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AS MODIFIED
Jul 21, 2014
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**Informed Consent for Future Specimen Testing and Permission to Contact for Follow-up Information**

**TITLE:** Identification of Effective Treatment Algorithms For Individuals Diagnosed with PANDAS/PANS

**PROTOCOL NO.:** 2014-101-M
WIRB® Protocol #20140907

**SPONSOR:** Moleculera Labs, Inc.

**INVESTIGATOR:** Craig Shimasaki, PhD, MBA
Suite 410
755 Research Parkway
Oklahoma City, Oklahoma 73104
United States

**SITE(S):** Moleculera Labs, Inc.
Suite 410
755 Research Parkway
Oklahoma City, Oklahoma 73104
United States

**STUDY-RELATED PHONE NUMBER(S):** Amy Cross, RN
405-239-5250
405-239-5254 (24 hours)

**INTRODUCTION**

If you are a parent or guardian consenting for your child or minor, all references to "you" are applicable to the minor or your child. You are considering allowing Moleculera Labs to 1) store your unused specimen for future research testing to better understand and potentially develop additional tests for Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcal Infection (PANDAS) or Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) and 2) contact you for follow-up about your post-treatment condition and treatment outcomes. This form describes the risks, limitations, and benefits of participation. Read it carefully before you decide whether or not to participate. Participation in this research is voluntary.

**PURPOSE**

Your physician has ordered The Cunningham Panel™ of Tests, which is used to aid their diagnosis of Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcal Infection (PANDAS) or Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS). You will have blood drawn to perform these tests. Most likely, there will be unused sample remaining after completing the Cunningham Panel™ of Tests. We will store the unused portion of your sample (if any is remaining) in our freezer for an indefinite period of time.

It is possible that there are additional biomarkers or other tests that have not been discovered or developed which could help physicians make more accurate diagnoses and know what treatments could be most effective for future patients. One purpose of this consent is to retain your unused specimen for future research on additional biomarkers and tests to help better diagnose PANDAS/PANS. A second purpose of this consent is to obtain your permission to contact you sometime in the future to find out about your condition, treatments, and treatment outcomes.

**RISKS**
You will be told about any new information that might change your decision to be in this study.

**BENEFITS**
For this research participation, there is no direct or immediate benefit to you and/or your child. You will not receive any results from research performed on your specimen. However, by enabling us to perform research studies, your sample may help lead to future clinical tests and better ways of diagnosing and treating PANDAS/PANS, Sydenham chorea, OCD, and other autoimmune-related neurological diseases.

**PAYMENT FOR PARTICIPATION**
You will not be paid for being in this study.

**ALTERNATIVES**
Your alternative is to not be in this study.

**VOLUNTARY PARTICIPATION**
Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;

**SAMPLE USE AND CONTACT PLANS**
Certain laws may require that a sample analyzed in clinical testing be destroyed within a certain period of time after testing has been completed. We must comply with such laws or regulations and will do so unless you provide consent to store your specimen for future research use. Current anticipated uses of these samples in research include improvement of testing by studying additional biomarkers and antibody levels directed against other receptors and antigens with a role in the cellular response and causes of neurological disorders that could impact neurological function such as observed in PANDAS/PANS, Sydenham chorea, Tourette's Syndrome, or other similar related disorders with tic or behavioral OCD symptoms. Future use of your sample may involve investigation of new biomarkers for assessment of these diseases and may use as yet undiscovered technologies in medical research.

By signing this consent, you are giving Moleculera Labs permission to contact you for information about you or your child's condition, treatments provided and an assessment of any improvements after treatment. You may be asked to complete standardized assessment questionnaires or surveys, fill-in-the-blank forms, answer open-ended questions, or provide narrative information unique to your situation. You may be asked to provide specific dates of symptom onset, time intervals between events (such as the time interval between a strep infection and the onset of neurological symptoms), and types of treatment with dates and frequency. You may be asked to sign a release form allowing us to contact your healthcare provider for additional medical or treatment information. You may be asked to provide information by telephone, in writing, or in an online format. We estimate that participation in this research may require approximately 1 to 2 hours of your time and can be completed/scheduled at your convenience.

**CONFIDENTIALITY STATEMENT**
Every effort will be made to keep your personal information confidential. You will not be identifiable by name to any third party in any reports or publications about the results from this panel or other information you provide to us relevant to our panel. A request in writing by you (or a person legally authorized to act on your behalf) is required to release information to another healthcare provider. Information may be disclosed if required by applicable laws.

**QUESTIONS**

Contact Amy Cross, RN, at 405-239-5250 or 405-239-5254 (24 hours) for any of the following reasons:

- if you have any questions about your participation in this study,
- if you have questions, concerns, or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns, input, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

**PATIENT'S STATEMENT**

I have read this document in its entirety. I have had the opportunity to discuss this consent with a health care professional if desired.

I AM INTERESTED IN PARTICIPATING IN RESEARCH STUDIES TO FURTHER ADVANCE THE DIAGNOSIS, TREATMENT AND PREVENTION OF PANDAS AND RELATED NEUROLOGICAL DISEASES. I understand and agree that the sample remaining from this panel may be stored indefinitely and may be used in performing research. I also understand that I may be contacted by Moleculera Labs for follow-up on my current disease status and that additional information may be requested.

☐ Yes ☐ No

***Consent and Assent Instructions:***

*Consent: Subjects 18 years and older must sign on the subject line below*
*For subjects under 18, consent is provided by the parent or guardian*

*Assent: Is not required for subjects 6 years and younger*
*Verbal assent is required for subjects ages 7 through 17 years using the Assent section below*

_____
Subject Name (printed)

**CONSENT SIGNATURE:**

_____ _____
Signature of Subject (18 years and older) Date

_____ _____
Signature of Parent or Guardian Date
(when applicable)

**ASSENT SECTION:**

Statement of person conducting assent discussion:

- I have explained all aspects of the research to the subject to the best of his or her ability to understand.
- I have answered all the questions of the subject relating to this research.
- The subject agrees to be in the research.
- I believe the subject's decision to enroll is voluntary.
- The study doctor and study staff agree to respect the subject's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

Statement of Parent or Guardian:

My child appears to understand the research to the best of his or her ability and has agreed to participate.

_____ _____
Signature of Parent or Guardian Date

_____ _____
Printed Name of Person Conducting the Informed Assent Discussion Position

_____ _____
Signature of Person Conducting the Informed Assent Discussion Date