



SolveCFS BioBank

***Providing ME/CFS patients and those that care about them
the opportunity to participate in ME/CFS research***

How does the SolveCFS BioBank work?

The SolveCFS BioBank uses a secure electronic data capture system developed by Vanderbilt University, REDCap, to collect clinical information. Information you provide is safe and kept private.

Step 1 - Provide your consent to participate in the SolveCFS BioBank.

BioBank coordinator, Gloria Smith, will send you a paper consent form. Sign it, keep a copy for yourself and send the original by mail to Gloria at the CFIDS Association of America. By consenting, you are giving the CFIDS Association of America your permission to use the clinical information and biological samples you provide in ME/CFS research.

Step 2 – Assignment of ID number & completion of SolveCFS BioBank Questionnaire

After your initial consent, Gloria will contact you by phone to determine your preferred method to complete the SolveCFS BioBank questionnaire; using the Internet or paper forms sent by the US Postal Service. Your name and clinical information will be used to assign you a unique identification (ID) number. This ID number is specific to you and is used to keep your information secure. All information is entered into REDCap, regardless of being received online or via hard copy.

Forms to Complete:

General Registration. You will receive an email or packet it in the mail, based on your preference. The email will contain a link that will bring you to REDCap; the packet will have paperwork for you to return that will be entered into REDCap. The General Registration form collects your full birth name, birth date and place and current contact information. This information is needed to generate a unique identifier that is specific to you (like a PIN). ***This unique identifier is then used to replace all personal identifying information.*** This way, we can share your clinical information and your biological sample with researchers around the world WITHOUT sharing your personal information.

Additional forms: Demographic Information. Once the unique identifier is generated, you will receive another email with a link to additional forms. These forms collect specific demographic information (age, gender, ethnicity), symptoms (important to define ME/CFS) and medical history and medication use (collected so we can determine if you qualify for specific research).

Step 3 – Biological Sample

We will ask you to provide a biological sample when you match to a specific research study. For example, we may fund research looking at the genetics of ME/CFS in families. We would search our database for families, make contact and determine if the families are interested in participating. If so, we would send a kit for the sample to be collected.

Research may require us to collect additional information. For example, the genetics of ME/CFS in families would require completion of a family history form. The additional information depends on the particular research study. **It is important to understand that sharing your personal and clinical information and providing a biological**

sample is strictly voluntary and, subject to certain limitations, you can change your mind about it at any time.

Who can participate in the SolveCFS BioBank?

Anyone age 10 years and older can participate in the SolveCFS BioBank. The SolveCFS BioBank has been built to be a robust resource for ME/CFS research. For this reason it is best that patients have a ME/CFS diagnosis from a healthcare provider. We also invite the family and friends of ME/CFS patients to participate. Family and friends are very important because it helps us understand what is different and possibly causing ME/CFS.

When will you provide a biological sample to the SolveCFS BioBank?

The SolveCFS BioBank uses an on-demand sample collection approach. This means that once an investigator is approved to conduct a research study using the SolveCFS BioBank, we collect the type of sample they require. For example, an investigator may need saliva and blood. The SolveCFS BioBank then sends you a kit so these samples can be collected. For certain samples, like blood, you will need to go to your physician or a local laboratory (like Quest Labs) to have the blood collected. Pre-addressed express mail envelopes and instructions are provided to ensure your sample is handled properly and that it is sent to our BioBank facility.

You won't be contacted until you are deemed eligible in an approved study. This may mean a long period of time between your registration and being called to give a sample. *Your registration and pre-consent in the Biobank is a critical component to being a viable resource to researchers so just registering is of great value, ensuring you and others are ready to participate when the time comes.*

What are the risks or discomforts for providing a blood or saliva sample?

The risks of drawing blood include brief pain, slight bruising, and rarely, infection at the site of the needle insertion. The laboratory or clinic where the blood is drawn will take every precaution to prevent infection. Some people feel dizzy when they have blood drawn, but this goes away when the person lies down. The risks of getting a saliva or a buccal swab include brief pressure or slight discomfort. The cheeks should not be scraped hard enough to draw blood.

Who can use the SolveCFS BioBank information and samples?

Researchers who would like to study ME/CFS will submit research proposals to the CFIDS Association of America. These research proposals are then sent out for expert review. If the study is approved and the information you provided indicates you are eligible for the study, we will contact you to see if you are interested in participating in the study. If so, you may be asked to provide additional information (answer more questions) and provide a biological sample. The type of sample will depend on the research study.

Only your de-identified information and coded sample will be shared with the approved researcher. This ensures that your information is kept private and importantly, that all results generated are returned to REDCap where they can be shared and permanently archived (no longer will scientific results be lost because of lost funding, etc).

What are the benefits to me?

There will be no direct benefit to you from participating in the SolveCFS BioBank. You will not receive any personalized information from any research that uses your information or sample. However, we hope **information gained from researchers who obtain samples from the SolveCFS BioBank will help in the early detection, objective diagnosis and effective treatments and interventions of individuals affected by ME/CFS.** From time to time, the CFIDS Association of America will provide information in the newsletter, website or at other events about what research studies have been supported through the approved distribution of samples and clinical information.



Are there any financial considerations?

There is no payment to you for participating in the SolveCFS BioBank or for providing a sample. The laboratory or clinic drawing the blood may request payment for services rendered.

Once you have donated your sample the CFIDS Association of America will steward and own the sample. Researchers who use the sample may make a discovery that has commercial value. You will not be entitled to any compensation due to discoveries that are made and commercialized using your samples.

What are my alternatives?

You may choose not to participate or provide a sample. Your decision to participate or not will have no effect on your healthcare, or the services that the CFIDS Association of America offers to you, either now or in the future.

How long will my sample and clinical history be stored?

Your health information and sample will be stored for an indefinite period of time subject to your right to revoke your consent. You will be contacted from time-to-time to update your information, provide additional samples as new studies are approved, or participate in other types of follow-up research.

Will my sample be used for anything else?

The purpose of the SolveCFS BioBank is to promote research into biomarkers and safe and effective treatments for ME/CFS. However, researchers who are studying other diseases may find ME/CFS samples valuable to their area of research as well that may benefit patients with ME/CFS or other patient populations. You have the option of giving permission to use your sample just for research in ME/CFS or for other medical research as well.

Can I change my mind and withdraw my sample?

You can change your mind about participating and providing a sample at any time. Just contact Gloria Smith at our office. Unless researchers have combined your sample with others in such a way that it cannot be separated or extracted, upon receipt of your request, your sample and your health information will be destroyed by both the SolveCFS BioBank and the researcher. If you have donated a sample to a researcher in the past, please let Gloria know.

Where can I go for answers to any questions I may have now or in the future?

Gloria E. Smith, SolveCFS BioBank Coordinator
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