

Institute for the Study of Peak States - Research Consent Form

Protocol Title: Parkinson's Disease Rev 1.0

Protocol Director: Mary Pellicer MD

Approval Date: _____

Expiration Date: _____

Institute for the Study of Peak States (ISPS) Parkinson's Disease Study Consent/Liability Form

Revision 1.0

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

Based on the Stanford University Sample Consent Forms at <https://researchcompliance.stanford.edu>

Meeting Date: _____

*Are you participating in any other research studies? _____ yes _____ no. If yes, please explain:

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions (for example, about a procedure, drug or device's safety and its effectiveness). Being in a research study is different from being a patient or client. When you are a patient or client, you and your health care provider have a great deal of freedom in making decisions about your health care. When you are a research study 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 Parkinson's disease (PD). We hope to learn how effective our current process is, and to improve on it, if possible. You were selected as a possible subject for this study because you (or your ward) has medically diagnosed and verified Parkinson's disease 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 the Protocol Director, Dr. Mary Pellicer, by phone (509-949-1843) and by email at DrMary@PeakStates.com.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 3 to 5 sessions scheduled over one to two months with follow-up contact at 6 months, one year, and two years.

PROCEDURES

If you choose to participate, the ISPS and their research study staff will use trauma therapy (such as regression therapies WHH and EMDR or meridian therapies EFT and TFT), possibly with music and repeated verbal phrases, to achieve the desired outcome.

- The experimental part of the study is a test of the connection between PD symptoms and pathogen infections.

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- The purpose of the procedures is quite simple – to see if there is an immediate decrease or elimination of PD symptoms.
- Each session will be about 2 to 3 hours long.
- Meridian therapies use touch or tapping on the patient's meridian points (face, chest, and hands) by the therapist or patient. They may also use certain eye movements
- After we believe that the process is stabilized and symptoms eliminated, we require examination by your physician who is treating your PD, as an independent check of results.
- The process we are testing is experimental – hence there is the possibility of needing to do more sessions over a longer period of time. 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

To reduce the chance of other factors interfering with the test (what are technically called "confounding variables"), pregnant women are not suitable subjects for this test. If you become pregnant we will stop the testing.

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.
- Tell the Protocol Director or research staff if you start feeling suicidal.
- Tell the Protocol Director if you experience any change in your PD symptoms between sessions (improvements as well as worsening).
- Keep your 'symptom diary' 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

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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.

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 Protocol Director Dr. Mary Pellicer by phone (509-949-1843) and by email (at DrMary@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 research staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy (if applicable).
- Suicidal feelings arising.
- 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 pre-birth-related trauma. There may also be the inconvenience of travel to an 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 of unrealistic expectations – the subject may have other, unrelated problems which may remain even after the slowness/stiffness/tremor symptoms are removed; any rebuilding of muscular strength will need addressing outside of this study; and guidance and counseling may be required around the subject's past interactions with other people, including family and friends.

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- If the treatment gives positive results, any drug treatment plan the subject is on will need to be reduced or eliminated in consultation with and monitored by the subject's own physician.
- 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 permanently eliminate the PD symptoms of slowness of movements, and tremors. Our goal is to also accomplish this in a relatively short amount of time (3-5 sessions).
- **WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.**

ALTERNATIVES

- There are other procedures available that, in some cases, may reduce PD symptoms (such as via dietary changes or drug therapy). Please inform the ISPS research staff of any treatments you are using at the start of the study, and any changes that you make to them during the time of the study.

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

Aggregate data results from this study may be presented to conferences or for publication. No specific information that could identify you will be released without your express written consent. In the event that we need specific case examples related to how you were helped by this treatment, we may ask for release of information for specific identified purposes for up to two years after the study is completed.

*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.)

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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 and/or video calls if needed. However, there is an indirect cost – as the subject, you must have a reputable diagnosis of PD by a licensed specialist before you will be acceptable for the procedure. The specialist's name and qualifications will be kept as supporting evidence to back up any published material about your condition.

If the procedure is successful, the subject will also be obligated for another diagnostic meeting with a licensed professional who specializes in PD, to verify the change in diagnosis and symptoms. The cost of this diagnostic procedure will be charged to you.

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 the Protocol Director, Dr. Mary Pellicer by phone (+1-509-949-1843 in Yakima, Washington USA), 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 Dr. Mary Pellicer (phone +1-509-949-1843 or by email DrMary@PeakStates.com). If you have any additional questions later, she will be happy to answer them.
- *If you think you have experienced a research-related injury call the Protocol Director Dr. Mary Pellicer at +1-509-949-1843 and the Research Director Dr. Kirsten Lykkegaard at +1-250-509-0514 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 not participating in this study. Note, however, that you DO waive any liability rights for personal injury by signing this form.

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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 arise;
- 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 PD 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

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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 as a subject in this research study, take complete responsibility for my own emotional and/or physical well being both during and after this procedure. This applies to the subject, the provider(s), and any guardian(s) of the subject 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 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. These costs would be paid for by the Institute (except for one visit to a specialist in diagnosing PD.)

9. In the event that the Institute's process succeeds in significantly alleviating or curing your disorder, we will ask you to write a testimonial describing your experience, which may be used by the Institute for promotional purposes; the option to include your name and/or contact information is totally voluntary.

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 written inventory of current medical problems is required before the procedure begins via a separate Medical History Form. In particular, we need to know of any potentially dangerous pre-existing conditions (such as heart conditions, diabetes, etc.) that may mean that the subject should not use the PD procedure. We also need to know about any prescription and/or non-prescription drugs being taken (such as tranquilizers, herbs, etc.) up to 3 months before, and during, the procedure. Be sure you put this information into your Medical History Form.

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 subject 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

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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

(Print Name of Subject) _____

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

WITNESS TO SIGNING

Signature of Witness

Date

(Print Name of Witness) _____

Staff 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, 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 Staff Person Obtaining Consent

Date

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(Print Name of Staff) _____