DIRECTIONS FOR USE OF THIS TEMPLATE:

- *Required sections appear in black font.*
- *All changes made to this template must be done using **Tracked Changes**.*
- *Instructions to insert site specific information, contact information or institution name are indicated in blue colored font.*
    - *Institution Name must be the institution/university/hospital where you are recruiting subjects*
- *Do not remove the CAMEO Version Date in the footer. You should edit the local site Version Date.*
- *Review italicized highlighted instructions and insert requested information where applicable. **Delete** the instructions (including this instructions section) once information has been added.*
- *If a separate HIPAA form is required locally, remove all HIPAA related sections. Review both documents for redundancy and accuracy.*
- Please note, the Connecticut Children's IRB cannot consider general requests for modifications of the consent form(s). Only local context human subject related issues will be considered.

INFORMED CONSENT AND HIPAA AUTHORIZATION FOR PARTICIPATION IN RESEARCH ACTIVITIES

Study Title: Clinical, imaging, and endoscopic outcomes of children newly diagnosed with Crohn's disease (CAMEO): Phase 1

Site Principal Investigator: [Site PI Name] (Institution Name)

Co-Principal Investigators: Jeffrey Hyams, MD (Connecticut Children's), Lee Denson, MD (Cincinnati Children's Hospital Medical Center) and Subra Kugathasan, MD (Emory University)

Phone: [phone]

KEY INFORMATION

The following is a short summary of this study to help you decide whether to be a participant in it. 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 including having any questions or concerns answered.

What is the study about and how long will it last?

We are asking you to choose whether or not to participate in a research study about outcomes of patients newly diagnosed with Crohn's disease (CD). Crohn's disease is a condition that causes inflammation of the lining of the small intestine, large intestine, or both. Inflammation means that the small or large intestine may be red, swollen, and sore. Crohn's disease may be associated with loose stools (diarrhea), blood in the stool, abdominal cramps/pain, weight loss,

or delayed growth. This study is being conducted to determine the reasons why some children with newly diagnosed CD heal their bowel inflammation after one type of therapy and why others do not.

At this point it is not known whether you have CD, but that is likely to be further understood after the colonoscopy. If Crohn's disease is found it is likely your doctor will want to start some type of treatment. As this study will be looking at outcomes following one type of treatment it is important we examine inflammation before any treatment is given. We are asking to collect blood, stool and biopsy (tissue) samples during this study. If Crohn's disease is found most doctors will order a MRI of your abdomen (called an MRE) as part of your standard diagnostic testing. If one is not ordered we will ask you to have one for the study and it will be provided free of charge. Your participation in this phase of the research will last from the time of consent until the completion of your diagnostic procedures, and then possibly for a period of 6 months observation if you do have Crohn's disease.

What are key reasons you might choose to participate in this study?
Your participation may help further the understanding of treatment for Crohn's disease in children. If you are found to have Crohn's disease, you may be eligible for Phase 2 depending upon therapies given. Potential benefits will be reviewed at that time.

What are key reasons you might choose not to participate in this study?
All studies have some risks. For this study, this includes discomfort and infection from the blood draw. The blood draw will be done through the intravenous line that is being inserted for this procedure so there will be no extra "stick". Biopsies are being taken as a routine part of the colonoscopy, and a minimal risk of bleeding from the area where the biopsy is taken. There are several extra biopsies for this research study. The remote risk of bleeding will be explained to you by the doctor performing the test. There is also a small risk of loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Do you have to take part in the study?
If you decide to take part in the study, it should be because you want to participate in helping us answer our research objectives. You will not lose any services, benefits or rights you would normally have if you choose not to participate.

Is there compensation for participating?
You will receive up to $[site to insert the total compensation if all visits/specimen collection completed] for the completion of Phase 1 of the study by providing the biospecimens (stool, blood, biopsies) noted above.

What if you have questions, suggestions or concerns?

The person in charge of the study is [PI name]. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [phone]. If you have any questions, suggestions or concerns about your rights as a participant in this research, contact the Institutional Review Board at [institution name] at [phone].

INFORMED CONSENT AND HIPAA AUTHORIZATION FOR PARTICIPATION IN RESEARCH ACTIVITIES

If you are 18 years and older: This is a consent form. It explains this research study. Since you have recently turned 18 while in the study, we are asking if you would like to continue to participate. If you decide that you want to continue, 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:
Crohn’s disease is a condition that causes inflammation of the lining of the small intestine, large intestine, or both. Inflammation means that the small or large intestine may be red, swollen, and sore. Crohn’s disease may be associated with loose stools (diarrhea), blood in the stool, abdominal cramps/pain, weight loss, or delayed growth. This study is being conducted to determine the reasons why some children with newly diagnosed CD heal their bowel inflammation after one type of therapy and why others do not.

At this point it is not known whether you have CD, but that will be better understood after the colonoscopy. If your doctors make a diagnosis of CD, different treatment choices will be discussed. The doctors running this study are interested in being able to predict outcomes following a certain type of therapy. In order to do this, it is important that biospecimens (blood, stool, biopsy tissue) be collected before any type of therapy is started. If you are found to have Crohn’s disease, Phase 1 can continue up to 6 months while you are being observed, or until you are eligible for Phase 2. To be enrolled in Phase 2 requires that you are found to have Crohn’s disease and that you receive a certain type of medical therapy. Any therapy that you receive will be after you and your doctor discuss a variety of approaches.

By obtaining biospecimens in this study, we will also identify biomarkers for CD. Biomarkers are molecules that doctors can find in blood, stool, or bowel tissue that indicate how much

inflammation is in the bowel, how the inflammation is produced, and whether the inflammation is responding to treatment. Monitoring response to therapy along with colonoscopy and special imaging can help doctors create a model, or plan, to know which children with CD will heal the bowel with specific medical therapies.

Who is conducting this research study, and where is it being conducted?
This is a multi-center study sponsored by the National Institutes of Health (NIH) taking place at 27 medical centers in North America.

How many people will take part in the study?
Approximately 900 children in North America, ages 6 to 17 at the time of enrollment, will be asked to participate in Phase 1 of this study. At [institution name], we anticipate enrolling up to 40 patients over 3 years in Phase 1.

How long will you be in this study?
Your participation in this study will last from the time of consent until the diagnostic procedures are completed. If you do not have CD, you will no longer be in the study. If you do have CD, you will be followed for up to 6 months while initial therapies are given. If one of these therapies includes a biologic medicine (known as anti-TNF), you will be eligible for Phase 2. We will contact you at that time and review the second part of the study.

What is involved in this study?
The following procedures will take place if you decide to participate in the research study.

- Information will be collected from your medical records.
- A one-time blood sample (about 1.3 tablespoons) will be collected on the day of your colonoscopy.
- We will collect up to 8 additional biopsies for the research study during your colonoscopy. Each biopsy is smaller than a grain of rice. Taking these extra biopsies will add about 2-3 minutes to the procedure.
- You will provide a stool sample prior to the start of any therapy.
- If your doctor does not order an MRE of your intestines as part of their standard evaluation for Crohn's disease, the study will provide one at no charge.
- The research team will observe you to see if your doctor decides to start anti-TNF treatment. If you start this treatment, you may be eligible to participate in a second phase of the study.

Following a diagnosis of CD, your doctor will discuss treatments to reduce the symptoms, and hopefully cause a remission (stopping of symptoms) from the inflammation. Medical treatment does not cure CD, but can be successful in bringing on remission. Depending upon the

treatment decided by you and your doctor, you may remain in the study or leave the study as noted above.

Initial treatment: Common initial choices for therapy in a child newly diagnosed with CD include corticosteroids (steroids, prednisone) which reduce inflammation, biologic agents (anti-TNF) which are antibodies directed against important drivers of bowel inflammation, specific anti-inflammatory diets, and immune modifying drugs, which also decrease inflammation. The benefits and risks of any therapy will be discussed by your doctor and the choice of medications is up to you and your doctor. If you start an anti-TNF medication within 6 months of diagnosis then a new consent form (Phase 2) will be discussed with you.

Medical information: Information will be gathered from your medical chart. This will include information including your age at diagnosis, gender, race and ethnicity, past medical history, and any family history of CD. We will record the clinical and laboratory characteristics of your condition at the time of your diagnosis and several times during the 6 month period of observation.

Questionnaires: You will be asked to answer questions about your symptoms.

Blood Samples: If you participate in this study, about 1.3 tablespoons of blood will be taken at the time of the diagnostic colonoscopy for genetic research and immune studies. Genetic research involves isolating your genes from these sample(s). Every person has their own unique set of genes, or “genome.” Genes carry the information that helps to determine your characteristics. Genes are made up of DNA; between people, the DNA sequence of a gene can vary slightly. These differences in DNA sequence are called variants. These variants may or may not be harmful. Genes are passed down from parents to children, but sometimes genes can change between generations or because of other factors (e.g., environment). We will perform whole genome sequencing, or determine the order of DNA building blocks (nucleotides), in your genetic code. We will look for known inflammatory bowel disease risk genes as well as new genes that may be linked to anti-TNF drug levels. This blood sample is taken at the time the intravenous line is started, so there will be no additional stick.

Stool Sample: You will be asked to provide a stool sample before treatment. Stool can be collected at home and shipped directly to the study lab, or brought to the clinic to be shipped. We will use the stool samples to look at the extremely small microorganisms called microflora, which are always living inside our intestines. Proportions of these microorganisms in newly diagnosed children will be linked with genetic and immune biomarkers, and we are hoping that this new information will help us understand the response of CD to certain treatments.

Small bowel (ileum) and colon (rectum) biopsies: Patients participating in this study will have a colonoscopy requested and performed by their doctor to determine if they have Crohn’s

disease. The colonoscopy is a standard medical procedure in which a small, thin tube with a camera on the end is inserted slowly into the anus to reach the small and large intestine. Consent for the colonoscopy is separate from consenting for this study.

During this procedure, doctors have the ability to take a "biopsy," to obtain a very small tissue sample less than the size of a grain of rice from the inside of the intestine. These biopsies allow your doctor to see inflammation on a microscopic level. During a normal diagnostic colonoscopy, approximately 20-30 biopsies are taken. In addition to the routine biopsies, we will collect 4 biopsies during the colonoscopy procedure from the ileum (lower small intestine) and 4 from the rectum for research purposes. We will study the microorganisms in the lining of the bowel and perform genetic studies to examine the relationship between gene expression and bowel healing.

Video recording of the colonoscopy: While the colonoscopy is taking place, we will capture a video-image of your colonoscopy. The study doctors will review it and give it a score based on the amount of inflammation seen. The video will be labeled with your study ID and stripped of other identifiers. Your doctor will also review the video along with their own impressions from doing the study.

MRE: Your doctor may decide to order a special type of MRI imaging of the bowel to look for inflammation as part of the evaluation for Crohn's disease, called an MRE. If your doctor does not order an MRE, we will perform one free of charge for the research study. Prior to the MRE you will be given a drink, called Breeza, which helps us get better MRE images of your bowel. If Breeza is not tolerated, water may be substituted. You will be awake for the MRE scan and will be given hearing protection during the scan. The MRE will take pictures of your abdomen and last up to 45 minutes. The images will be labeled with your study ID and stripped of other identifiers before they are reviewed by study doctors.

How will my samples and information be stored and shared?

The blood, stool and biopsy specimens that are obtained during this study will initially be stored at a specimen bank at Emory University in Atlanta, Georgia. Specimens will then be shipped to different laboratories in North America for research testing.

Following the completion of the CAMEO study, specimens other than a portion of the genetic samples will be shipped to the NIDDK (National Institute of Diabetes and Digestive and Kidney Diseases) Central Repository. Part of the genetic samples will continue to be stored at Emory University. The blood, stool, and biopsy tissue will be stored at the NIDDK Central Repository and will be shared for use in future scientific research after this study is completed. The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may

have come from. It is possible that the samples will be used by for-profit institutions, and future investigators may conduct genetic or genomic analyses from study biospecimens. The samples will be retained by the NIDDK Central Repository indefinitely or until they are used up. Genomic sequencing data will be deposited in a public repository in accordance with NIH policies.

The NIDDK Central Repository will take measures to protect your privacy, although no guarantee of confidentiality can be absolute. Before the researchers in this study send samples to the NIDDK Central Repository, each sample will be given a code number. Your name and direct identifying information, such as address and medical record number, will be removed. Therefore, the NIDDK Central Repository will not be able to give out your name or other information that identifies you to the scientists who receive the samples. However, the NIH and scientists will have some data about you, such as age (in years and months), sex, diagnosis, treatments, race, and outcomes of the initial study.

Will the results of my research-related tests be available?
The research testing results from the specimen collections sent to Emory and other collaborating research labs will not be available to you.

What are the possible risks or discomforts of the study?
Specific risks of participation are noted below.

Blood draws: We will take the blood sample at the time the IV is placed for your procedure, so you do not have to have another needle stick. Taking blood may cause some pain, bleeding or bruising at the spot where the needle enters your body. Rarely, taking blood may cause fainting or infection.

Stool sample: There is no specific risk to you in obtaining a stool sample, though this may be inconvenient.

Tissue biopsies during colonoscopy: Your doctor will discuss the risks involved with the colonoscopy and anesthesia as part of standard of care. Those risks are not part of participating in this study. Your doctor will take small tissue samples called biopsies during the colonoscopy to examine the tissue for specific features of inflammation that could help make a diagnosis of Crohn's disease. It is customary to take several biopsies from the lower small bowel (ileum) as well as multiple places in the colon. In the study, the doctor will be taking 4 extra biopsies from the ileum and 4 from the rectum. Each biopsy is smaller than a grain of rice. The risk of taking biopsies is minimal.

MRE: Having an MRE may be inconvenient or uncomfortable due to having to drink the Breeza liquid, and being exposed to loud noises. Hearing protection will be provided to participants. For appropriately screened patients, there are minimal risks to MRE. Possible but very rare risks

include projectile injury, tissue heating, peripheral nerve stimulation, and claustrophobia. These are the same risks as a routine clinical MRE.

Risk of loss of confidentiality: Your privacy is of great concern to us. All study information is stored in a locked cabinet in the Gastroenterology offices when not in use. Access to the information is given only to delegated study team members. All information is entered into an electronic database that is password protected. Your information will be given a unique study identification code to keep your information confidential.

As described earlier, your data and samples from this study will be stored in NIH sample/data banks. Data, images and samples may also be shared with study collaborators working for the Investigator and be used in the future. We do not think that there will be further risks to your privacy and confidentiality by sharing your health information, samples and/or genetic information with these banks and collaborators. However, we cannot predict how genetic information and other study information will be used in the future. The samples and data will be sent with only your research code number attached. Your name or other directly identifiable information will not be given to these central banks or study collaborators, which allows the use of the information and samples without obtaining additional informed consent from you. There are many safeguards in place to protect your privacy.

What are the benefits of being part of this research study?
Participating in Phase 1 could also benefit you by covering the costs of MRE at diagnosis if your doctor does not order one for routine clinical care. This study is the first step in establishing baseline knowledge of why some children have intestinal healing following a common treatment and others do not. An improved understanding may allow doctors to build improved treatments in the future.

What happens if you decide not to take part in this study?
Participation in this study is voluntary. You do not have to take part in order to receive care at [institution name]. If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Do you need to give your consent in order to participate?
If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

Can you stop your participation in the study early?
Participating in this study means you agree to share your data and biospecimens. You can change your mind about sharing your data and biospecimens at any time. If you change your mind, please contact the study Principal Investigator in writing at: [address]. Then we will not share your data and biospecimens going forward. We will do our best to retrieve all your data

and biospecimens that have already been shared, but it may not be possible. For example, if some research with your data and biospecimens has already been done, the information from that research may still be used. We will not know which data and biospecimens are yours if the identifying information was removed. Also, if the data and biospecimens have been shared already with other researchers, it will not be possible to get them back. If you do not want your data and biospecimens used for other projects, you should not participate in this study.

Are there costs associated with the study?
You do not have to pay for any of the research study procedures. You will still be responsible for the costs of your routine clinical care (for example your colonoscopy, if you are having one).

Will I receive any payments for participating in this study?
If you agree to take part in this research study, we will compensate you for your time and effort (please see the chart below). You will receive compensation for this study in the form of [insert compensation information].

You are responsible for paying any state, federal, or other taxes on payments you receive. Since [institution name] may be required to report the amount of payment you receive to the Internal Revenue Service (IRS), you may be asked to complete a W-9 form in order to receive payment.
Replace the compensation amounts in this section with your local incentive amount, based on ranges provided below.

Type of sample provided	Compensation amount
Blood	$10-15
Stool	$15-25
Biopsy	$20-35
Total for Participation	**$45-75**

Who owns my study information and samples?
During the study, the study group will be responsible for the data and samples, and will make decisions about how these are used. After the study concludes, the NIDDK Central Repository will be responsible for the data and samples and make decisions about how these are used and shared in secondary research. If you join this study, you will be donating your samples and study information; you will not receive any financial benefits. NIH-NIDDK and the study group do not financially profit in any way from this research.

How is my genetic information protected? What are the risks?
The Genetic Information Nondiscrimination Act (GINA) is a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the

following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.

In Case of Injury:

Replace text in this section with specific hospital injury/compensation language if required.

If you have an injury or health problem that is directly related to taking part in this study, please contact the Principal Investigator immediately at [phone]. Treatment for injuries or health problems related to this study is available at [institution name]. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. You do not give up any of your legal rights by signing this consent form.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

You may insert your sites additional required HIPAA/Privacy statements or use the following language. If a separate HIPAA form is required locally, remove this HIPAA related section entirely.

As part of this research, health information about you will be collected. This will include information from medical records, procedures, and questionnaires. Information related to your medical care at [institution] will go in your medical record. This could include physical exams, imaging studies (x-rays or MRE scans) or tests done in the clinical lab.

Medical records are available to staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. Medical information that is collected from this study and is determined to be pertinent to your care at [institution name] or [institution name] affiliates or subsidiaries may become part of your medical record.

We will do our best to keep your personal information private and confidential. However, we

cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

The study doctor and research staff will give identifiable health information about you to the sponsor and people or companies working for the sponsor or Investigator (for example, research monitors and auditors, clinical laboratories that may perform testing or other clinical services for this study).They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at [institution name]
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections
- The National Institutes of Health who is sponsoring this research
- The Food and Drug Administration
- Groups monitoring the safety of this study, such as the Data Safety Monitoring Board
- The Data Coordinating Center at the University of North Carolina Chapel Hill
- The Clinical Coordinating Center at Connecticut Children's
- Your samples/data will be shared with outside laboratories including Emory University, Broad Institute, and Georgia Tech, who will analyze and store your samples.
- Alimentiv, a study collaborator who will assist with colonoscopy recordings and scoring
- Motilent, a study collaborator who will assist with storing MRE images
- Cincinnati Children's Hospital Medical Center, Emory University, and Toronto SickKids Hospital, who will assist with scoring MRE images

By law, [institution name] is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing [institution name] to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study.

Your permission to use and share the health information and data from this study will continue until the research study ends and will not expire. Researchers will continue to analyze data for many years and it is not possible to know when they will be completely finished.

Certificate of Confidentiality (CoC)
A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information cannot be used as evidence even if there is a court subpoena.

If you consent, your data or biological samples could be shared for other scientific research.

The CoC does not prevent some disclosures.

- The researchers cannot refuse requests for information from those funding this research. The National Institutes of Health may need information to assess this project.
- The US Food and Drug Administration (FDA) may need information.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?
You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

[PI name and address]

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

If you agree to participate in the CAMEO study, you can change your mind up until the end of the study. If study researchers receive written instructions from you, they will stop collecting samples and information from you. However, we will retain and use samples and data collected up to that point to maintain scientific validity. After the study ends, you will not be able to withdraw your sample because the central repository at NIDDK will not know which one is yours. The sample will stay in the central repository at NIDDK indefinitely.

Additional Information
A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.

What if you have questions about the study?

I can call…	At	If I have questions or concerns about
Investigator: [PI name]	Phone: **[phone]**	▪ General questions about the research ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Coordinator: [name]	Phone: **[phone]**	▪ General questions about the study ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Institutional Review Board providing oversight for all participating sites: Connecticut Children's Institutional Review Board	Phone: **860-837-5515**	▪ Rights of a research participant ▪ Use of protected health information. ▪ Compensation in event of research-related injury ▪ Any research-related concerns or complaints. ▪ If investigator/research contact cannot be reached. ▪ If I want to speak with someone other than the Investigator, Research Contact or research staff.
Local Institutional Review Board:	Phone: **[phone]**	

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Documentation of Informed Consent and Authorization

- **I have read this consent form and was given enough time to consider the decision to participate in this research.**
- **This research has been satisfactorily explained to me, including possible risks and benefits.**

- **All my questions were satisfactorily answered.**
- **I understand that participation in this research is voluntary and that I can withdraw at any time.**
- **I am signing this consent form prior to participation in any research activities.**
- **I give permission for participation in this research and for the use of associated protected health information as described above (HIPAA).**

If the child to be involved in this research is a foster child or a ward of the state please notify the researcher or their staff who is obtaining your consent.

Name of Participant	
Signature of Participant (18 years or older)	Date
Name of Authorized Representative (if different than participant)	Relationship to participant: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

Research Investigator /or Associate's Statement & Signature

- **I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant /parents/legal guardian as applicable).**
- **I have answered and will answer all questions to the best of my ability.**
- **I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.**

- **I have provided a copy of the consent form signed by the participant / parent / guardian and a copy of the hospital's privacy notification (if requested).**

Date Signature of **Research Investigator or Associate**

Witness Statement & Signature

A witness must be present for the entire consent process in the following situations (please check the appropriate box)

☐ The individual is not English speaking and, through an interpreter, a short form consent document was presented orally to the participant or legal representative and this consent document serves as the summary for such consent.

I confirm that the information in this consent form was presented orally to the participant, parent or legally authorized representative, in a language they could understand and the individual had the opportunity to ask questions.

Date Signature of Witness

ASSENT
Ages 7-17

Why are you being ask to take part in this study?
Your doctor and parents have talked to you about being part of a study of kids that might have something called Crohn's disease. We want to learn more about Crohn's disease. We also want to find out what may help kids with Crohn's disease heal inflammation in their colon. Right now we do not know if you have Crohn's disease. That is why you are having the colonoscopy and stool studies.

What will happen to you while you are taking part in the study?
During your colonoscopy, the doctor will look at your colon through a long tube with a camera on the end. They will take biopsies of the colon to look at under the microscope. A biopsy is where they take a small piece of tissue, about the size of a grain of rice. The doctor will take 8 extra biopsies for the research study. We will also take about 1.3 tablespoons of blood for the study, and ask you to collect a stool sample at home.

Around the time of your colonoscopy, you may also have an MRI exam if you have not already had one. This is a special type of MRI called an MRE that will take pictures of your abdomen and lasts up to 45 minutes. Prior to the MRE you will be given a drink, called Breeza, which helps us get better MRE images of your bowel. You will be awake for the MRE scan and will be given hearing protection during the scan.

The tests are being done to see whether there is inflammation suggesting you have Crohn's disease, and if so, how much inflammation there is. Also, we will ask some questions about how you are feeling. Your doctor will follow how you are doing for up to 6 months.

Will any part of the research study hurt you?
You will need to have an IV put in for the colonoscopy procedure. The IV is for your colonoscopy, not this research project. An IV is a tiny tube that will be placed in your vein so that you can have medicine. We will take the blood sample from this tube, so there will be no additional needles for the study. You will be sleeping when the doctor takes the biopsies, and you will not feel it.

Will the research study help you or anyone else?
This study will help us learn more about Crohn's disease and help other kids in the future. You will receive up to $[site to insert the total compensation if all visits/specimen collection completed] for providing your specimens to the study.

Can you say no?
You can decide not to be in this study, or after entering the study you can decide that you want to be taken out of it. Whatever you decide to do, your doctor will not be angry with you and will continue to treat you as his/her patient.

What if you have questions?
You may ask questions about this study at any time. If you have a question later that you do not think of now, you can call Dr. [name] at [phone number].

Confidentiality:
Your information relating to this study will be given to a coordinating center in North Carolina and/or to the National Institute of Health, FDA (Food and Drug Administration) Connecticut Children's Medical Center IRB (Institutional Review Board), and the Research Monitor at Connecticut Children's Medical Center. Your identity will remain a secret, unless the law says we have to reveal it.

Assent

_____ _____

Signature of **Child/Adolescent Participant** Date

If child/adolescent's assent is **not** documented above, please indicate reason below (check one):

☐ Assent is documented on a separate IRB-approved assent form

☐ Child is too young

☐ Other reason (e.g. sedated), please specify:

_____

Form approved on: **04/03/2023**

DIRECTIONS FOR USE OF THIS TEMPLATE:

- *Required sections appear in black font.*
- *All changes made to this template must be done using **Tracked Changes**.*
- *Instructions to insert site specific information, contact information or institution name are indicated in blue colored font.*
    - *Institution Name must be the institution/university/hospital where you are recruiting subjects*
- *Do not remove the CAMEO Version Date in the footer. You should edit the local site Version Date.*
- *Review italicized highlighted instructions and insert requested information where applicable. **Delete** the instructions (including this instructions section) once information has been added.*
- *If a separate HIPAA form is required locally, remove all HIPAA related sections. Review both documents for redundancy and accuracy.*
- Please note, the Connecticut Children's IRB cannot consider general requests for modifications of the consent form(s). Only local context human subject related issues will be considered.

INFORMED CONSENT AND HIPAA AUTHORIZATION FOR PARTICIPATION IN RESEARCH ACTIVITIES

Study Title: Clinical, imaging, and endoscopic outcomes of children newly diagnosed with Crohn's disease (CAMEO): Phase 2

Site Principal Investigator: [Site PI Name] (Institution Name)

Co-Principal Investigators: Jeffrey Hyams, MD (Connecticut Children's), Lee Denson, MD (Cincinnati Children's Hospital Medical Center) and Subra Kugathasan, MD (Emory University)

Phone: [phone]

KEY INFORMATION

The following is a short summary of this study to help you decide whether to be a participant in it. 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 including having any questions or concerns answered.

What is the study about and how long will it last?

We are asking you to choose whether or not to participate in a research study about outcomes of patients newly diagnosed with Crohn's disease (CD). Your doctor has made a diagnosis of Crohn's disease and a decision has been made with your doctor to use an anti-TNF medication for treatment. The study will provide testing to determine the level of the anti-TNF medicine in

your blood and will then use a computer program to suggest dosing to your doctor to achieve what are believed to be optimal (the best) drug levels in your body. The final decision on dosing is always up to your doctor. The study also includes collecting blood when you would normally have blood tests done, stool collection, and biopsy tissue collection when your doctor does a follow-up colonoscopy in a year to assess response to treatment. Lastly, the study also provides an MRI of your abdomen (called an MRE) at one year if your doctor does not order one for routine clinical care. Your participation in the study will last approximately one year.

What are key reasons you might choose to participate in this study?
Your participation may help further the understanding of treatment for Crohn's disease in children. This study will provide free tests to check your anti-TNF drug level as well as an MRE at one year, which may benefit you if your insurance does not fully cover the MRE.

What are key reasons you might choose not to participate in this study?
All studies have some risks. For this study, this includes discomfort and infection from the blood draw. The blood draw will be done through the intravenous line that is being inserted, or during a routine blood draw, so there will be no extra "stick." Biopsies are being taken as a routine part of the colonoscopy. There are several extra biopsies for this research study. The remote risk of bleeding will be explained to you by the doctor performing the test. There is also a small risk of loss of privacy and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Do you have to take part in the study?
If you decide to take part in the study, it should be because you want to participate in helping us answer our research objectives. You will not lose any services, benefits or rights you would normally have if you choose not to participate.

Is there compensation for participating?
You will receive up to $[site to insert the total compensation if all visits/specimen collection completed] for the completion of Phase 2 of the study by providing the biospecimens (stool, blood, biopsies) noted above.

What if you have questions, suggestions or concerns?
The person in charge of the study is [PI name]. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [phone]. If you have any questions, suggestions or concerns about your rights as a participant in this research, contact the Institutional Review Board at [institution name] at [phone].

INFORMED CONSENT AND HIPAA AUTHORIZATION FOR PARTICIPATION IN RESEARCH ACTIVITIES

If you are 18 years and older: This is a consent form. It explains this research study. Since you have recently turned 18 while in the study, we are asking if you would like to continue to participate. If you decide that you want to continue, 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:
Crohn's disease is a condition that causes inflammation of the lining of the small intestine, large intestine, or both. Inflammation means that the small or large intestine may be red, swollen, and sore. Crohn's disease may be associated with loose stools (diarrhea), blood in the stool, abdominal cramps/pain, weight loss, or delayed growth. This study is being conducted to determine the reasons why some children with newly diagnosed CD heal their bowel inflammation after being treated with anti-TNF therapy and why others do not.

You and your doctor have discussed treatment options and have decided to use an anti-TNF agent. Anti-TNF agents can be given by intravenous infusion or by shots. No matter what type of anti-TNF therapy you get, we know that monitoring the level of the medicine in your blood will tell us if we are giving enough. While we have standard doses that we usually start with, we know that at least 50% of the time we need to make adjustments to dosing based on symptoms, laboratory tests, and blood level monitoring. Checking blood levels of anti-TNF therapy is now standard practice for children with Crohn's disease. In the CAMEO study, we will be checking the level of these medicines at key times. We will use a computer algorithm (program) called the RoadMAB™ Clinical Decision Support Tool that will suggest the best dose going forward based on your blood level, disease activity, weight, and standard blood tests reflecting inflammation. We believe this will optimize the treatment for participants, and help us to learn about other factors that influence healing. The final decision on dosing will always be left up to your doctor.

We will ask for small samples of blood when you normally have a blood test or intravenous line placed to measure biomarkers of inflammation. We will also ask you to collect stool samples so we can measure markers of inflammation as well as amounts of microbes (germs) in your intestine. Our goal in the treatment of Crohn's disease is to heal the bowel. The way we determine if the bowel has healed is with a colonoscopy and an MRE one year after you start

the anti-TNF therapy. These tests are considered standard of care for the treatment of pediatric Crohn's disease. The CAMEO study will provide the blood tests monitoring your anti-TNF levels for free as well as the MRE at one year if your doctor does not order one for routine clinical care.

Observing the response to therapy, anti-TNF blood levels, results of colonoscopy and special imaging can help doctors create a model (or plan) to know which children with CD will heal the bowel with this therapy.

Who is conducting this research study, and where is it being conducted?
This is a multi-center study sponsored by the National Institutes of Health (NIH) taking place at 27 medical centers in North America that specialize in the treatment of children with Crohn's disease.

How many people will take part in the study?
Approximately 550 children in North America, ages 6 to 17 at the time of enrollment, will be asked to participate in Phase 2 of this study. At the [institution name], we anticipate enrolling up to 40 patients over three years in Phase 2.

How long will you be in this study?
Your participation in this study will last from the time of consent until the follow-up procedures are completed at one year. As the CAMEO study is finishing, we will review your medical record for your current condition and therapies.

What is involved in this study?
The following procedures will take place if you decide to participate in the research study.

- Information will be collected from your medical records.
- You will be asked to complete a symptom questionnaire several different times.
- You will provide blood samples taken in connection to receiving your medication.
    - We will check the level of the anti-TNF in your blood. Your doctor will use RoadMAB to adjust the dose of your medication.
- You will provide stool samples.
- We will collect up to 8 additional biopsies for the research study during your routine colonoscopy at one year after starting therapy. This is the same procedure and number of research biopsies as when the original colonoscopy was performed. Each biopsy is smaller than a grain of rice. Taking these extra biopsies will add about 2-3 minutes to the procedure.
- You will be asked to have an MRE scan of your abdomen approximately one year after starting anti-TNF treatment. If your doctor does not order an MRE of your intestines as

part of their standard re-evaluation, the study will provide one at no charge.

- The research team will observe you to document your progress during the anti-TNF treatment.
- There will be diet interviews by phone at various time points in the study.

Medical information: Information will be gathered from your medical chart including your clinical condition, laboratory tests, colonoscopy results, MRE results, medicine dosing, and any other medical issues you might have during the study.

Questionnaires: You will be asked to answer questions about your symptoms at several different time points.

Blood Samples: If you participate in this study, up to 1.3 tablespoons of blood will be taken for the study at four time points during the study. This blood will be used to study your immune system and to measure the level of anti-TNF drug in your body. This blood sample is taken at the time the intravenous line is started or at the time you are having another routine blood test, so there will be no additional stick for the research study. If you are receiving adalimumab (Humira), we will try to perform the blood test at the time of routine blood work whenever possible.

Anti-TNF treatment: Anti-TNF agents are now commonly used and approved by the US Food and Drug Administration (FDA) for the treatment of Crohn's disease in children 6 years of age and older. In the CAMEO study, we will be checking the blood level of these medicines at key times. We will use a computer algorithm called RoadMAB that will suggest the best dose going forward. RoadMAB is based on the most current knowledge about anti-TNF therapy. The final decision about your dose will be up to your doctor.

Stool Sample: You will be asked to provide a stool sample at three time points during the study. Stool can be collected at home and shipped directly to the study lab, or brought to the clinic to be shipped. We will use the stool samples to look at the extremely small microorganisms called microflora, which are always living inside our intestines. Proportions of these microorganisms in newly diagnosed children will be linked with genetic and immune biomarkers, and we are hoping that this new information will help us understand the response of CD to anti-TNF therapy.

Small bowel (ileum) and colon (rectum) biopsies: A colonoscopy is performed for routine clinical care to check for healing after one year of therapy (or earlier, if needed). During this procedure, doctors have the ability to take a "biopsy," to obtain a very small tissue sample less than the size of a grain of rice from the inside of the intestine. These biopsies allow your doctor to see inflammation on a microscopic level. During a normal diagnostic colonoscopy, approximately 20-30 biopsies are taken. In addition to the routine biopsies, we will collect 4 biopsies during the

colonoscopy procedure from the ileum (lower small intestine) and 4 from the rectum for research purposes. We will study the microorganisms in the lining of the bowel and perform genetic studies of this tissue.

Genetic research involves isolating your genes from their sample(s). Every person has their own unique set of genes, or "genome." Genes carry the information that helps to determine your characteristics. Genes are made up of DNA; between people, the DNA sequence of a gene can vary slightly. These differences in DNA sequence are called variants. These variants may or may not be harmful. Genes are passed down from parents to children, but sometimes genes can change between generations or because of other factors (e.g., environment). We will look at the pattern of gene expression in the biopsy tissue in relationship to bowel healing.

Video recording of the colonoscopy: While the colonoscopy is taking place, we will capture a video-image of your colonoscopy. The study doctors will review it and give it a score based on the amount of inflammation seen. The video will be labeled with your study ID and stripped of other identifiers. Your doctor will also review the video along with their own impressions from doing the study.

MRE: Approximately 1 year after starting treatment, your doctor may decide to order a special type of imaging called an MRE of your abdomen to look for healing as part of routine care for Crohn's disease. If your doctor does not order an MRE, we will perform one free of charge for the research study. Prior to the MRE you will be given a drink, called Breeza, which helps us get better MRE images of your bowel. If Breeza is not tolerated, water may be substituted. You will be awake for the MRE scan and will be given hearing protection during the scan. The MRE will take pictures of your abdomen and last up to 45 minutes. The images will be labeled with your study ID and stripped of other identifiers before they are reviewed by study doctors.

24-hour dietary recall: During the study, there will be diet interviews (approximately 9) where you will be asked to report what you had to eat for the past 24 hours. This is called a "24-hour dietary recall." This recall may be completed over the phone or at a study visit. Expert interviewers from Cincinnati Children's Hospital Medical Center and the Medical College of Wisconsin will be conducting these interviews.

How will my samples and information be stored and shared?

The blood, stool and biopsy specimens that are obtained during this study will initially be stored at a specimen bank at Emory University in Atlanta, Georgia. Specimens will then be shipped to different laboratories in North America for research testing. Following the completion of the CAMEO study, specimens other than a portion of the genetic samples will be shipped to the NIDDK (National Institute of Diabetes and Digestive and Kidney Diseases) Central Repository. Part of the genetic samples will continue to be stored at Emory University.

The blood, stool, and biopsy tissue will be stored at the NIDDK Central Repository and will be shared for use in future scientific research after this study is completed. The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from. It is possible that the samples will be used by for profit institutions, and future investigators may conduct genetic or genomic analyses from study biospecimens. The samples will be retained by the NIDDK Central Repository indefinitely or until they are used up. Genomic sequencing data will be deposited in a public repository in accordance with NIH policies.

The NIDDK Central Repository will take measures to protect your privacy, although no guarantee of confidentiality can be absolute. Before the researchers in this study send samples to the NIDDK Central Repository, each sample will be given a code number. Your name and direct identifying information, such as address and medical record number, will be removed. Therefore, the NIDDK Central Repository will not be able to give out your name or other information that identifies you to the scientists who receive the samples. However, the NIH and scientists will have some data about you, such as age (in years and months), sex, diagnosis, treatments, race, and outcomes of the initial study.

Will the results of my research-related tests be available?
Your doctor will receive the results of the anti-TNF blood level tests and MRE and this information will be shared with you. Your doctor will use the RoadMAB program to guide anti-TNF dosing, and may share the recommended dose with you. The final decision about your anti-TNF dose will be up to your doctor and you, and will be shared with you.

The research testing results from the specimen collections sent to Emory and other collaborating research labs will not be available to you.

What are the possible risks or discomforts of the study?
Specific risks of participation are noted below.

Blood draws: Whenever possible, we will take blood samples at the time an IV is placed for routine care or when you are having another routine blood test so you do not have to have another needle stick. Taking blood may cause some pain, bleeding or bruising at the spot where the needle enters your body. Rarely, taking blood may cause fainting or infection.

Stool sample: There is no specific risk to you in obtaining a stool sample, though this may be inconvenient.

Tissue biopsies during colonoscopy. Your doctor will discuss the risks involved with the colonoscopy and anesthesia as part of standard of care. Those risks are not part of participating in this study. Your doctor will take small tissue samples called biopsies during the colonoscopy to examine the tissue for specific features of inflammation that help us follow your progress on anti-TNF therapy. It is customary to take several biopsies from the lower small bowel (ileum) as well as multiple places in the colon. In the study, the doctor will be taking 4 extra biopsies from the ileum and 4 from the rectum. Each biopsy is smaller than a grain of rice. The risk of taking biopsies is minimal.

MRE: Having an MRE may be inconvenient or uncomfortable due to having to drink the Breeza liquid, and being exposed to loud noises. Hearing protection will be provided to participants. For appropriately screened patients, there are minimal risks to MRE. Possible but very rare risks include projectile injury, tissue heating, peripheral nerve stimulation, and claustrophobia. These are the same risks as a routine clinical MRE.

Risk of loss of confidentiality: Your privacy is of great concern to us. All study information is stored in a locked cabinet in the Gastroenterology offices when not in use. Access to the information is given only to delegated study team members. All information is entered into an electronic database that is password protected. Your information will be given a unique study identification code to keep your information confidential.

As described earlier, your data and samples from this study will be stored in NIH sample/data banks. Data, images and samples may also be shared with study collaborators working for the Investigator and be used in the future. We do not think that there will be further risks to your privacy and confidentiality by sharing your health information, samples and/or genetic information with these banks and collaborators. However, we cannot predict how genetic information and other study information will be used in the future. The samples and data will be sent with only your research code number attached. Your name or other directly identifiable information will not be given to these central banks or study collaborators, which allows the use of the information and samples without obtaining additional informed consent from you. There are many safeguards in place to protect your privacy.

What are the benefits of being part of this research study?

We believe this study is an important step in establishing baseline knowledge of why some children have intestinal healing following anti-TNF therapy and others do not. An improved understanding may allow doctors to build improved treatments in the future. As part of this study, you will receive personalized dosing recommendations for your therapy that would not otherwise be available outside of the study. We believe that this personalized dosing may optimize your treatment with anti-TNF therapy. Participating in Phase 2 could also benefit you by covering the costs of the tests to monitor the level of medicine in your blood as well as the

MRE at one year if your doctor does not order one for routine clinical care.

What happens if you decide not to take part in this study?
Participation in this study is voluntary. You do not have to take part in order to receive care at [institution name]. If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled. If you do not participate in CAMEO, treatment will be at the discretion of the treating physician. You may still receive treatment with an anti-TNF agent; however, the RoadMAB™ Clinical Decision Support Tool is not available outside of the study.

Do you need to give your consent in order to participate?
If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

Can you stop your participation in the study early?
Participating in this study means you agree to share your data and biospecimens. You can change your mind about sharing your data and biospecimens at any time. If you change your mind, please contact the study Principal Investigator in writing at: [Site PI name and address]. Then we will not share your data and biospecimens going forward. We will do our best to retrieve all your data and biospecimens that have already been shared, but it may not be possible. For example, if some research with your data and biospecimens has already been done, the information from that research may still be used. We will not know which data and biospecimens are yours if the identifying information was removed. Also, if the data and biospecimens have been shared already with other researchers, it will not be possible to get them back. If you do not want your data and biospecimens used for other projects, you should not participate in this study.

Are there costs associated with the study?
There are no costs to you to participate in this study. You will still be responsible for the costs of your routine clinical care (for example your colonoscopy, if you are having one).

Will I receive any payments for participating in this study?
If you agree to take part in this research study, we will compensate you for your time and effort (please see the chart below). You will receive compensation for this study in the form of [insert compensation information].

You are responsible for paying any state, federal, or other taxes on payments you receive. Since [Institution name] may be required to report the amount of payment you receive to the Internal Revenue Service (IRS), you may be asked to complete a W-9 form in order to receive payment.

Replace the compensation amounts in this section with your local incentive amount, based on ranges provided below.

Type of sample provided	Compensation amount	Maximum number of times collected	Total compensation
Blood	$10-15	3	$30-45
Stool	$15-25	3	$45-75
Biopsy	$20-35	1	$20-35
Total for participation			**$95-155**

Who owns my study information and samples?
During the study, the study group will be responsible for the data and samples, and will make decisions about how these are used. After the study concludes, the NIDDK Central Repository will be responsible for the data and samples and make decisions about how these are used and shared in secondary research. If you join this study, you will be donating your samples and study information; you will not receive any financial benefits. NIH-NIDDK and the study group do not financially profit in any way from this research.

How is my genetic information protected? What are the risks?
The Genetic Information Nondiscrimination Act (GINA) is a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.

In Case of Injury:
Replace text in this section with specific hospital injury/compensation language if required.
If you have an injury or health problem that is directly related to taking part in this study, please contact the Principal Investigator immediately at [phone]. Treatment for injuries or health

problems related to this study is available at [institution name]. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. You do not give up any of your legal rights by signing this consent form.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality? *You may insert your sites additional required HIPAA/Privacy statements or use the following language. If a separate HIPAA form is required locally, remove this HIPAA related section entirely.*

As part of this research, health information about you will be collected. This will include information from medical records, procedures, and questionnaires. Information related to your medical care at [institution name] will go in your medical record. This could include physical exams, imaging studies (x-rays or MRE scans) or tests done in the clinical lab.

Medical records are available to staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. Medical information that is collected from this study and is determined to be pertinent to your care at [institution name] or [institution name] affiliates or subsidiaries may become part of your medical record.

We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

The study doctor and research staff will give identifiable health information about you to the sponsor and people or companies working for the sponsor or Investigator (for example, research monitors and auditors, clinical laboratories that may perform testing or other clinical services for this study).They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at [institution name]
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections

- The National Institutes of Health who is sponsoring this research
- The Food and Drug Administration
- Groups monitoring the safety of this study, such as the Data Safety Monitoring Board
- The Data Coordinating Center at the University of North Carolina Chapel Hill
- The Clinical Coordinating Center at Connecticut Children's
- Your samples/data will be shared with outside laboratories including Emory University, LabCorp, Broad Institute, and Georgia Tech, who will analyze and store your samples.
- Alimentiv, a study collaborator who will assist with colonoscopy recordings and scoring.
- Motilent, a study vendor who will assist with storing MRE images
- Radiologists at Cincinnati Children's Hospital Medical Center, Emory University, and Toronto SickKids Hospital, who will assist with scoring MRE images
- Dieticians at Cincinnati Children's Hospital Medical Center and Medical College of Wisconsin, who will be conducting the diet interviews

By law, [institution name] is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing [institution name] to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study.

Your permission to use and share the health information and data from this study will continue until the research study ends and will not expire. Researchers will continue to analyze data for many years and it is not possible to know when they will be completely finished.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information cannot be used as evidence even if there is a court subpoena.

If you consent, your data or biological samples could be shared for other scientific research.

The CoC does not prevent some disclosures.

- The researchers cannot refuse requests for information from those funding this research.

The National Institutes of Health may need information to assess this project.

- The US Food and Drug Administration (FDA) may need information.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?
You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

[PI name and address]

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

If you agree to participate in the CAMEO study, you can change your mind up until the end of the study. If study researchers receive written instructions from you, they will stop collecting samples and information from you. However, we will retain and use samples and data collected up to that point to maintain scientific validity. After the study ends, you will not be able to withdraw your sample because the central repository at NIDDK will not know which one is yours. The sample will stay in the central repository at NIDDK indefinitely.

Additional Information
A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.

What if you have questions about the study?

I can call…	At	If I have questions or concerns about
Investigator: [PI name]	Phone: **[phone]**	▪ General questions about the research ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Coordinator:	Phone: **[phone]**	▪ General questions about the study

[name]		▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Institutional Review Board providing oversight for all participating sites: Connecticut Children's Institutional Review Board	Phone: **860-837-5515**	▪ Rights of a research participant ▪ Use of protected health information. ▪ Compensation in event of research-related injury ▪ Any research-related concerns or complaints. ▪ If investigator/research contact cannot be reached. ▪ If I want to speak with someone other than the Investigator, Research Contact or research staff.
Local Institutional Review Board:	Phone: **[phone]**	

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Documentation of Informed Consent and Authorization

- **I have read this consent form and was given enough time to consider the decision to participate in this research.**
- **This research has been satisfactorily explained to me, including possible risks and benefits.**
- **All my questions were satisfactorily answered.**
- **I understand that participation in this research is voluntary and that I can withdraw at any time.**
- **I am signing this consent form prior to participation in <u>any</u> research activities.**
- **I give permission for participation in this research and for the use of associated protected health information as described above (HIPAA).**

If the child to be involved in this research is a <u>foster child</u> or a <u>ward of the state</u> please notify the researcher or their staff who is obtaining your consent.

Name of Participant	
Signature of Participant (18 years or older)	Date
Name of Authorized Representative (if different than participant)	Relationship to participant: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

Research Investigator /or Associate's Statement & Signature

- **I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant /parents/legal guardian as applicable).**
- **I have answered and will answer all questions to the best of my ability.**
- **I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.**
- **I have provided a copy of the consent form signed by the participant / parent / guardian and a copy of the hospital's privacy notification (if requested).**

Date	Signature of **Research Investigator or Associate**

Witness Statement & Signature

A witness must be present for the entire consent process in the following situations (please check the appropriate box)

☐ The individual is not English speaking and, through an interpreter, a short form consent document was presented orally to the participant or legal representative and this consent document serves as the summary for such consent.

I confirm that the information in this consent form was presented orally to the participant, parent or legally authorized representative, in a language they could understand and the individual had the opportunity to ask questions.

Date Signature of Witness

ASSENT
Ages 7-17

Why are you being ask to take part in this study?
Your doctor and parents have talked to you about being part of a study of kids that have Crohn's disease. We want to find out what may help kids with Crohn's disease heal inflammation in their intestine when they are taking a certain type of medicine called an anti-TNF. Your doctor has prescribed this medicine to you to help you with your Crohn's disease.

What will happen to you while you are taking part in the study?
The study staff will follow you over the first year that you are taking an anti-TNF for Crohn's disease. During the study at certain time points the doctor will take up to 1.3 tablespoons of blood for the study. This will only happen when we would normally be collecting blood for testing. At certain times we will ask you to collect a stool sample at home and ship it to the study lab.

Toward the end of the year, when the doctor looks at your colon through a long tube with a camera on the end, they will take biopsies of the intestine to look at under the microscope. A biopsy is where they take a small piece of tissue, about the size of a grain of rice. The doctor will take 8 extra biopsies for the research study.

Around the end of the year, you may also have an MRI exam of your abdomen. This is a special type of MRI called an MRE that will take pictures of your abdomen and lasts up to 45 minutes. Prior to the MRE you will be given a drink, called Breeza, which helps us get better MRE images of your bowel. You will be awake for the MRE scan and will be given hearing protection during the scan.

Also, we will ask some questions about how you are feeling. On several occasions during the study, we will also ask you to tell us about what you ate on the previous day. The study tests are done to see how your Crohn's disease is doing and to get information about how the disease works and how the anti-TNF medicine may be helping to heal the intestine.

Will any part of the research study hurt you?
If you are taking an IV anti-TNF medication, you will need to have an IV put in your arm. The IV is for your medicine, not the study. An IV is a tiny tube that will be placed in your vein so that you can have medicine. We will take the blood sample from this tube, so there will be no additional needles for the study. If you are taking your medicine through a shot, we will try to get the blood sample at the same time as you get other blood tests done. You will be sleeping when the doctor takes the biopsies during the colonoscopy, and you will not feel it.

Will the research study help you or anyone else?
This study will provide you with tests for your doctor to see how much medicine is in your body, as well as an MRE exam to see how your bowel has healed. The MRE is provided if your doctor does not already order it for clinical care. The study will help us learn more about Crohn's disease and help other kids in the future. You will receive up to $[site to insert the total compensation if all visits/specimen collection completed] for providing your specimens for the

study.

Can you say no?
You can decide not to be in this study, or after entering the study you can decide that you want to be taken out of it. Whatever you decide to do, your doctor will not be angry with you and will continue to treat you as his/her patient.

What if you have questions?
You may ask questions about this study at any time. If you have a question later that you do not think of now, you can call Dr. [name] at [phone number].

Confidentiality:
Your information relating to this study will be given to a coordinating center in North Carolina and/or to the National Institute of Health, FDA (Food and Drug Administration) Connecticut Children's Medical Center IRB (Institutional Review Board), and the Research Monitor at Connecticut Children's Medical Center. Your identity will remain a secret, unless the law says we have to reveal it.

Assent

_____ _____

Signature of **Child/Adolescent Participant** Date

If child/adolescent's assent is **not** documented above, please indicate reason below (check one):

☐ Assent is documented on a separate IRB-approved assent form

☐ Child is too young

☐ Other reason (e.g. sedated), please specify:

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