

## **Informed Consent**

**Feasibility of a care team-focused action plan to improve quality of care for children and adolescents with inflammatory bowel disease**

**NCT number** NCT06186752  
**Document Date** 11/10/2023

**University of North Carolina at Chapel Hill  
Consent to Participate in a Research Study  
Adult Participants**

**Consent Form Version Date:** 11/10/2023

**IRB Study #** 23-2704

**Title of Study:** Feasibility of a care team-focused action plan to improve quality of care for children and adolescents with inflammatory bowel disease

**Principal Investigator:** Neal deJong, MD

**Principal Investigator Department:** Pediatrics

**Principal Investigator Phone number:** 919-966-2504

**Principal Investigator Email Address:** dejong@med.unc.edu

**Funding Source and/or Sponsor:** NIH National Center for Advancing Translational Sciences (NCATS)

**CONCISE SUMMARY**

We are testing a new way to organize and share information with you about your health needs (or your child's) with inflammatory bowel disease (IBD). This study randomly assigns participants to one of two groups. One group will receive the new tool, a document called MyIBD, at the start of the study. The second group will receive the new tool after one year. Both groups will complete three short surveys over one year, then participation in the study will be over. Participation in this study is voluntary and is estimated to take a total of 1 to 2 hours total over the coming year. The information we learn through this study will be used to improve the way that families and their children's doctors work together to meet the many health needs that children with IBD have. Participants receive up to a \$40 incentive for completing the surveys.

**What are some general things you should know about research studies?**

You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty. Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

**What is the purpose of this study?**

The purpose of this research study is to test how feasible it is to share individualized health guidance through the electronic medical record with teen patients who have IBD. The goals of sharing information in this new way are to improve the quality of care delivered to pediatric patients with IBD and to help advance their independence with their health care. You are being asked to be in the study because you are a young adult patient with IBD or the parent of a younger teen patient (13-17 years old) with IBD.

**Are there any reasons you should not be in this study?**

You should not be in this study if you were/your child was just diagnosed with IBD for the first time in the past 3 months, or if you are not planning to continue getting care with the UNC Pediatric Gastroenterology Clinic (IBD program).

**How many people will take part in this study?**

Approximately 60 patients – and one parent for those who are between the ages of 13 years and 17 years old – at UNC will take part in this study.

**How long will your part in this study last?**

Your participation in this study will last one year (twelve months). Being in the study does not involve any extra clinic visits, procedures, or other health care beyond what your IBD care team would usually recommend. Participation involves completing a series of three short surveys: one at the start of the study (about 15 minutes), one in six months (about 10 minutes), and one in twelve months (about 20 minutes). Total time to participate in the study, starting with enrollment and ending with completion of the study, is expected to be 1 to 2 hours over the year.

**What will happen if you take part in the study?**

If you join the study, you will be assigned by chance to one of two groups. Both groups will continue to receive all care from their usual IBD team at UNC. In addition, members of the first group will receive an individualized summary (MyIBD) of health-related recommendations to follow in between appointments. This summary will be sent by your usual IBD clinic nurse through the electronic medical record's patient portal and provided on paper as needed. Members of the second group can receive the summary after the study ends (in one year). Both groups will receive electronic surveys to complete at the start of the study, in six months, and in twelve months. Completing the surveys is necessary to remain in the study and receive the study-related incentives. In each of the surveys, you may choose not to answer a question for any reason.

**What are the possible benefits from being in this study?**

Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be that expected actions for you to take in between appointments may be more clearly communicated when you receive a MyIBD document.

**What are the possible risks or discomforts involved from being in this study?**

The main risk possible from being in this study is the chance that other people could find out that you have/your child has IBD if information about the study is accidentally released. There may be uncommon or previously unknown risks. You should report any problems to the researcher.

**What if we learn about new findings or information during the study?**

You will be given any new information gained during the study that might affect your willingness to keep participating.

**How will information about you be protected?**

All study documents sent to participants will not include identifiers, and all study data will be stored on a secure, university-maintained research server. Any paper copies of documents will be stored in a locked file cabinet in the researcher's campus office. Phone calls will be made from

university-owned phone lines and only by study personnel. Only the usual IBD care team, the researcher, and the researcher's assistant will have access to identifiable data. All identifiers (names, addresses, phone numbers) will be stored separately from the survey data, and identifying information will be destroyed at the end of the study.

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

### **What is a Certificate of Confidentiality?**

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use. The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

You will be asked to sign a separate form ("HIPAA Authorization") to allow researchers to review your medical records.

### **What if you want to stop before your part in the study is complete?**

You can withdraw from this study at any time, without penalty. The researchers also have the right to stop your participation at any time. This could be because you have failed to follow instructions, or because the entire study has been stopped. If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

**Will you receive anything for being in this study?**

You will be receiving up to \$40 for taking part in this study. The study incentives are tiered for each of the three surveys involved in study completion: \$15 for completing the baseline survey; \$10 for completing the shorter six-month survey; and \$15 for completing the twelve-month survey. In order to process payments, the University may share certain identifiable information about you, such as your name and contact information.

**Will it cost you anything to be in this study?**

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

**Who is sponsoring this study?**

This research is funded by the National Institutes of Health (NIH). This means that the research team is being paid by the NIH to do the study. The researchers do not have any direct financial interest with the sponsor or in the final results of the study.

**What if you have questions about this study?**

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form. A description of this clinical trial will be available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**What if you have questions about your rights as a research participant?**

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to [IRB\\_subjects@unc.edu](mailto:IRB_subjects@unc.edu).

**Participant's Agreement:**

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

\_\_\_\_\_  
Signature of Research Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Research Participant

\_\_\_\_\_  
Signature of Witness if applicable; e.g. literacy issues,  
visually impaired, physically unable to sign, witness/interpreter for  
non-English speaking participants using the short form

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Witness