CONSENT
For Collection of Medical Information

DESCRIPTION: You are invited to participate in a research study on chronic unexplained illnesses. From the information collected and studied in this project we hope to learn more about the causes and effects of chronic unexplained illnesses.

PROCEDURES: With your permission, we would like to collect health information about you, including your responses to several questionnaires, information about your general health (results from blood tests, medications, physical exam findings) related to medical treatments and care you receive. The questionnaires and assessments will be administered online and at your clinic visits. We would like to collect this information about you after each medical visit you have for as long as you are treated at a Stanford Clinic or hospital. This study does not involve any treatment; just the collection and study of medical information.

RISKS AND BENEFITS: Risks of participating in this research are minimal and consist of possible breaches of confidentiality. Though we make every effort to protect your health information, there is always a small risk that your information will be accessed by unauthorized persons, especially if a paper forms are mailed or faxed. You will not receive any direct benefit from participation. We cannot and do not guarantee or promise that you will receive any benefits from this study.

TIME INVOLVEMENT: Your participation in this study will require that you complete an intake questionnaire consisting of a health history questionnaire and several other questionnaires and assessments, which may take anywhere from 5 minutes to 30 minutes to complete, as well as a shorter version of the questionnaire which will be administered at or before your follow-up clinic appointments. The shorter version of the questionnaire will take 30 minutes or less to complete. We will ask you to complete the shorter questionnaire at your follow-up appointments for the duration of the study, which is anticipated to be ten years. You will not have any further time involvement in this study following the completion of the project. If you agree to participate, you will complete the questionnaires securely online or you may also request a paper copy of the questionnaires. If you agree to participate, we will collect medical information from your medical record after each visit, which does not involve any direct participation by you.

PAYMENTS: You will not be paid to participate in this study.

PARTICIPANT'S RIGHTS: Your decision whether or not to participate in this study will not affect your medical care. If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You have the right to refuse to answer particular questions.

Your identity will not be disclosed in any published and written material resulting from the study.

Authorization to Use Your Health Information for Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your authorization. If you participate in this study, your participation will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before participating.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this project is to study the causes and effects of chronic unexplained illnesses. Your responses to several questionnaires and your medical information will be used to learn more about chronic unexplained illnesses.

Do I have to sign this authorization form or participate in this research?

You do not have to sign this authorization form or participate in this research.

If I agree to participate, can I revoke my permission or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must do so in writing. Please provide the written withdrawal to Dr. Montoya's research team at 1000 Welch Road, Suite 202, Palo Alto, CA 94304.

What Personal Information Will Be Used or Disclosed?

We will be looking at the following categories of health information, where * denotes embedded identifiers: * laboratory and pathology test results with embedded identifiers, coded diagnoses and procedures, * clinical records with embedded identifiers, * images and imaging reports with embedded identifiers, * demographics with embedded identifiers.

We will be obtaining and using the following protected health information: laboratory and pathology test results with embedded identifiers, clinical records with embedded identifiers, images and imaging reports with embedded identifiers, demographics with embedded identifiers (names, telephone numbers, address (all geographic subdivisions smaller than a state), dates more precise than year only, e.g. date of birth or death, date of service, diagnosis, admission, electronic mail addresses, medical record numbers).

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff working on this project

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will expire on December 31, 2100.

CONTACT INFORMATION:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask Dr. Montoya's research coordinator Tullia Lieb, at 650-723-8126. You should also contact her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

Please print a copy of this consent form for you to keep.