member of the ImproveCareNow Network. ImproveCareNow is a network of thousands of doctors, other healthcare professionals and patients who are working together to improve the care and health of children, adolescents and young adults with Crohn's disease and ulcerative colitis, also called Inflammatory Bowel Disease (IBD). The ImproveCareNow doctors have established guidelines for best practices, and they measure how patients are doing and how doctors are providing care at each of the participating centers. By sharing information about all of the patients and all of the doctors, ImproveCareNow doctors are able to learn how to provide better care and achieve better health for all of the patients so that everyone can benefit.

In order to achieve these goals, all of the doctors in ImproveCareNow contribute specific information about their IBD patients to a confidential secure database. The includes information about your health and medical status (height, weight, disease location, and type), medications, treatment response, as well as any information that you provide to your doctor about your daily experience with IBD and your overall well-being as part of your routine care. These pieces of information allow doctors to track your disease over time, and to provide the best care for your individual needs.

What are we asking for today? We are asking for your permission to use some of the information that is already collected as part of your clinical care to be shared with researchers in ICN. ICN cannot use your information for research without your permission.

What information are we asking to use?
We are asking to use information about your health, your daily experiences with IBD, and your overall well-being that are typically collected at your doctor visits. We are also asking to use information about your medical care, medical tests, and treatments. This includes your age, date of birth, zip code, medical treatments, treatment dates, dates of office visits, and the results of tests.

We are also asking for your email address and phone number. By providing this, we can make sure you are told how your participation is improving care for you and others. We will use your contact information to tell you the results of the research that your information was used for, and to invite you to participate in additional research studies. We will NOT use your name, email address, or phone number for any reason other than to contact you about this research.

☐ Please initial here and provide your information below if you agree to receive updates about the research results that used your information and to be contacted to invite you to participate in additional research studies.

Email Address: _____

Phone Number: _____

☐ Please initial here if you do not wish to be contacted to receive updates about the research results that used your information or to be contacted about participating in additional research studies.

Confidentiality

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law passed to protect the privacy of your child's Protected Health Information (PHI). PHI is any information about your child that could tell someone else who your child is. "Researchers" are what we call the people who are conducting the study. Government agencies may also need to look at your child's health information; these agencies make rules and policies about how research is done. The Institutional Review Board (IRB) can also look at your child's health information.

The IRB is a committee that reviews research to make sure your child's rights and welfare are protected while being in the study. Sponsors who pay for the research also have the right to review your child's health information. Your child's health information may be disclosed if a court of law should order it. We will not use or share your child's health information in any way other than what we explain in this form. We will keep your child's health information private to the extent allowed by law. We will use a study number or other code rather than your child's name on study records when we can. Your child's name or any other fact that might point to your child will not appear if we publish the study results or make a presentation about the study.

Signing this document means you allow the researchers conducting the research to use your child's health information for this research study.

It is your choice to let the researchers use and share your child's health information. You can, at any time, change your mind about the researchers using your child's health information. If you no longer want your child's health information used or shared you must make the request in writing by signing a "Request for Withdrawal of Authorization". The researcher will give you a copy of this form to sign. This is called "withdrawing your authorization".

If you withdraw your authorization it will not affect your child's current or future health care at this hospital or office and there will be no penalty or loss of any benefits you may be otherwise entitled to. If you withdraw your authorization we will not be able to collect any new health information for research and your child will be withdrawn from the research study. However, we can continue to use the health information we have already collected as needed to protect the integrity of the research. You have the right to look at the information we collect.

However, the information from the results of the study will not be available during the study, it will be available after the study is finished.

Who will collect the information:

The research staff conducting this study will collect and copy the PHI described above. If any of the PHI is to be shared with other people, as described later in this section, then the research staff will be responsible for sharing the information.

Who else will see the information at this hospital or office:

- Children's Healthcare of Atlanta Institutional Review Board (IRB), the committee that oversees research studying people.
- Other people that work for Children's Healthcare of Atlanta who need the information to perform their job duties (for example, to provide treatment, to ensure the integrity of the research, or for accounting and billing matters).
- People that work where your child will be seen for office visits.
- Other people that work at Children's Healthcare of Atlanta who need the information to perform their job duties.
- Office for Human Research Protections (OHRP), a government agency that makes rules and policies about how research is done.
- The Food and Drug Administration (FDA), another government agency that makes rules and policies about how research is done.
- IRB's at other places where this study is being conducted.

Who should I contact if I have more questions? If you have questions about this purpose of this study, please contact Benjamin Gold, MD at 404-257-0799.

For general questions about your rights as a participant in research, for any questions, concerns, or complaints about the project, or if you would like to talk to someone who is not directly involved with the project, please call 513-636-8039 and ask to speak with the Human Subject Protection Analyst assigned to ImproveCareNow.

Statement of Consent

I have read or have had read to me the information provided above. Any questions I had about the project have been answered. If I have any more questions I can contact Benjamin Gold, MD at 404-257-0799. I understand that my permission is voluntary and that I may refuse to participate or withdraw at any time without penalty or impact on my present and/or future care.

By signing below I give my permission to allow the use of my or my child's information contained in the ImproveCareNow database for research purposes as described in this document. I will also receive a signed copy of this form for my records.

_____ _____
Participant's signature indicating consent or assent Date

_____
Participant's printed name

_____ _____
Signature of Participant's Parent or Legally Authorized Representative* Date

***If signed by a legally authorized representative, a description of such representative's authority must be provided**

_____ _____
Signature of individual obtaining permission Date