Title of research study: ***Using Patient Data to Transform Care and Improve Outcomes for Children, Adolescents and Young Adults with Inflammatory Bowel Disease***

Key Information:

The following is a summary of this study to help you decide if you want to participate. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study. We want to be sure you we answer your questions or concerns.

Investigator:
Benjamin Gold, MD FAAP, FACG

Contact Info:
404-257-0799

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: If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this form, we mean you or your child; "we" means the study doctor and other staff.

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 Crohn's disease and ulcerative colitis, also called Inflammatory Bowel Disease (IBD). 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. Many of the doctors who are part of ImproveCareNow are also interested in using the information for research purposes. The research would study things such as evaluating current IBD medications to determine which ones work best, and to develop better recommendations for the care of patients with Crohn's Disease or ulcerative colitis.

Procedures:
We are asking to use information about your health and medical status, tests, treatment, treatment response, as well as information about your daily experiences with IBD and your overall well-being. 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 the neighborhood in which you live we are also asking for your address and zip code. Lastly, 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 access your information for research purposes until you decide that you no longer want to have your information used for research.

More detailed information about the study procedures can be found under ***"(Detailed Procedures)"***

Risks to Participate:
The only risk associated with participating in this research is the potential that your personal information would be accessed by someone who is not part of the research team.

Benefits to Participate:
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include creating a resource for researchers to more quickly understand how to best care for children, adolescents and young adults with IBD.

Other Options:
Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive.

Your alternative to participating in this research study is to not participate.

Payment:
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 information shared 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. These pieces of information allow doctors to track your disease over time, and to provide the best care for your individual needs.

What is the purpose of this study? Many of the doctors who are part of ImproveCareNow are interested in also using the information for research. The research would study such things as evaluating current IBD medications to determine which ones work best, and to develop better recommendations for the care of patients with Crohn's disease or ulcerative colitis. However, ImproveCareNow cannot use your information for research without your permission. We are asking for your permission to use some of the data that is already collected as part of your clinical care for these research purposes.

What information are we asking to use? We are asking to use the information about your health and medical status, tests, treatments, treatment response, as well as information about your daily experience with IBD and your overall well-being. 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 address and zip code. Lastly, 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.

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.

How will my information be protected? Protecting the security and privacy of your data is extremely important to us. In order to protect your privacy, the only personal information that will be used for the planned research will be limited to your birth date and zip code. No other personal information will be included in data that is used for research. All records used for research will be assigned a research code number and all research data will be stored on secure confidential computer systems that can only be accessed by approved researchers with a unique username and password. Any researchers wishing to use the ImproveCareNow data for research purposes must agree to follow specific ImproveCareNow policies that restrict how the data can be used and mandate security requirements.

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.

How long will my information be used? If you agree, researchers may continue to access your information for research purposes until you decide that you no longer want to have your information used for research.

Are there any risks from allowing your information to be used for research?? The only risk associated with participating in this research is the potential that your personal information would be accessed by someone who is not part of the research team. As discussed above several rigorous steps are being taken to minimize the risk of a loss of privacy.

Will I receive any direct benefits from participating? You will not receive any immediate direct benefit from agreeing to allow us to use your information for research. However, the goal of this research is to create a resource for researchers to more quickly understand how to best care for children, adolescents and young adults with IBD. Therefore, it is anticipated that you will benefit from the results of this research in the future.

Are there any EXTRA costs to participate? No.

Will I be paid or given anything extra for participating? No

Can I choose NOT to participate in the research use of my information? Yes. As discussed earlier, we cannot use your information for this research without your permission.

Will participating or NOT participating in this study negatively affect my clinical care? No. It is important to us that you understand that as your doctor we will continue to provide the best quality IBD care regardless of whether or not you agree to allow your information to be used for research. We will still be able to take advantage of the benefits that ImproveCareNow is already providing even if you choose not to allow your information to be used for research.

Can I stop participating in the study at any time in the future? Yes. You can stop having your information used for research at any time by writing or calling Benjamin Gold, MD. There is no penalty for withdrawing and you will not lose any benefits to which you are otherwise entitled. If you decide to stop participating, all information that was already included in the database will continue to be used, but no new information will be added to the database for research purposes.

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 study participant, 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 prejudice to 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