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Department of Clinical Immunology
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Consent Form for Participation in the Research Study Entitled
ME/CFS Genes Study

Funding Source: Donation based

IRB protocol No.:

Principal investigator
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For questions/concerns about your research rights, contact: Human Research Oversight Board (Institutional Review Board or IRB) Nova Southeastern University (954) 262-5369/Toll Free: 866-499-0790, IRB@nsu.nova.edu

Site information: Nova Southeastern University Institute for Neuro Immune Medicine
Davie site: 3440 S. University Drive, Davie, FL 33328
Kendall site: 8501 SW 124th Avenue, Suite 111, Miami, FL 33183

What is the study about?
Chronic Fatigue Syndrome (CFS), as well as other fatigue related illness are poorly understood illnesses. Individuals can have severe, long-lasting fatigue, which cannot be explained by any diagnosed medical problem. They also have many other symptoms that their doctors cannot explain. Information obtained may help doctors understand how these illnesses affect their patients and could be used to develop better understanding for improved care. There is no direct benefit from being in the study. However, you will be contributing to the knowledge and understanding of these illnesses. With your help, people with CFS or other fatiguing illnesses may be better tested and treated in the future. If so, that could be of benefit to you or to someone you know. You may not have chronic fatigue or fatigue, and are participating in this study because you have a different immune based illness or you are healthy and serving as a healthy control.

Why are you asking me?
You are being asked to participate in a long-term clinic based research study (up to **20 years**) designed to investigate the genetics involving Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), also called Systemic Exertion Intolerance Disease (SEID). We are requesting permission to use genetic data from publicly available genetic testing websites.

What will I be doing if I agree to be in the study?

If you agree to participate, you will be asked to report genetic data from a publicly available genetic testing website, and provide responses in a confidential survey.

The questions will cover such topics as fatigue symptoms, sleep, mood, general health and stressful events in your life. Some of the questions are personal and may be upsetting. If you are concerned about a question, you may choose not to answer it for any reason. Several of the questionnaires will address possible psychological problems. We estimate that the questionnaires and interview will not take longer than 2 hours total to complete. However, you may take as much time as you need.

In some instances, study participants will be emailed a link which will allow them to log on using a unique study number without any identifying information in order to complete the study questionnaires. Thus you will have the ability to complete the instruments on line in the comfort of their home using a secure web-based platform.

What are the dangers to me?
We expect the risks to you for being in this study will be rare, but we cannot rule them out:

1. Risk from patient-reported outcome measure assessments: You may feel uncomfortable about some of the questions you are asked. You may choose not to answer any question that you do not want to answer. You may also feel some fatigue, we encourage you to take your time completing the questionnaires.
2. Agreeing to map your genetic data may result in learning about an elevated risk for a condition which can cause concern. When you sign up for genetic testing, the site offering the test also has information on publicly available genetic data testing websites which offer counseling services and provide more information on concerns you may have once you receive your data. Provided are direct links for various publicly available genetic testing websites responding to this concern as well as other counseling resources. Participants are not obligated to use any of the companies below for their genetic testing. **Genetic counseling is not offered by this research team** here at Nova Southeastern University.

   DNA.Ancestry.com: http://dna.ancestry.com/legal/informedConsent#8
   23andme:https://customercare.23andme.com/hc/en-us/articles/202907320-I-m-concerned-about-my-data-What-do-I-do-
   National Society of Genetic Counselors: http://www.nsgc.org/
   InformedDNA: http://www.informeddna.com/for-patients

Being in this study may have other risks that we do not know about. If we become aware of more risks, we will inform you, and you may decide whether to continue in the study.

The main risk of allowing us to store and use certain limited health information for research is a potential loss of privacy and confidentiality. We will protect your privacy and confidentiality. By labeling all information only with a code, and keeping the key to the codes in a password protected database. Access to your records will be limited to the study clinic staff.

We will keep your records under a study ID number so that we do not use your name. Any staff with access to a participants identifying information will be required to complete privacy training and be certified in privacy as it relates to research, further assuring confidentiality. All information obtained in this study is deidentified in the analysis, and linking data to a specific subject is strictly confidential unless disclosure is required by law.

Contact
If you have a medical or psychiatric emergency during your participation, NSU COM INIM clinic will not pay for any treatment you receive at that time or in the future. Although we believe that the chance is very small, if you are harmed during this study, we will give you emergency health and/or psychiatric care until formal care can be arranged. You or your insurer will be billed in the usual manner if such services are necessary. However, by signing this consent form and agreeing to be in this study, you are not giving up any of your rights.

If you have any questions about the research, your research rights, or have a research-related injury, please contact Irma Rey, M.D., principal investigator Tel: 954.262.2850 or Ana Del Alamo, study coordinator Tel: 954.262.2888. Co-Investigators, Dr. Nancy Klimas and Dr. Maria Vera can be reached at 305.595.4300. You may also contact the IRB at the numbers indicated above with questions as to your research rights. Someone will return your call as soon as possible. Please leave a brief message including your name and phone number. Also, mention that you are calling in reference to IRB Protocol No. ###.

Are there any benefits for taking part in this research study?
There are no direct benefits from joining this study, though you may have the laboratory results should you wish to share them with your clinician.

Will I get paid for being in the study? Will it cost me anything?
You will not receive any payment for participating in this study. The cost to you for being in our study is cost of your time spent answering the questions in our on line research site and the donation of the data you previously paid for by participating in a publicly accessible genetic testing site such as 23 and Me or Ancestry.com .

How will you keep my information private?
The investigators and their assistants will consider your records confidential to the extent permitted by law. Laboratory test results, physical and medical history exams, and psychological questionnaires, will be identified by code number. Access to your records will be limited to the study clinic staff. We will keep the records under a study ID number so that we do not use your name. This number and your name will appear together only on one form kept in a separate file in a secure, encrypted web platform. All other forms will have only your study ID number, not your name. Your name or other facts that might point to you will not appear when we present this study or publish its results. Any staff with access to your identifying information will be required to sign a confidentiality pledge, which prevents them from sharing your personal information with anyone else. All information obtained in this study is strictly confidential unless disclosure is required by law. Identifiable data such as signed consent form and coding key linking a subject to an assigned study number will be retained for a period of up to 20 years in order to re-contact you for participation of future studies and inform you of this study's results. At the end of 20 years all identifiable data will be deleted and only de-identified data will be maintained. IRB and regulatory agencies may review research records.

What if I do not want to participate or I want to leave the study?
Your participation is voluntary. You may refuse to participate or withdraw from the study at any time without penalty or loss of benefits that you normally receive or could expect to receive in the future. This will not affect the medical care you receive from the study doctor or the INIM. If you decide to join the study, you are also free to drop out later for any reason. There will be no adverse consequences experienced by you should you decide not to participate in this study. Your decision will not change in any way your physician's willingness to continue to provide excellent care to you.

The investigators reserve the right to remove you from the study without your consent at such time as they feel that it is in your best interest medically or for administrative reasons. The Institutional Review Board (IRB) or regulatory authorities may also discontinue your participation in the study. If you choose to withdraw, any information collected about you **before** the date you leave the study will be kept in the research records for 10 years from the conclusion of the study but you may request that it not be used.

Other Considerations:
If significant new information relating to the study becomes available, which may relate to your willingness to continue to participate, this information will be provided to you by the investigators.

Voluntary Consent by Participant:

By signing below, you indicate that

- this study has been explained to you
- you have read this document or it has been read to you
- your questions about this research study have been answered
- you have been told that you may ask the researchers any study related questions in the future or contact them in the event of a research-related injury
- you have been told that you may ask Institutional Review Board (IRB) personnel questions about your study rights
- you are entitled to a copy of this form after you have read and signed it
- you voluntarily agree to participate in the study entitled: ME/CFS Genes Study

Participant's Signature: _____ Date: _____

Participant's Name: _____ Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Consent to be re-contacted:

We may wish to contact you again for future studies. By giving consent to be contacted, you do not have to participate in future studies. You are just giving us permission to contact you and invite you to participate in other studies of CFS and related illnesses.

Please check one box:

☐ I give consent to be contacted for participation in future studies as outlined in this consent form.

☐ I DO NOT give consent to be contacted for participation in future studies as outlined in this consent form.

Participant's Signature: _____ Date: _____

Participant's Name: _____ Date: _____

Signature of Person Obtaining Consent: _____

Date: _____

Initials: _____ **Date:** _____