PARTICIPANT INFORMED CONSENT FORM AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE: INPACTS CORE: **I**mpact of **N**ANO SOMA® on **P**articipant-**A**ssessed **C**OVID **T**reatment **S**equelae – **C**linically **O**bserved **R**eported **E**ffects

PROTOCOL NO: NS 004
PRINCIPAL INVESTIGATOR: Rima E. Laibow,MD
STUDY SITE: Virtual
TELEPHONE: 908-337-6115
SPONSOR: MagicDichol LLC
TERM OF STUDY: The Expected Term of the Study is: 6 months

Provision Providing for Method to Leave the Study:You are being asked to participate in a research study on a nutritional supplement. Your participation in this research study is strictly voluntary, meaning that you may or may not choose to take part.

To decide whether or not you want to be part of this research, the risks and possible benefits of the study are described in this form so that you can make an informed decision. This process is known as "Informed Consent".

This consent form describes the purpose, procedures, possible benefits and risks of the study. This form explains how your medical information will be used and who may see it. You may have a copy of this form to review at your leisure or to ask advice from others.

The Principal Investigator (PI) or study staff will answer any questions you may have about this form or about the study. Please read this document carefully and do not hesitate to ask anything about this information. This form may contain words that you do not understand. Please ask the PI or study staff to explain the words or information that you do not understand.

After reading the consent form, if you would like to participate, you will be asked to sign this form. You will be given a signed copy of your consent form to keep for your records.

BACKGROUND: You are being asked to participate in this study because you have identified health issues which you associate with either receiving one or more COVID-19 injections or being in contact with one or more people who have received one or more COVID-19 injections.

Your participation is based on your own Informed Consent and must be voluntary and knowing. The Goal of the study is to find out whether NANO SOMA can support a positive change in the health situation of people who meet the criteria for this study.

MEDICAL HISTORY: The PI or study staff will ask you about your SARS-COV2 vaccination history (please provide your vaccination records) including the type, lot number and date of each SARS-COV2 (COVID) vaccination, if any. The PI or study staff will also ask you about your smoking history and other health-related questions. You will be asked to provide a Medical History and a list of all medications and supplements which you take.

ACTIVE MATERIAL OR PLACEBO: You will be given a supply of the study supplement, which may be the active ingredient or a placebo. The PI or study staff will instruct you on how to take it. You will be provided with a symptom and usage log and instructed on how to use them.

PROHIBITED MEDICATIONS: There are no prohibited medications or supplements. You should take all prescription medications, supplements or other substances you use on a regular basis during the study.

Tell the PI or study staff about all medications and supplements that you are taking. Please tell the PI if you receive any additional medications from a health practitioner for the treatment of any condition at any time during the study or if you start any new supplements, herbal products or similar during the study.

POTENTIAL RISKS, SIDE EFFECTS, DISCOMFORTS, INCONVENIENCES:

- No allergic reactions to the active material have been reported. Some things that may happen during an allergic reaction are :

• A Rash
• Difficulty breathing
• Wheezing when you breath
• Sudden drop in blood pressure
• Swelling around the mouth, throat, or eyes
• Fast pulse
• Sweating
• Anxiety or agitation

There are no known side effects from NANO SOMA; however, it is possible, though rare, to experience a healing crisis or Herxheimer Reaction as you get started with NANO SOMA. You should get medical help and contact the PI or study staff if you have any of these or any other side effects during the study. Please tell the PI or study staff right away if you have any side effects or adverse reactions. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think they are related to the study supplement. There may be risks of the study supplement that are unknown at this time.

- WHAT ARE THE RISKS OF THE STUDY PROCEDURES? There are no known risks of the study procedures.
- ARE THERE RISKS TO ME IF I AM PREGNANT DURING THE STUDY? NANO SOMA is made from food-based ingredients that are generally recognized as safe, including policosanol and pristine Swiss water. However, if you are a woman, you cannot be in this study if you are pregnant or breast-feeding a baby. If you decide to be in this study:
  • You must not be pregnant.
  • You must not plan to become pregnant during your participation in the study.
  • You must not be breast-feeding a baby.
  If you are a woman who is neither post-menopausal for one year nor surgically sterile, the PI will talk to you about birth control options you must use during the study. Medically acceptable methods include oral contraceptive medication, an intrauterine device (IUD), an implantable contraceptive (such as Implanon®), an injectable contraceptive (such as Depo-Provera®), or a barrier method (such as condom or diaphragm with spermicide). If you become pregnant during the study, you must tell the PI immediately. If you are pregnant, you will be removed from the study without your consent.

POTENTIAL BENEFITS: The study supplement may help your health, but you may not directly benefit from participating in the study. Your health may get better or may even get worse while you are in the study. The information from this study might help researchers develop a protocol to help others with health issues related to COVID-19 injections in the future.

ALTERNATIVE TREATMENTS OR THERAPIES: You do not have to be in this study to get help for any problems related to COVID-19 injections. You do not have to be in this study to use NANO SOMA, which is sold commercially.

The PI will talk to you about other things you can do, including the important risks and benefits. Some of the things you may be able to do are:

• Take FDA-approved medications for COVID-19 injection-related issues (we know of none).
• Change your diet and exercise patterns (we know of no correlation between COVID-19 injection-related issues and diet or exercise patterns)

NEW INFORMATION: You will be informed in a timely manner if new information that may influence your willingness to continue participation in the study becomes available.

COMPENSATION TO YOU: You will not be compensated but will receive the substance (or placebo) free of charge. At the end of the study, you will be offered a 1-month supply of the Active Material. You will not be charged for this supply of the Active Material.

There is no guarantee of success offered by the use of the Active Material in dealing with COVID-19 related issues.

COSTS TO YOU: While you are in the study, you may still need to get regular medical care. You (and/or your health care payer) will have to pay for the costs of your regular medical care that are not a part of this study. You do not have to pay for the study supplement that is part of the study.

VOLUNTARY PARTICIPATION / WITHDRAWAL: Your decision to participate is entirely voluntary. You may elect to receive an alternative approach. You may refuse to participate or withdraw from the study, at any time, without penalty or loss of benefits to which you are otherwise entitled. Your ongoing medical care will not be affected by your decision to be in this study or to withdraw from the study. If you decide to withdraw from the study, please talk to your PI to make sure this is done safely. You must withdraw from the study in writing, communicated to the PI by mail, email or text message. Your withdrawal message must be dated.

Your participation may be terminated without your consent by the PI for any reason. For example, your participation may be stopped:

- If it is deemed to be in the best interest of your health and welfare.
- If your condition worsens or you have severe or unacceptable side effects.
- If you fail to follow instructions as directed.

If you stop being in the study early, the PI or study staff may ask you some questions about being in the study.

STUDY COMPLICATIONS AND COMPENSATION: The Active Material under investigation is a commercially available product purchased over the counter. If you are injured or experience severe side effects due to this product, whatever remedies which would apply as to product liability will apply in this study. The above statement does not waive your legal rights.

CONFIDENTIALITY AND AUTHORIZATION TO COLLECT, USE AND DISCLOSE YOUR MEDICAL INFORMATION: As a part of this research, records that contain information or data about you and your health may be collected and used. These records may identify you and will be kept as confidential as possible. To the extent permitted by applicable laws and regulations, the records identifying you will not be made publicly available. We will make every reasonable effort to mask your identity in any publication.

Under the privacy laws, you have the right to decide who can use your protected health information (called PHI). When you sign this form, you are saying that you will allow the use of your protected health information for this study. The information that will be collected about you as a part of this research includes but is not limited to:

Name, Address, Telephone number, Birth Date, Race, Sex, Allergies, Medications you take (current and past), Medical History.

Information collected about you for the study will be kept in a research file that is separate from your medical chart. You will not be able to see your research file until after the end of the study. The PI and study team will know your identity; however, your records will be labeled with a code that is randomly assigned to you. The research staff are the only people who will have this code and its key. The PI and study associates may review and use your study information but not your contact information (name, address, email, and phone number). They may review your study information to make sure that it is correct. They may also review your information to make sure that the study is being conducted properly. The study sponsor (or sponsor representatives such as monitors and/or auditors) and the Institute for Health Research Institutional Review Board (IRB) may review your study information.

Your study information may be released to the groups listed above. However, this access to your records will be granted without revealing contact information such as name, address, email, and phone number.

Your confidentiality will not be violated to the extent permitted by applicable laws and regulations. By signing this form, you are authorizing this access to your records. The results of the study may also be presented at meetings or in articles written about the study (publications). If the results of the study are published, your identity will remain confidential. You have a right to see your study records; however, you will not be able to see your study records until after the study has ended. The PI's contact information is 908-337-6115. In the case of your withdrawing your permission to use your information, the PI will still be able to use the health information collected about you before you withdrew your permission. Information that has already been sent to the sponsor of the study cannot be taken back.

If you withdraw your permission after you have entered the study, you cannot continue participating in the study.

QUESTIONS: If you have questions, concerns or complaints about the research study or you experience a research-related injury, please contact Dr. Laibow or the study staff at 908-337-6115. If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact: the PI, Rima E. Laibow, MD, releyes3@gmail.com

PARTICIPANT STATEMENT AND AUTHORIZATION: I have read the Participant Informed Consent Form and Authorization to Use and Disclose Medical Information and I agree to participate voluntarily in this study. I give my permission to the PI to use and

disclose my protected health information as described in this consent form, and to publish the results of the study.

I will receive a signed copy of this form. All my questions have been answered. I have not waived any of my legal rights by signing this document.

_____ Printed Name of Participant

_____ Signature of Participant

_____ Date

_____ Printed Name of Person Explaining Consent

_____ Signature of Person Explaining Consent (if other than the Principal Investigator)

_____ Date

_____ Signature of Principal Investigator

_____ Date