

Informed Consent, Liability, and Medical History forms

Peak States® COVID-19 Psycho-immunology Process

Phase 1b Effectiveness Trial

Rev 1.0; Aug 1, 2020

Welcome!

Thank you for joining our research trial to test the effectiveness and safety of our new, experimental psycho-immunology process for eliminating (or reducing) COVID-19's symptoms. Below is liability and informed consent material, which you will have to sign after you've read and understood it. Once the paperwork is done, we will assign you a therapist to do the process with you. But first, let's cover some background so you get a better feel for us and the process.

Who are we?

We are the worldwide Institute for the Study of Peak States, a group of physicians, PhD's, and therapists who volunteer their time to research and develop psychological techniques and processes for a variety of different diseases. You can read about us and our work at www.PeakStates.com.

Process development:

We specialize in developing what are called 'psycho-immunology' processes for various diseases. This type of process **doesn't** use drugs, vaccines, or surgery, but rather uses psychological techniques to eliminate the disease symptoms. When the coronavirus first broke out, we immediately started work on a psycho-immunology process with our staff members who had contracted the disease. By May, we had derived an experimental process that worked on them, and we then tested it on 17 Institute volunteers who did not have COVID-19 to check for safety and ease-of-use issues. From this testing, we found that 82% of them could complete the process, and that the mean time to completion was about 40 minutes. At this point, we were ready to start what is called a Phase 1b trial, that is, more testing on people who are actively sick, or still have various COVID-19 symptoms even after having the infection.

How is the process done, and how long does it take?

This process does **not** use drugs or vaccines. It **does** use a psycho-immunology technique to reduce or eliminate COVID-19 symptoms. This means we play music, use a repeated phrase, have you put your hand in a particular position, focus on feelings of suffocation, and do light tapping on a meridian point in the hand. The process takes about 2 hours, with two short follow-up sessions. You can end any individual session or the full trial at any time, although you might have some temporary discomfort afterwards due to triggered but unresolved sensations or feelings.

What if it doesn't work?

If for some reason the trial process is not fully successful, we may then ask if you would be willing to work with our research staff to see if we can find out why. Your therapist would then guide you in doing a regression and would then use trauma therapy techniques with you.

Are there side-effects?

As of this writing (Aug 1, 2020) we don't know of any side-effects from this rev 3 process. However, this does *not* mean that you won't have a problem with the process. You need to read the disclosure and liability forms below and make a decision based on what we know at this time.

From all of us at the Institute, thank you again for joining us in this important research!

**Peak States® COVID-19 Psycho-immunology Process Phase 1b Testing
Informed Consent Agreement**

Rev 1.0, Aug 1, 2020

Therapist's name: an assigned Institute for the Study of Peak States staff member
Mailing address: 3310 Cowie Rd., Hornby Island BC V0R1Z0 Canada
Medical Director message phone: +1-509-965-4502 (USA)
Medical Director email: DrMary@PeakStates.com
Main office phone: +1-250-509-0514 (Canada)
Main office email: Grant@PeakStates.com

Hello,

We're going to start our work together by going over this informed consent form. Many countries have laws requiring that we do this; but it is a good idea to do anyway, as it will answer some question you wanted answered, or may not have even thought about before. As we cover each item, we'll have you check it off to show that we have covered it to your satisfaction. You will keep the original form, and give us a signed copy (jpg or PDF) for our records.

You will be working with a certified therapist who is volunteering at the Institute for the Study of Peak States to test our new COVID-19 psycho-immunology process. Your session will be likely done via Zoom or Skype, and not in person, with a therapist who might be living anywhere in the world. Thus, if you have any non-emergency problems after your session (relevant to the COVID-19 testing), you should first call your therapist, and if for any reason you can't get through or can't get help, call our main office phone numbers above.

What are my test facilitator's qualifications and orientation as a therapist?

When you need your car engine fixed, you need to go to a mechanic who knows all about engines – you don't go to the transmission guy. In the same way, therapists also specialize, and are better at some things than others; and some things they just don't have the right training for. Our psycho-immunology process uses trauma therapy to get its results. Thus, your practitioner is a trauma therapist, specializing in healing traumatic memories that you may or may not realize can cause you problems. Although the academic backgrounds of our therapists vary, they all have been certified by the Institute in trauma therapy, and are licensed in their respective countries.

- Academic qualifications: varies from therapist to therapist (MDs, psychology, etc.).
- Formal licensure: as a therapist or counsellor is in our home country.
- Certified: by the Institute for the Study of Peak States to use their techniques.
- Therapeutic orientation: Trauma and developmental psychotherapy

I understand what my therapist's qualifications and therapeutic orientation are.

What clients won't we work with?

There are certain issues that disqualify you from using our rev 3.x COVID-19 process. The most important for you to know about is the issue of suicide. If you have suicidal feelings, have attempted to commit suicide, or have made plans to commit suicide, you need to see someone else who specializes in this problem. If this comes up during our work together, I will end our sessions and refer you to another therapist (or other professional) who works with this issue.

Another problem that might come up involves physical problems like heart conditions. Because therapy might bring up strong emotional and physical reactions, if you have any medical conditions that might put you at risk, we cannot start the COVID-19 process trial with you.

I understand the areas that disqualify me from doing the testing, and I understand and agree to this. Thus, I don't have any of the suicidal issues that we discussed, nor do I have any physical condition (like heart troubles) that might be triggered by this COVID-19 process.

Confidentiality and its exceptions

During our sessions, we may be taking written notes, or audio or video recordings. This helps us remember what we accomplished or still need to do, and is used to help us make a better COVID-19 process. This material is confidential and is not for other people, even after we finish working together. However, there are some exceptions:

- a) if a child is, or may be at risk of abuse or neglect, or in need of protection;
- b) if I believe that you or another person is at clear risk of imminent harm;
- c) for the purpose of complying with a legal order such as a subpoena, or if the disclosure is otherwise required or authorized by law.
- d) Do not tell me anything you wish kept secret from your partner.
- e) I may also disclose information for the purpose of a professional consultation, or for a professional presentation or paper, in which case your identity will remain confidential.
- f) I may also be sharing anonymous data (length of time, effectiveness, unusual problems) from our sessions to help improve the quality of the processes we are using.
- g) You should be aware that email, Zoom, Skype, or cell phones can be monitored by others, so don't communicate in this way if you wish confidentiality.

I understand the exceptions to confidentiality, and I understand and agree with these terms of the test.

Benefits and risks of the COVID-19 PeakStates psycho-immunology process

So, what are the difficulties or risks with using a psycho-immunology process? First, although the trial process does not involve any regression, it actually works by healing very early prenatal trauma. If you don't heal this past event fully, you may feel badly for a period of time ranging from hours to days, and perhaps longer, until these memories re-submerge and leave your awareness. Secondly, these processes are relatively new and experimental. Long-term effects, if any, have not been studied or researched. This means that there is always the possibility that problems may occur that we have never seen before, and do not know how to deal with. By analogy, this is like a new drug that after a few years turns out to have side effects that only affected some people. If problems happen, we will call in specialists to help, but even they may not be able to solve your problem. Given this, why would you ever want to use such a process? The reason is the same as why you would use a new drug – it can do things that you really want done, and there are no obvious problems (at least so far).

Obviously, due to safety concerns only a therapist who is trained in these techniques should be using them. If you go ahead with this type of psychological process, you must not share the techniques with others, including your spouse or other therapists you know.

Also, the COVID-19 process you use is for you only, and not to be taught to others, be they partners, family, friends, therapists or clients. This is for their safety, because formal training is needed in case something goes wrong; and because this is a new, experimental process and we expect it will be changed to improve it over time.

I understand the PeakStates psycho-immunology process benefits and risks. I understand that there may be problems that remain after the process trial is finished. Yes, I am willing to accept the risks and any consequences that may arise, and use these processes. I agree to not share the techniques to anyone else.

Benefits and risks of trauma therapy

The trauma-based process that we will be doing is intended to eliminate all or some of the symptoms of COVID-19.

You should know, however, that this trauma therapy process may feel challenging and difficult at times. Uncomfortable feelings and experiences may be addressed (in that you may feel anger, sadness, guilt, grief, loss, frustration, etc.) as well as physical discomforts or pains (suffocation, nausea, aches, other pains). During the session, you may feel worse before you start to feel better. And we simply may not be able to help you, or, in rare cases, make you feel worse than when we started.

In your session, we will be using a state-of-the-art meridian trauma therapy. You should also know that this technique, although widely used for over 20 years, is still considered experimental and may cause you problems that have not yet been recognized.

I understand the trauma therapy's benefits, risks, and other options available to me, and I understand I can choose to continue testing with trauma therapy if appropriate for my situation.

Benefits and risks of regression with Whole-Hearted Healing™ (WHH)

If we find that the process did not work for you, we'll ask you if you would like to continue testing to find out why with our research staff. If we continue, we would use the state-of-the-art therapy WHH that often involves regression to traumatic prenatal experiences. We may use it because WHH may work when other techniques don't; it can also heal some problems that the other therapies we know of can't. On the other hand, as with all the latest powerful trauma therapies, there is a possibility that you may feel emotionally or physically worse after the session than you did before. This happens because we have made you even more aware of your issue (or triggered a different issue) and been unable to heal it. If this isn't something you are willing to accept, we recommend that you do not start the process trial at this time.

For safety reasons, this WHH technique is for your own use and not to be taught to others, be they partners, family, friends, therapists or clients. This is simply because formal training is needed to know what to do in case unusual problems arise.

If the trial process does not work, I can choose to continue research testing. If so, we have discussed the risks and benefits of using WHH; I understand that problems may remain after the process is finished. I am willing to accept the risks and any consequences that may arise.

Practical details, like withdrawing from the trial

If you decide to start the COVID-19 testing process, you can expect the first session to take approximately two hours, but can run overtime; and there are two short follow-up sessions. Thus, our trial process will typically take three sessions, and will terminate at that point. We'll agree on a schedule that works for both of us. If you miss three sessions without cancelling or with less than 24-hour notice, we will discontinue the trial with you.

We encourage you to phone if any emergency situations arise from our work between sessions, but other concerns or pre-existing problems won't be addressed in our process. Our phone number is at the beginning of this document.

You can decide to stop process trial at any time. However, be aware that any feelings or sensations you have when you stop may continue for some time, generally just a few hours but possibly up to weeks. If you decide to continue the process trial later, this will generally get rid of any long-term uncomfortable sensations that have persisted when you quit the session.

If you have a life-threatening emergency, you must either phone your country's emergency services (in Canada and the US at 911), or go to the nearest emergency room. If the issue involves suicidal feelings, call your local Suicide and Crisis Hotline (in the US, 1-800-273-8255 (US); or in Canada, 1-833-456-4566). We provide only non-emergency therapeutic services by scheduled appointments. If you may need additional or more intensive services, we may refer me to another organization to receive extended services.

I understand practical details of our work together, especially about emergencies, and I understand and agree to these terms.

Reviews, referrals and ending

In this process trial, it is your right at any time to:

- a) have a review of your progress and of any of the topics in this form;
- b) be provided with a referral to another counsellor or health professional;
- c) withdraw consent for the collection, use, or disclosure of your personal information, except where precluded by law;
- d) end the test by so advising the therapist;
- e) access or obtain a copy of the information in your counselling records, subject to legal requirements (which normally would simply list pre-existing symptoms, symptoms after the test, your test duration, and any difficulties in using the process).

Your right of access to or to obtain a copy of your personal information continues after the end of the test.

We reserve the right to terminate the testing at any time. This may occur, for example, if I believe that I simply can't help you.

I understand my rights around the termination of therapy, and I understand and agree to these terms.

Concerns or complaints

If you have a concern about any aspect of your testing, we would prefer that you first address it with your test therapist. If you feel that this is impossible or unsafe, or if your concern is not resolved through discussion with your test therapist, you should contact the Institute for the Study of Peak States at +1-250-509-0514. If this doesn't resolve your complaint, you should then contact the local governmental body that regulates therapists in your country.

I understand how to deal with any complaints or problems I have with my testing therapist, and I understand and agree to these terms.

Subject's responsibilities and other legal issues

1. I hereby declare that I am informed about the objectives of the study and its procedure as well as the possible risks associated with the study have been explained orally in detail and in a comprehensible manner. All my questions have been answered to my satisfaction.
 2. I had enough time to reconsider my decision to participate in the study and to make a free decision.
 3. I am aware that I can withdraw my consent to participate in the study at any time and without giving reasons. Withdrawal from the study orally or in writing will not have any disadvantages for me besides the possible loss of benefits from this experimental process.
 4. I am aware that personal data is collected during the study and written down in protocols or stored electronically. The data is secured against unauthorized access. An evaluation as well as the publication of the data is only carried out in anonymous form (i.e. a personal reference is only attached to the data).
 5. I will immediately tell my assigned therapist of any side effects or unusual reactions during and after the process trial, including during the month following the completion of the process.
 6. I will honestly and completely fill out the attached medical history form.
 7. If I am involved in some other COVID-19 treatment or vaccine trial, I won't start this process test. This both makes sure our study is valid, and keeps any potential odd interactions from occurring.
- I understand these legal issues, and I understand and agree to these terms.

**Peak States® COVID-19 Psycho-immunology Process Phase 1b Testing
Liability Agreement**

Rev 1.0, Aug 1, 2020

Intent: The COVID-19 psycho-immunology process (rev 3.0 or any later version) that you will be using is state of the art and still 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 techniques, we require that you not start with our process trial. This is all common sense given the nature of experimental testing, but we want to make it perfectly explicit up front.

Be aware that this process **won't** work for everyone. And even if all your symptoms are gone, we don't yet know if it will have long-term stability, nor if it will partly or completely eliminate the virus. Regardless of the outcome of this process, you should continue to use your country's official sanitary protocols - social distancing, face masks in public, and hand washing (since you could still pass the virus via your hands even if you were immune).

I do agree to the following:

8. I take complete responsibility for my own emotional and/or physical well being both during and after this process.
9. I agree to hold harmless the person who guides me in the use of the Institute for the Study of Peak States (ISPS) process, the ISPS, and anyone associated with the ISPS now, in the past or in the future, from any claims.
10. I will only use the process under the supervision of a qualified, certified therapist or physician as legally appropriate.
11. I will not use this process by myself.
12. I agree not to record any of the music used for this process.
13. For safety reasons I agree not to disclose this process to anyone else, including my partner, family, friends, therapists and clients.
14. I agree not to teach this process to others.
15. I have read, understood and signed the Informed Consent and Medical History documents.
16. I understand that Peak States® is a trademark and cannot be used without approval by the Institute.

Signature

“My signature below confirms that I (the client) have read the Informed Consent and Liability Agreement information above, had an opportunity to discuss it with the assigned therapist, had

Institute for the Study of Peak States

sufficient time to consider it carefully, and had my questions answered to my satisfaction. I have also filled out the medical history form to the best of my ability. I agree to start the COVID-19 psycho-immunology process trial.”

Printed Name of Client

Name of Witness (if any)

Signature of Client

Signature of Witness (if any)

Address

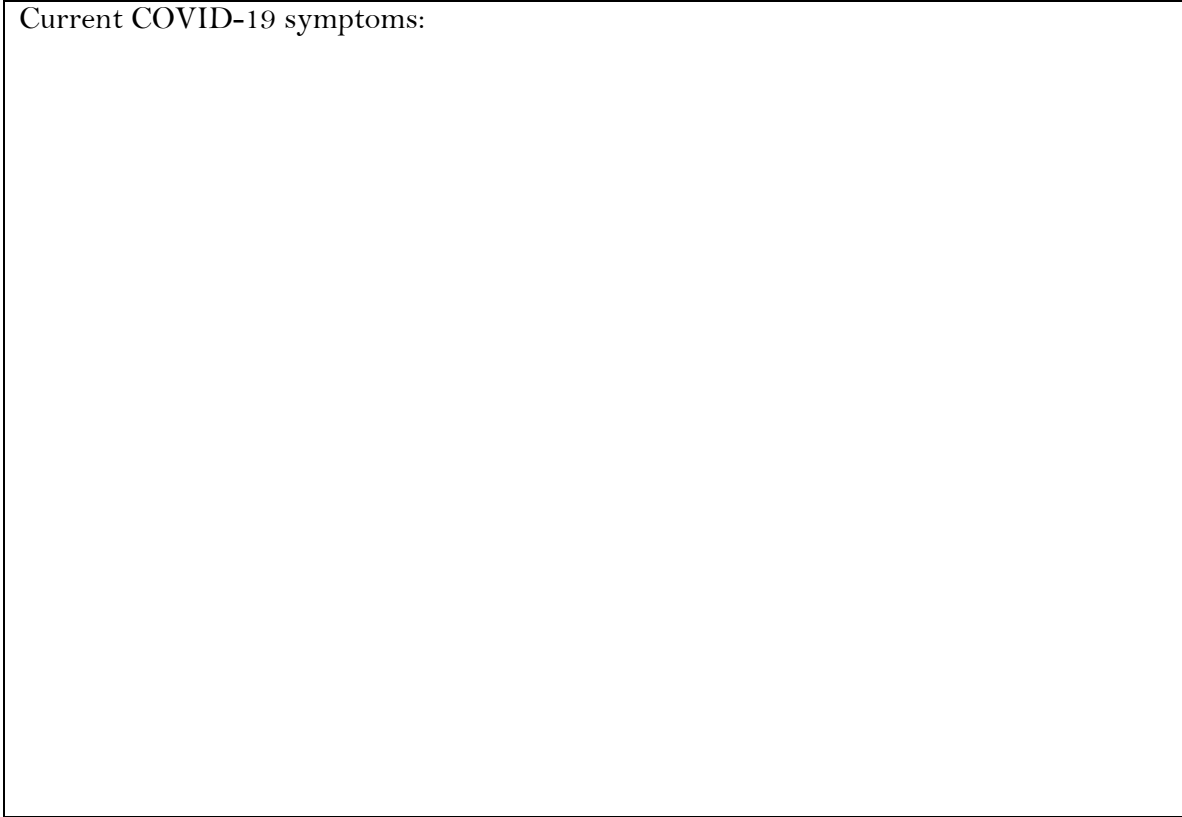
Date signed

Medical History Form

Revision 1.4 May 25, 2019

Name:		Phone:
Address:		
Email:	Date of birth:	
Relationship status:	Occupation:	
Emergency contact person:		
Contact's phone number:		
Physician's name:	Physician's Tel/address:	
Current state of health:		
Current medical treatments/medication:	Current alternative treatments/supplements:	
Contagious ailments (current HIV, Hep C, other):		
Past major medical conditions and treatments:		
In the last 5 years, have you felt suicidal?		
In any time in your life, did you attempt to commit suicide?		
Have you ever been diagnosed with mental illness?		
Drug and alcohol history:		

Current COVID-19 symptoms:



This information is confidential.

Revision History:

Rev 1.0, Aug 1, 2020: First revision based on existing therapist documents. Additional material included from Stanford University's Sample Consent Form for experimental research.