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

Revision 1.1

Available online at www.peakstates.com/autism.html

Based on the Stanford University Sample Consent Form at http://humansubjects.stanford.edu/medical/SUSampCons.rtf

Meeting Date:

OPTIONAL FORMAT to use when there are BOTH adults and minors in the same study.

(We use one consent form for both the adult subjects and for the parents or guardians granting consent for a subject who is a minor.)

Please check one of the following:

_____ You are an adult subject in this study.

_____ You are the parent or guardian granting consent for a minor in this study.

Print minor's name here:

_____

The following information applies to the individual or to his/her minor child. If the subject is a minor, use of "you" refers to "your child".

*Are you participating in any other research studies? _____ yes _____no

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions, sometimes about a procedure, drug or device's safety and its effectiveness. 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 Protocol Director and 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 a potential method for reducing or eliminating the symptoms of autism. We hope to learn how effective our current process is, and improve on it, if possible. You were selected as a possible subject in this study because you (or your ward) has a medically diagnosed and verified autistic symptoms.

*Your participation in this study is entirely voluntary.
#Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice to you or effect on your medical care. If you decide to terminate your participation in this study, you must notify Grant McFetridge (ISPS Research Director) at 250-413-3211.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 3 months (e.g., this is a 2 year study; approximately 5 days of active participation by each subject; and 2 days collection of medical information for each subject, by a physician outside of the study who is competent to diagnose autism).

- The follow up period may last up to 2 years after the treatments.

PROCEDURES

If you choose to participate, the ISPS and their research study staff will use a combination of meridian therapies (EFT, TAT) along with music and phrases. We may also use proprietary healing techniques which do not involve client participation, other than checking of symptoms.

- *The experimental part of the study is the test of the connection between autism symptoms and prenatal trauma. We will also be*

testing the suitability of meridian therapies for the healing of this condition.

- *The purpose of the procedures is quite simple – to see if there is an immediate decrease or elimination of autistic symptoms.*
- *Each procedure will be about 2 to 3 hours long.*
- *Meridian therapies use touch or tapping on the patient's meridian points (face, chest, and hands).*
- *After we believe that the process is stabilized, we require examination by a physician who specializes in diagnosing autism as an independent check of results.*
- *The course of treatment is experimental – hence there is the possibility of a number of sessions over a three month period. We will also be doing follow-up studies to verify the changes are stable, and to look for any unexpected reactions or changes.*

WOMEN OF CHILDBEARING POTENTIAL

*(The following language is recommended when **women of childbearing potential** (non-pregnant) will be enrolled in an investigational study.)*

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous procedure with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

To confirm to the extent medically possible that you are not pregnant, you agree to have a pregnancy test done before beginning this research study, or to begin the study after the onset of your next menstrual period. You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

SUBJECT'S RESPONSIBILITIES

You should:

- Follow the procedures as instructed by the facilitator during the tests.
- Keep your appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Keep your diaries as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

#While participating in this research study, you should not take part in any other research project without approval from all of the Protocol Directors. This is to protect you from possible injury or other hazards, and to keep the study's results from being potentially corrupted by unpredictable influences.

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. Clearly outline the study withdrawal procedures (Suggestion: check your protocol).

If you withdraw from the study,

- there may be the possibility of emotional or physical symptoms that potentially could last for indefinite periods of time.
- If you decide to withdraw from the study, you must inform the ISPS research director by phone (250-413-3211) and by email (at

grant@peakstates.com). You must make sure that your withdrawal request has been received. We may recommend that you get assistance from a licensed trauma therapist if you have any symptoms from the procedure, but this is optional.

- You must return all study-related supplies. The procedure is confidential – you are not allowed to discuss or pass on anything that you have learned, seen or heard during the procedures.

#The Protocol Director may also withdraw you from the study and the study procedure may be stopped without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and/or study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy (if applicable).
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- *Unanticipated circumstances.

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 Protocol Director if you have any questions.

- *You should expect the following discomforts and inconveniences from the procedure. During the procedure, somewhat painful emotional and physical symptoms arising from re-experiencing birth-related trauma. There may also be the inconvenience of travel to a ISPS staff's place of work (if applicable for the procedure).*
- *There are reasonably foreseeable risks. First, there may exist the risk that the subject's disease/condition may worsen during the course of the procedure. Secondly, if the procedure is successful, there is the problem that the client now has emotions and feelings that are unfamiliar. These*

may cause disruption and discomfort as the client learns to deal with the ordinary problems that arise for people without autism. Third, there is the problem of unrealistic expectations – removing autistic symptoms does not make up for the fact that the client has not had a normal developmental cycle, and their social skills will probably be unchanged, and need guidance and counseling.

- *This treatment is new and has not been tested on large numbers of people. Thus, the treatment or procedure may involve risks to the subject, which are currently unforeseeable.*

POTENTIAL BENEFITS

- *The objective of this procedure is to eliminate all or some autistic symptoms permanently in a short amount of time.*
- **WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.**

ALTERNATIVES

- There are other procedures available which, in some cases, may reduce autism symptoms (such as via dietary changes or chelation therapy). (Note, however, that you must not be using an alternative therapy during the course of the ISPS procedure, without approval and coordination with the ISPS research staff.)

SUBJECT'S RIGHTS

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

If you decide not to participate, tell the Protocol Director.

*You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

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.

COSTS

There are no direct costs for the procedure, other than long distance phone calls if needed. However, there is an indirect cost – the client must have a reputable diagnosis of autism by an MD who will be used as a reference in the publication material. If the procedure is successful, the client will also be obligated for another diagnostic meeting with an MD who specializes in autism, to verify the change in diagnosis and symptoms.

SPONSOR

The Institute for the Study of Peak States is providing all the financial support and/or material for this study.

CONSULTATIVE OR FINANCIAL RELATIONSHIPS

All the people in the study are staff at the Institute for the Study of Peak States.

CONTACT INFORMATION

- If you need to change your appointment, please contact Grant McFetridge at 250-413-3211 in Canada, or other contact person as arranged during the procedure.

- *If you have any questions about this **research study**, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director. You may contact Grant McFetridge at 250-413-3211 in Canada. If you have any additional questions later, Grant McFetridge will be happy to answer them.
- *If you think you have experienced a **research-related injury** call the research director Grant McFetridge immediately.

COMPENSATION

*All forms of medical diagnosis and treatment -- whether routine or experimental -- involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for additional medical or other costs. Additionally, the ISPS is not responsible for research and medical care by other institutions or personnel participating in this study. Note, however, that you DO waive any liability rights for personal injury by signing this form.

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.

PERMISSION TO CONTACT PHYSICIAN(S)

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

Names Addresses, and Phone Numbers of Physician(s):

LEGAL AND LIABILITY AGREEMENTS

The process that you will be using on your autism is state of the art and very 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. This is all common sense given the nature of our work, but we want to make it perfectly explicit up front.

Thus, you agree to the following:

1. I take complete responsibility for my own emotional and/or physical well being both during and after this procedure. This applies to the healer, the healee, and any guardian(s) of the healee as appropriate.

2. I agree to hold harmless The Institute For The Study of Peak States and anyone involved with these Institute 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 use the techniques under the supervision of a qualified therapist or physician as legally appropriate.

4. I will not expect these techniques will solve problems where common sense would tell me that it is not appropriate.

5. I have no physical or emotional problems that might make treatment physically or emotionally risky or dangerous (such as suicidal experiences, heart conditions, etc.)

6. I agree to not disclose the methodology or procedure that was used for my treatment, or to attempt to try to use what I learned during the treatment on anyone else.

7. I agree to allow the Institute access to relevant portions of my medical records.

8. I agree to undergo any required lab or psychological tests as required by the Institute, and in a timely manner.

9. In the event that the Institute's process succeeds in significantly alleviating or curing my disorder, I agree to write a testimonial describing my experience, which may be used by the Institute for promotional purposes; and to allow my name and contact information to be given out by the Institute to prospective patients.

10. I agree that I will not share in any financial benefits that may result from this study.

PHYSICAL OR PSYCHOLOGICAL PROBLEMS AND DRUG USE

A physical inventory of current medical problems is required before the procedure begins. In particular, we need to know of any potentially dangerous pre-existing conditions (such as heart conditions, diabetes, etc.) that may mean that the client should not use the autism procedure. We also need to know about any prescription or non-prescription drugs being taken (such as tranquilizers, herbs, etc.) up to 3 months before, and during, the procedure.

In addition, we need to know of any other psychological conditions that may affect or be a potential problem for the procedure. In particular, if the client has had suicidal feelings or actions, the procedure should not be used.

*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

_____
Social Security # (if in the USA, or other identifying data if from another country).

(If consent is to be obtained from a legally authorized representative (e.g., parent(s), legal guardian or conservator), signature line(s) for representative must be included on the consent form, as well as a description of his/her authority to act for the subject.)

_____

Signature of Legally Authorized Representative

*Date*_____

_____

Description of Representative's Authority to Act for Subject

*Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with the Experimental Subject's Bill of Rights, if appropriate, 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