Institute for the Study of Peak States
GENE CLINIC STUDY CONSENT/LIABILITY FORM

Revision 1.0

This form can be found online at www.peakstates.com/gene.html. The content of this agreement is based on the standard Stanford University Research Consent Form. The original Stanford document can be seen online at http://humansubjects.stanford.edu/medical/SUSampleCons.rtf.

This study is a project of the Institute for the Study of Peak States. The Gene Clinic is our name for the research group working on the project of healing genetic disorders.

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions about a new approach to treatment. Being in a research study is different from being a patient. When you are a patient, you and your personal doctor have a great deal of freedom in making decisions about your health care. When you are a research subject, the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

PURPOSE OF RESEARCH

You are invited to participate in a research study of noninvasive correction of hereditary illnesses. We hope to learn whether such an approach to genetic repair is possible, and if so, how it can best be accomplished. You were selected as a possible subject in this study because you have a genetic disease that the Gene Clinic has chosen as a promising research topic.

Your participation in this study is entirely voluntary.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately three weekends, every three weeks. However, medical tests of the response to treatment depend on available local testing schedules. In addition, you should expect to have followup checks with our staff to monitor stability of the treatment.

PROCEDURES

If you choose to participate, the Gene Clinic staff will collect baseline information on your illness, using your medical records, personal interviews, and laboratory tests as necessary. Follow-up testing may also be needed, to document any improvement in your disease that the Gene Clinic work may bring about. Where possible, this follow-up testing will be integrated into the care provided by your regular physician.

For the study itself, you will not be taking any drugs or undergoing any procedures. You will simply have to be physically present in the room with the Gene Clinic staff during research sessions, and perhaps answer questions they may have about how you are feeling or what you are experiencing during the session.

Between and after Clinic visits, the staff will contact you to follow up on any effects you may be experiencing as a result of the Clinic's methods.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. To do so, you must inform the Institute by phone (250-413-3211) and by email (grant@peakstates.com) in a timely manner.

The Gene Clinic may also withdraw you from the study without your consent for one or more of the following reasons:
1. Failure to follow the instructions of the Gene Clinic staff.
2. The Gene Clinic decides that continuing your participation could be harmful to you.
3. The study is cancelled.
4. Other administrative reasons.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Gene Clinic staff if you have any questions.

The discomforts and inconveniences reasonably expected in this study include the inconvenience of travel to and from Hornby Island.

The study procedure may involve risks to you that are currently unforeseeable. The process that will be used on your genetic disorder is noninvasive, but is completely experimental. Long-term effects, if any, have not been studied or researched. Thus, we cannot guarantee that you will not have some sort of adverse reaction that we did not anticipate. If you are not willing to take full and complete responsibility for what happens by using our process we require that you not start with the process.

POTENTIAL BENEFITS

Participation in this study may result in a lessening of symptoms or, ideally, a complete cure of your genetic illness.
We cannot and do not guarantee or promise that you will receive any benefits from this study.

SUBJECT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a human subject you have the following rights. These rights include, but are not limited to, the subject's right to:
-be informed of the nature and purpose of the experiment;
-be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
-be given a description of any attendant discomforts and risks reasonably to be expected;
-be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
-be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
-be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should rise;
-be given an opportunity to ask questions concerning the experiment or the procedures involved;
-be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
-be given a copy of the signed and dated consent form;
-and be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

CONFIDENTIALITY

If the procedure is successful, you do agree to let the ISPS use your name and contact information publicly as verification for the effectiveness of the treatment. This may involve laypeople, researchers, other autistics, and journalists contacting you for several years after the procedure has been used.

#The results of this research study may be presented at scientific or medical meetings or published in scientific journals.

*****Patient information may be provided to Federal and other regulatory agencies as required in the country that the procedure is used. (For example, in the USA, the Food and Drug Administration (FDA) may inspect research records and learn your identity if this study falls within its jurisdiction.)

FINANCIAL CONSIDERATIONS

Payment
You will not be paid to participate in this research study.
Expenses
The Gene Clinic will cover the costs of food and lodging while you are on Hornby Island. The Gene Clinic will also cover the costs of any procedures or tests that may be required for the study. You will be responsible for the cost of travel to and from Hornby Island.

CONTACT INFORMATION

·If you need to change your appointment, please contact the study director Dr. Laura Chalfin at her office. (If you lose the number, contact the ISPS office at 250-413-3211.)
·If you have any questions about this research study, you should ask the physician in charge, Dr. Chalfin. You may contact Dr. Chalfin through the Institute's main number, 250-413-3211.

TERMS OF AGREEMENT

I, _____

located at the address,

_____

_____

agree to the following terms regarding this study:

1. I take complete responsibility for my own emotional and/or physical well being both during and after the procedures.
2. I agree to hold harmless the Gene Clinic and the Institute For The Study of Peak States and anyone involved with these techniques from any claims made by anyone including myself, or from any claims made on the behalf of anyone else, due to direct or indirect results from the processes used.
3. I agree to remain under the supervision of a qualified physician as appropriate.
4. I agree to allow the Gene Clinic access to relevant portions of my medical records.
5. I agree to undergo any required lab or psychological tests as required by the Gene Clinic, and in a timely manner.
6. I will not disclose to others any details of the process being used, except in a general way.
7. In the event that the Gene Clinic process succeeds in significantly alleviating or curing my genetic disorder, I agree to write a testimonial describing my experience, which may be used by the Gene Clinic for promotional purposes; and to allow my name and contact information to be given out by the Gene Clinic to prospective patients.
8. I agree that I will not share in any financial benefits that may result from this study.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

_____
(Signature of Subject)

_____
(Date)

_____
(Witness)

_____
(Date witnessed)

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

Signature of Person Obtaining Consent _____

Date_____

PERMISSION TO CONTACT PHYSICIANS
I agree to provide the name, address and phone number of my current and past physicians, so that the medical staff of the Gene Clinic can discuss my condition, test results, and any other relevant information with them. I also agree to release my medical records to the Gene Clinic medical staff for the same purpose.

Signature _____

Printed Name_____

Names Addresses, and Phone Numbers of Physicians: