**CCFA Partners – Consent**

Thank you for expressing interest in participating in CCFA Partners, a patient-centered long-term registry study. “Patient-centered research” means that patients and the IBD research community partner with each other and work as a team. Your input as a patient is critical to the research process. Working together, patients and scientists hope to improve the quality of life for patients with IBD through sharing information and conducting research.

By joining CCFA Partners you can contribute to IBD research by completing surveys and providing additional data to help all of us better understand the impact of IBD on patients and the factors that affect the course of the disease. You will also be able to make and vote on research suggestions and team up with researchers to answer important questions about IBD. In addition, you will be able to use our website to track your health trends and see how your treatments and IBD status compare to that of others in the network.

**Here’s what you can expect:**

If you choose to participate, we will ask you to provide information about your disease and treatment by completing online surveys. If you do not feel comfortable answering a survey question, you do not have to answer it. You will also have the option, if you want, to connect a variety of mobile health applications (e.g. Fitbit, Jawbone, etc.) to our patient centered network.

We will touch base with you periodically to let you know about the progress of the program and to provide information about IBD. You can log on to our website to view up-to-date information about the study and update and track your health status. Every 6 months, we will ask you to provide an update about your treatments and health. From time to time, we will let you know about additional research studies for which you might be eligible. You can accept or decline participation at that time.

The Crohn’s and Colitis Foundation of America (CCFA) may contact you for purposes related to its programs and activities such as educational, fundraising, and research opportunities. You can opt out of receiving these emails at any time by unsubscribing to the CCFA mailing list.

**Here’s what we’ll do:**

We will work diligently to protect the health data we collect from you during this study. The CCFA or CCFA Partners research team will never release your contact information to anyone at any time without your permission. Identifiers, such as your name and address, will not be used in research and will be maintained securely. All research studies using data from the network must first undergo review and approval by a project selection committee of expert scientists and IBD patients. Counts of patients who meet certain criteria, are sometimes needed to assist in planning studies. At times we will make this aggregate count data available to qualified researchers prior to committee review.

We will not sell your data to drug companies for market research. Before sending any de-identified information to industry investigators (e.g., a researcher funded by a pharmaceutical company), we will always notify you and give you the opportunity to opt out.

You will be able to view the names of researchers who have been granted access to your de-identified data along with a description of the particular research study on the network website. We will also notify you about research findings published in abstracts and scientific papers that utilized your data.

**Here’s what you need to know as you get started:**

Completing the confidential baseline survey should only take 20-30 minutes of your time. The survey is implemented by the CCFA Data Management Center at the University of North Carolina at Chapel Hill (UNC). Your email address is linked to your survey so we can contact you in the future. Your information is kept completely confidential on UNC’s secure servers. For details please click here to see our Privacy Policy and Data Security Measures.

Keep in mind all questions are optional; that is, you don’t have to answer any questions that you don’t want to answer. You can withdraw from the study at any time. We will not associate you with any response in any reports of survey results. There is no cost to you and there is no compensation for taking the survey.

Again thank you for helping us. We believe this project has excellent long-term potential to improve our understanding of IBD.

Sincerely,

Robert S. Sandler, MD, MPH

Principal Investigator, CCFA Partners

By continuing to the survey you are consenting to be part of this study.

**PRIVACY POLICY AND DATA SECURITY MEASURES**

* *We will use your information for research:* We collect information about your identity, your health, and some of your behaviors that might help us predict your future health. This information will be used in research analysis, presented at scientific conferences, and then published. These presentations and publications will never show any information that identifies you or any other individual in the study.
* *We will not share your information:* We will never sell, rent, or lease your information, and we will never voluntarily share identifying information about you without your permission. We may share de-identified health data with other researchers for the purpose of research.
* *You will be able to see some of your study information:* When you registered for the study, you provided us with a username and a password. You will use the username and password to sign into the study to see your dashboard and some of the health information you have provided (e.g., My Health Data graphs). You should be very careful not to share your login information with anyone else, or they could sign in as you and be able to see that same health information. If you are worried that someone else may be using your login information, please let us know immediately, or change your password yourself through the participant homepage.
* *Protection again involuntary disclosure of your information:* We will do everything we can to keep your study information private. To further help us protect your privacy, we have obtained a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS). Under the terms of this certificate, CCFA Partners study staff cannot be compelled to disclose study information that identifies you, even if ordered to do so by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate of Confidentiality to resist any demands for information that would identify you, except to prevent serious harm to you or to others. You should understand that we will, in all cases, take the necessary action, including reporting to authorities, to prevent serious harm to you or to others. Also, please note that a Certificate of Confidentiality does not represent an endorsement of the research study by DHHS or the National Institutes of Health.
* *Electronic security and adherence to the HIPAA privacy rule:* The CCFA Partners study follows the general security guidelines of the U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA). All study data is transmitted, stored, and processed in a secure environment.
* While we cannot provide an absolute data security guarantee, your information will be transmitted and stored using state-of-the-art security systems similar to those that protect websites used by banks and electronic health systems. If despite our best efforts, we ever experience a breach of the security of your personal information, we will notify you in accordance with federal and state laws. For any questions, please contact your study coordinator.

**DATA SECURITY MEASURES**

The following is a technical explanation of the measures we take to protect your data. If you have any questions about this information, please contact us by email at [Info@CCFAPartners.org](mailto:Info@CCFAPartners.org) or by using one of the other options described in the “Contact Us” section of the website.

All study information will be stored in linked data tables. Identifying information (name and email address) will be stored in separate (but linked) data tables so that health-related data can be viewed by study staff as needed without inadvertent association with identifiers when such linkage is not required.

The CCFA Partners study team will take the following data security measures:

* *Data Transmission:* The CCFA Partners study currently utilizes advanced encryption technology to protect all data transmitted over the Internet between the coordinating center’s web server and every client machine (including our research participants’ machines) that accesses our study web sites.
* *Secure Servers:* All study data is housed on secure servers.
* *Antivirus Software:* All servers are protected from viruses using anti-virus software. This software automatically checks for virus signature file updates once an hour, and if necessary, directly updates itself. All antivirus software is monitored and network personnel are notified in the event that the software stops functioning on a server.
* *Firewall:* The network, including all the servers that will store our research data, is behind a secure firewall that does not allow unauthorized access to any research data server.
* *Disaster Recovery:* The study database is backed up regularly to ensure that no data is lost. Our disaster recovery system also follows Standard Operating Procedures to maintain full security of backup data.
* *Cloud Services*: In addition to use of our secure servers, we may use your data in conjunction with cloud storage and computing services in order to assist with communication, data collection, storage, and processing. Third-party vendors will be vetted for their security practices and will meet or exceed privacy and security standards for the University of North Carolina at Chapel Hill electronic research health records management.

**Glossary:**

As such terms are used in this Privacy Policy:

“Personal Information” is information you supply to CCFA Partners that allows you to be individually identified. This includes (a) identifiable contact information, such as name, address, telephone, and email address, (b) information you provide about yourself, such as your health or lifestyle information, and (c) “coded information,” which is the same information as (b), but with all of your identifiers and contact information removed and a random alphanumeric code assigned to it for search purposes.

“De-Identified Data” means information that does not identify individuals. In regards to your health-related information, CCFA Partners will follow the standard set by a federal law called HIPAA (the Health Care Portability and Accountability Act). The HIPAA Privacy Rule specifies eighteen (18) data elements that, alone or in combination, could identify a person. These include information such as your name, address, phone number, social security number, and photos of your face. Generally speaking, when all 18 of these identifiers specified by HIPAA are removed, the information that remains is “de-identified”. For more information, see the Glossary of HIPAA Terms (ADD LINK), posted online by Yale University.

Thank you for reviewing our Privacy Policy.