Informed Consent to Take Part in a Research Study

Please print two copies of this form. After reading, please sign and send the signed copy to:

Natural Products Research Institute of New England
825 Atlantic Highway
Warren, ME 04864

Keep the second copy for your records.

Title of Study:

The general study of specific natural products for the treatment of various disease states alone or given in combination with standard of care medicines (OTC products and physician prescribed drugs). See specific studies:

Study 101	Pain and Inflammation
Study 102	Weight Management
Study 103	Cold Sores
Study 104	Prevention of Airborne Infections

Investigator:

The group responsible for conducting this study is the Natural Products Research Institute of New England and, unless specifically noted, the study director will be Dr. Jeff Leighton (Institute Director). Please refer all questions and comments to studydirector@nprine.org or mail to Natural Products Research Institute of New England, 825 Atlantic Highway, Warren, ME 04864.

Purpose:

The purpose of these studies is to assess the efficacy of various natural products to affect established disease and symptoms of disease when given alone or in combination with standard drug therapy (either OTC or physician prescribed). Desirable outcomes include:

- Demonstration of efficacy of the natural product alone
- Synergy of the natural product when taken alongside (not at the same time, but on the same days) standard therapy
- Replacement of drug therapy with natural product while maintaining equivalent efficacy

- Demonstration that same day therapy of a natural product with a drug product allows the patient to reduce standard meds without a loss of efficacy.

- Demonstration that same day therapy of a natural product with a drug product at lower dose strength provides equivalent efficacy with less side effects.

All of the above results will help to define the real therapeutic value of a natural product. Some, but not all, of the above criteria may be achieved.

General Method of Analysis:

Please refer to specific protocols for details. All protocols use either a number line assessment for efficacy or a diary format. The methods are non-invasive. In no cases are you asked to give blood or subject yourself to any invasive procedure. This type of study is referred to as an "Open Label Clinical Trial". Because these studies use only safe natural products, taken separately from drug products, this study does not require an IND submission with the FDA. However, studies are designed to be completed in a highly professional manner, so that meaningful information regarding efficacy or lack of efficacy can be determined.

General Information that you should know:

Are there any safety concerns that I should consider?

- All products are combinations of natural products and products that you might encounter in your diet.

- All products have been thoroughly researched and there are no reported safety issues.

- All ingredients in the final products have been sourced from bulk suppliers that qualify as ISO 9002 facilities (they conform to high FDA standards).

- All products have Certificates of Analysis.

- All data files are maintained by NPRINE.

- Final products are prepared according to FDA GMP guidelines.

Specific Information that you should know:

If you wish to enroll in a specific study, read the information related to that study carefully. If you have additional concerns or questions, pleased contact NPRINE by emailing studydirector@nprine.org

What you need to know about the Pain and Inflammation Study (Study 101) Prior to Agreeing to Enroll?

If you are currently taking, or have taken within the last 30 days, physician prescribed blood thinners such as Coumadin or Warfarin, you cannot enroll in this study.
In rare cases the combination of omega-3 oils and these agents could induce internal bleeding.

If you have allergies to fish, then you cannot enroll in this study.

In addition to the general information given above, if you plan to enroll in Study 101: Pain and Inflammation Trial, you should understand that you will be asked to take an all natural, high potency omega-3 oil (fish oil) in liquid form.

The most common side effect is "fish burp" which rarely occurs with high grade liquid oils.

In this study you will be using high grade omega-3 oil either alone or on the same day, but not at the same time, with other physician prescribed drugs. Do not mix the omega-3 oil and drug product together. Take each medication separately and separated from each other by at least 1 hour. Omega-3 oils and food fats may affect the absorption of certain drug products and you should, out of precaution, not take these products simultaneously.

If you experience any adverse reaction to the supplement, discontinue use and notify the study director immediately.

The omega-3 oil used in Study 101 has been 3rd party tested; it has no heavy metals (mercury, lead nickel aluminum arsenic or cadmium) as determined by modern, sensitive detection methods such as electro spray mass spectrometry and it has extremely low levels of environment toxins such as PCBs (polychlorinated biphenyls), dioxins and halogenated hydrocarbons. These agents are detectable in the range 1-10 PPT (parts per trillion). This is considered well within the safety range of all food products.

What you need to know about the Weight Management Study (Study 102)?

If you have an allergy to lactose or cannot drink milk products, you cannot enroll in this study.

If you have been diagnosed with kidney failure or elevated blood urea nitrogen (B.U.N.) you cannot enroll in this study.

If you suffer from phenylkomeurea (P.K.U.) you cannot enroll in this study.

This Study requires you to take twice daily a protein supplement. On a daily basis your total intake of protein will be less than 50 grams.

This supplement contains a small amount of lactose (0.5 grams/30 grams dose).

This product is not sweet tasting; it is taste neutral. It contains no added high glycemic sugar or carbohydrate. It does contain 10% cherry powder. It you are allergic to cherry powder, do not enter this study. If you have diagnosed with kidney disease or have abnormal BUN levels (blood urea nitrogen), do not enroll in this trial.

Side effects are minor with this product. Stomach and g.i. discomfort of a transient natural may occur in rare cases. A sense of stomach fullness may occur. However, this effect is regarded as a part of the mechanism.

If you experience any adverse reaction to the supplement, discontinue use and notify the study director immediately.

This protein product is sourced from companies within the US. The product is a whey product derived from cow milk. While we understand that these cows are grass feed, they are not organically certified and this whey may contain residual animal hormones not dissimilar to milk products that are not organic in grocery stores. In addition to protein from whey, this product contains other dietary supplements that have the ability to increase fat oxidation, increase muscle mass/enhance metabolic rate and decrease overshoot of insulin. All of these additives are considered to be safe, natural products. They have been combined to enhance weight loss. All ingredients in this product come from ISO 9002 certified labs and come with Certificates of Analysis. This product is prepared under GMP Guidelines.

Diabetics (Type I and II) have used this product without reported side effects.

What do I need to know about the Cold Sore Study (Study 103)?

To take part in this study, you must cease using any antiviral medicines such as Abreva, Valtrax or Acyclovir.

This study uses all natural products that have been combined in the form of a lip balm (similar to a Chap Stick®). This product should decrease local inflammation (redness, swelling, blistering, itchy feeling) and accelerate healing. There are no known side effects. There are no known skin sensitivities.

If you experience any skin effects that induce redness, or cause any sense of discomfort, immediately discontinue use of this product and notify the study director immediately.

This product can be used multiple times/day without any known side effects. See protocol for additional details.

What do I need to know about the Prevention of Airborne Infections Study (Study 104)?

This study uses all natural products in a combination that are designed to decrease the frequency of acquiring a cold and the severity a cold. This product does not contain zinc and can be used without limitation as frequently as needed. There are no known skin sensitivities. However, if you experience redness of the skin at or near the application site (nasal cavity) or any congestion (nasal stuffiness, or runny nose), discontinue this product and notify the study director immediately. Do not apply to eyes or lips.

Additional Information I Should Know

What will take place in this study?
During these studies you will be contacted by the Study Director's office staff, every week for the first 4 weeks and then every 2 weeks for the remainder of the study. The purpose of this contact is a general follow up. Are you adhering to protocol? Do you have any questions or concerns? Between these calls you may call or email the study director at any time.

How will I know if I am receiving an active medication or a placebo?
This is an Open Label Study. All patients will receive an active medication. There are no placebo controlled data in this initial study.

Does this study provide any benefit?
Based on you and your health care provider's assessment of efficacy, this study may allow you to alter or decrease your current medications.

Will it cost me anything to enroll in these studies?
There are no costs. All natural products will be sent to you free of cost.

Will I be paid to be in this study?
During the course of the study, you will receive a free supply of the product being studied. Upon completion, you will receive a $100 voucher. You may use this voucher to buy any Maine Natural Health product of your choice from either the Maine Natural Health Company via phone (800-797-2021) or from your local participating independent pharmacy (as specified on voucher).

Do I have to be in this study?
Participation is voluntary. You may stop participation at any time. If you stop participation before completion of the study, you will not receive your voucher for $100.00

Can I be removed from this study by the sponsor?

Yes, if:

- You stop adhering to the protocol.
- You are not available for contact on a bi-weekly basis.
- The sponsor cancels the study.
- If you develop side effects that, in the view of the sponsor, are not acceptable.

Who will have access to my test results?
This study is done in absolute confidence. You are viewed as a "number" in the study. Your specific results will be kept confidential. Group analysis will be completed by an independent statistician and the results will be published on the NPRINE website and may also be submitted to scientific journals for publication and in Monographs written by the company or its consultants.

I have read this information and reviewed the applicable enrollment and protocol forms and agree to participate in the following study. (Please check the study that you wish to join).

Further, I have had a chance to ask additional questions to NPRINE by contacting the Study Director. I am satisfied with the information presented.

Study 101; Pain and Inflammation ☐

Study 102: Weight Management ☐

Study 103: Cold Sore Study ☐

Study 104: Cold Prevention Study ☐

Name: (PRINTED) _____

(SIGNED) _____

Date: _____