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Website Content

<<General Public>>

(Overview reading level: 8.0)

(FAQs reading level: 7.5)

(CDC Website)

**Registry of Unexplained Fatiguing Illnesses and Chronic Fatigue Syndrome
(CFS)**

Study Overview For General Public

CDC is conducting a pilot study of a new registry. A registry collects information on patients with certain illnesses. CDC's registry is a registry of unexplained fatiguing illnesses, including chronic fatigue syndrome (CFS). By unexplained fatiguing illness, we mean severe tiredness with no known cause.

CDC wants to learn the best way to conduct this registry. Conducting a pilot study lets CDC run a small study to find out what makes the registry work best. This registry is a one-year pilot study. It is limited to Bibb County, Georgia. In the future, the registry may be extended. If extended, members will be interviewed annually to see if their illness changes. If extended, members will also be offered a chance to take part in intervention trials. In these trials, CDC will measure the effects of patient and provider education about CFS and ways of managing symptoms of fatigue and other symptoms of CFS

We have asked health care providers who are likely to see patients (or clients) with unexplained fatigue to take part in the study. Many of these health care providers are doctors. We have asked other health care providers to take part, also. This group includes chiropractors, nutritionists, physical therapists, nurse practitioners, and physician assistants.

The purpose of the registry is to find out:

1. How different are people with CFS from people with other fatiguing illnesses?
2. Among persons with CFS, how do their symptoms change over time?
3. What types of health care providers do people see for help with their fatigue?
4. What is the economic impact of CFS on individuals and families?
5. What do health care providers know about CFS and how to manage CFS?

To enroll in the registry, a person must:

- Be between the ages of 12 – 59
- Be referred by a participating health care provider in Bibb County
- Have fatigue that is not explained by having another illness

Once referred, a patient/client needs to complete 3 steps:

Step 1: Agree to be contacted by Abt Associates Inc. Abt Associates has been hired by CDC to run this study.

Step 2: Complete a phone interview. The interview will be used to find out how bad the person with fatigue feels, how long the fatigue has lasted, and to see if there is a reason for the fatigue.

Step 3: Complete a clinical evaluation. Qualified individuals will be invited for a free evaluation. It includes a physical examination, laboratory tests, and a mental health assessment. Clinical evaluations will take place at the CDC clinic in Macon.

Doctors at CDC will review the results. A person will be enrolled in the registry if his or her fatigue cannot be explained by illness, disease, or a condition.

CDC will update registry members about the registry. Registry members will find out how many persons have enrolled and what they are like in terms of age, race, sex. Included will be the latest findings from this study.

Taking part in this study is voluntary. People are free to take part in the study or not.

For answers to frequently asked questions, click on the links below.

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Registry of Unexplained Fatiguing Illnesses and CFS FAQs for Subjects

Participation:

How can I take part in the Registry of Unexplained Fatiguing Illnesses and CFS?

To take part in this study, a health care provider must refer you. The provider must work in Bibb County, Georgia and be a part of this study. Before the provider will refer you, the provider must see if you are a good candidate for the registry.

What kinds of health care providers are participating in this study?

We have asked health care professionals practicing these specialties in Bibb County, Georgia to participate:

Acupuncture	Internal Medicine
Allergy & Immunology	Massage Therapy (Registered)
Chiropractic	Neurology
Clinical Psychology	Nutrition (Registered)
Dentistry	Obstetrics/Gynecology (Primary Care)
Endocrinology	Pediatric & Adolescent Medicine
Family Medicine	Physical Therapy
Gastroenterology	Psychiatry
General Medicine	Rheumatology
Infectious Diseases	

My health care provider's specialty isn't listed. Can I still participate?

If your provider would like to participate, he/she should call Kate Ballard of Abt Associates, toll-free, at 1-800-451-4511.

My health care provider practices in Bibb County, Georgia, and he/she doesn't know about this study.

We have mailed invitations to providers in Bibb County, Georgia to ask them to join this study. We have not heard from all providers yet. It is possible that your provider does not know about the registry. If your health care provider would like to participate, the provider should call Kate Ballard at Abt Associates, toll-free, at 1-800-451-4511.

My health care provider practices in Bibb County, Georgia but he/she doesn't want to participate in this study.

All participants must be referred by a health care provider who has agreed to take part in the study. If your provider would like to join the study, he or she should call Kate Ballard of Abt Associates, toll-free, at 1-800-451-4511.

What happens if I change my mind about participating?

Your participation is voluntary. This means you can choose to participate or not. It also means that you can stop taking part in this study at any time. If you want to stop being in this study, please let Abt Associates know by calling 1-800-451-4511. You may also inform the Abt Associates representative when he/she calls you.

I don't live in Bibb County, Georgia. Can I still sign up for the Registry?

Yes, you may sign up if you live outside of Bibb County. However, you must be a patient of a provider who practices in Bibb County, Georgia. That provider must refer you to this registry.

Why am I getting calls about a clinical evaluation?

You completed a telephone interview. Now you are eligible for a clinical evaluation. If you take part in the clinical evaluation, you may be eligible to enroll in the registry.

Can a friend or relative take my place?

Your friend, relative, or acquaintance cannot take your place in this important research study. If you know someone who wants to take part in this study, he or she needs a referral from a provider who is in the study.

Registry Referrals:

Do I have to be referred by my primary care doctor?

No, the health care provider who refers you does not have to be your primary care doctor. The provider needs to practice in Bibb County, Georgia and agree to be part of the study.

My health care provider referred me. Does that mean I can't see that provider any more?

No, we want you to continue to see your provider(s) for your health care needs as you have always done. The registry is a research study and will not be providing treatment or management of your illness during the first year. Being in this study will not change your relationship with your health care provider(s).

I signed up. Does that mean I'm in the registry?

Thank you for your interest in this study! By consenting to be contacted, you took the first step toward enrolling in the registry. Abt Associates needs to make sure you are eligible for the registry. You must complete two more steps. Next, you will need to complete a telephone interview. An Abt Associates interviewer will call to interview you. If you qualify, based on your answers to the telephone interview, you will be asked to have a clinical evaluation. The evaluation will take place at the CDC clinic in Macon. If you are still eligible following the clinical evaluation, you will be notified of your enrollment in the Registry.

Why do I need a telephone interview and a clinical evaluation to be in the registry?

This is a registry of unexplained fatiguing illness. By unexplained fatigue, we mean severe fatigue that is *not* due to illness, disease, or a condition. In other words, we need to rule out reasons for a person's fatigue. The telephone interview serves two purposes. First, we need to know how bad the fatigue is. Second, we need to find out if there are reasons why you may be fatigued.

If the fatigue is severe and cannot be explained by other illnesses or conditions, you will be asked to have a clinical evaluation at the CDC clinic in Macon. The clinical evaluation includes a physical examination, laboratory tests, and a mental health assessment. A team of doctors from CDC will review your results. If your results do not explain the fatigue, you will be enrolled in the registry.

Registry Logistics:

Who is Abt Associates?

Abt Associates is a research firm that has been hired by CDC to run the telephone interviews and clinical evaluations. Since 1988, Abt Associates has helped CDC with a series of CFS studies. Abt Associates has telephone interviewers in Las Vegas, Nevada, and Hadley, Massachusetts, and field staff across the US.

Where is the clinic located?

[Site not yet identified.]

What will happen to me at the clinic?

Your clinical evaluation will include a physical examination, urine collection, blood draw, questionnaires to complete, and a mental health assessment. If you are an adult and complete the evaluation, you will receive \$400 for your time and effort. If you are an adolescent and complete the evaluation, you will receive \$100 and your parent/guardian who comes to clinic with you will receive \$300. You will also receive laboratory test results after they have been reviewed.

How long will this take?

The telephone interview lasts about thirty minutes.

The clinical evaluation lasts about 8½ hours for adults. Adult participants are reimbursed \$400 for their time and effort. The clinical evaluation lasts about 6½ hours for children between the ages of 12 and 17. The parent and child are reimbursed a total of \$400 for their combined time and effort.

Do I need to go to the clinic twice? I'm already in another CDC study.

It is possible to be in more than one CDC research study in the Macon area. Abt Associates runs both CDC studies of CFS in the Macon area. If you think you are in another CDC study that is taking place in Macon, please tell Abt Associates when they call you. They will verify your special situation and insure that you have only one

clinical evaluation at the CDC clinic. Information from that clinical evaluation can be used in both studies if you choose to participate in both studies.

How long does this study last?

Abt Associates will run a CDC clinic in Macon for one year, beginning in June 2007. During this one-year period, the registry is open to referrals. This is a pilot study to see if a registry is possible. If it is successful, the registry will be extended, and members of the registry will be interviewed once a year and offered the chance to take part in intervention trials.

Health:

My health care provider referred me. Does that mean I have chronic fatigue syndrome (CFS)?

You may or may not have CFS. CDC is looking for people with CFS and other forms of unexplained fatiguing illness.

I am not sure that I want to take part in this study. How will this help me get better?

This is a research study and does not provide treatment. By taking part in this study, you may find out about possible causes for your fatigue. We will interview you by phone to ask questions about your health. If we find out that there is an illness or condition that may explain your fatigue, then Abt Associates will let you know. Abt Associates will also recommend that you see a health care provider for follow-up care.

If your fatigue cannot be explained from what you tell us on the phone, you will be asked to take part in the clinical evaluation. The evaluation will include a physical examination, blood and urine tests, and a mental health assessment. A team of CDC doctors will study the data. They may find reasons for your fatigue. If they find something unusual in your physical exam or laboratory data, they will let Abt Associates know. Abt Associates will let you know about it and recommend that you see your doctor.

Confidentiality:

How do I know my information will be kept private?

Privacy is mandated by law. Only researchers at Abt Associates will know your name and other information that identifies you. They will not share this information with CDC. All staff at Abt Associates sign pledges of confidentiality. They may be fined and imprisoned if they reveal any private information.

Findings from this study will be published only in summary form. US law requires that your name not be linked with any information you provide.

I have more questions. Whom can I call?

If you have any questions about how the study works, call Abt Associates Study Director, Marjorie Morrissey, toll-free, at 1-866-710-9996. If you think that you have been harmed as a result of this study, contact CDC: Dr. James Jones at (404) 639-1412. This may be a toll call.

If you have questions about your rights as a participant in this research study, please contact the office of CDC's Deputy Associate Director for Science, toll-free, at 1-800-584-8814. Please leave a brief message including your name and phone number. Also, mention that you are calling in reference to CDC protocol #xxxx. Someone will return your call as soon as possible.