



**SOLVECFS
BIOBANK**

The CFIDS Association of America

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GENERAL ENROLLMENT REQUIREMENTS FOR SOLVE CFS BIOBANK Current as of June 8, 2010

General Enrollment

The CFIDS Association of America is now inviting participation in the **SolveCFS BioBank** under a new category, "General Enrollment." This enables interested individuals to provide written informed consent and complete detailed clinical questionnaires to become part of future **SolveCFS BioBank** studies. Blood and tissue samples will be requested from enrollees as they become eligible for approved studies. Creating this new enrollment status facilitates greater participation by members of the community, expands the clinical population available to interested investigators, and enables the Association to defer the expense of sample collection until those samples are needed for an approved study.

CFS Subjects

A subject will be eligible for general enrollment in the **SolveCFS BioBank** if they have previously been diagnosed with CFS by a licensed physician using either the Fukuda (1994) research criteria or the Canadian (2003) clinical criteria.

The general inclusion and exclusion criteria listed below also apply. Stricter requirements apply to BioBank enrollees included in the current BioBank study. Requirements for participation in the **BioBank** may change as further collaborations develop. Please check www.SolveCFS.org frequently for updates about the **SolveCFS BioBank**.

General Inclusion Criteria for CFS Subjects

You must fulfill all these criteria in order to be eligible for the current studies:

1. Fatigue persists for at least six months.
2. Post-exertional malaise defined as an inappropriate loss of physical and mental stamina, rapid muscular and cognitive fatigability, and/or fatigue and/or pain and a tendency for other associated symptoms within the patient's cluster of symptoms to worsen after even minimal physical or mental exertion. Pathologically slow recovery period usually lasting 24 hours or longer.
3. Significant cognitive impairment in short-term memory and concentration.
4. Minimum age of 10 at the time of signing the informed consent. There is no upper age limit.
5. A female subject is eligible to participate if she is not pregnant, not within three months postpartum, and not currently lactating per self-report.

6. Capable of giving written informed consent to the CFIDS Association of America, which includes compliance with the requirements and restrictions listed in the consent form.

General Exclusion Criteria for CFS Subjects

A subject will not be eligible for inclusion in current studies if they do not meet the Fukuda criteria or the Canadian criteria (see references below) or if the following general exclusion criteria apply:

1. Alcohol or substance abuse within two years before onset of chronic fatiguing illness defined as an average weekly intake of more than 14 drinks for males or more than 7 drinks for females. One drink is equivalent to 12 g of alcohol: 12 ounces (360 ml) of beer, 5 ounces (150 ml) of wine or 1.5 ounces (45 ml) of 80 proof distilled spirits.
2. Where participation in the study would result in donation of blood or blood products in excess of 500 mL within a 56-day period.
3. Major surgery within the last six months or minor surgery within the last three months.
4. Major infections such as sepsis or pneumonia within three months post-resolution.
5. Myocardial infarction or heart failure within five years after event.
6. Morbid obesity defined as body mass index (BMI) greater than 40.
7. Psychiatric conditions including lifetime diagnosis of bipolar affective disorders, schizophrenia of any subtype, delusional disorder of any subtype, organic brain disorders, or major depressive disorder with psychotic or melancholic features, anorexia nervosa, or bulimia within 5 years before the onset of chronically fatiguing illness.
8. Unwillingness or inability to provide written informed consent.
9. Mental or legal incapacitation.

Control Subjects

Exclusion Criteria for Controls

1. Control subjects do not have a disorder causing immunosuppression including, but not limited to cancer, severe infections, HIV, or other immunosuppressive disorders.
2. Alcohol or substance abuse defined as an average weekly intake of more than 14 drinks for males or more than 7 drinks for females. One drink is equivalent to 12 g of alcohol: 12 ounces (360 ml) of beer, 5 ounces (150 ml) of wine or 1.5 ounces (45 ml) of 80 proof distilled spirits.
3. Unwillingness or inability to follow the procedures outlined in the protocol.
4. Subject is mentally or legally incapacitated.

If you are interested in learning more about what is involved in donating samples and clinical information, please visit www.cfids.org/biobank or contact the Association's BioBank Coordinator Gloria E. Smith at (704) 362-2343, or biobank@cfids.org.

CFS Case and Clinical Definition References:

- Carruthers DM, Jain AK, De Meirleir KL, Peterson DL, Klimas NG, Lerner AM, et al. (2003). Myalgic encephalomyelitis/chronic fatigue syndrome: Clinical working case definition, diagnostic and treatment protocols. *Journal of Chronic Fatigue Syndrome*, *11* (1):7-115.
- Fukuda K, Straus SE, Hickie I, Sharpe MC, Dobbins JG, & Komaroff AL (1994). The chronic fatigue syndrome: A comprehensive approach to its definition and study. *Annals of Internal Medicine*, *121* (12):953-959.