CONSENT TO PARTICIPATE IN RESEARCH

The University of Mississippi Medical Center

Study Title: Impact of Oral Immulina ™ Supplementation on Natural Killer Cell activities and Other Biomarkers Associated with Increasing Host Immune Resilience to Upper Respiratory Viruses in Normal Human Volunteers, Group 1

Principal Investigator: Gailen D. Marshall, Jr., MD, PhD

Key Information

The purpose of this research study is to learn of the effects of Immulina™, a natural supplement, on specific immune substances (called biomarkers) in the blood that are associated with improving the ability to "bounce back" against the flu virus.

Group 1 of the research study wants to learn about (a) how soon the effects of the natural supplement, Immulina™, appears, (b) the highest dose of Immulina™ that affects specific immune biomarkers in the blood and (c) how long the response of Immulina™ lasts in the specific immune biomarkers in the blood. If you participate, you will be put into one of four groups and given either one of three doses of Immulina™ capsules or placebo (a pill that looks like the study pill but does not have Immulina™ in it) capsules. Your participation will last almost 5 months (20 weeks). If you receive Immulina™, you may experience rare, but minor risks including nausea, vomiting, diarrhea, stomach pain, dry mouth, fever, chest pain or discomfort, back pain, drowsiness, headache or skin rash or itching. If you receive Immulina™, it is unknown if you will receive a direct benefit. If you have questions, call Dr. Gailen D. Marshall, Jr. at (601) 815-1078.

Introduction

You are being invited to be in this experimental research study because you are aged 18-64, are generally healthy and may or may not have a disease controlled by medication. Please ask us about anything in this document or that we tell you that you do not understand.

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Purpose

The purpose of this three-phase study is to determine the effects of Immulina™ on specific immune biomarkers in the blood that are associated with improving the ability to "bounce back" against the flu virus.

Group 1 of the research study wants to learn about (a) how soon the effects of the natural supplement, Immulina™, appears in the specific immune biomarkers in the blood, (b) the highest dose of Immulina™ that affects the specific immune biomarkers in the blood and (c) how long the response of Immulina™ lasts in the specific immune biomarkers in the blood.

Procedures

If you agree to participate in this study, a study team member will talk to you about your medical and medication history. If you qualify for the study, your participation will involve up to 12 separate study visits over a 20-week time period. Visits will ideally be scheduled before noon. If morning appointments are not achievable, afternoon appointments may be available. The study requires a consistent schedule of either morning or afternoon appointments throughout all study visits. Each study visit will last for about 30-45 minutes and will take place at the UMMC Clinical Research and Trials unit. Participants have two schedule options to choose from for participation: either 7 visits or 12 visits. The tables below represent the study visit schedule for each option and the time intervals between the visits.

Study Visit 1 *(same for each schedule options)*

- We will review the informed consent with you and answer any questions you have.

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- We will draw about 3 tablespoons of blood to measure specific cells of your immune system and measure the cell's activities.
- We will give you 1 container with capsules.
- We will give you a daily log to record the date and time you took the study capsules, record missed doses, and note any side effects or other concerns while taking the capsules.

You will be randomized by chance, like pulling numbers out of a hat, to one of 4 study capsule groups. Neither you nor the study team will know ahead of time what group you will be in.

Study capsule group 1 – Placebo
If you are randomized to Group 1, you will receive placebo capsules (a study capsule that does not contain Immulina™).

Study capsule group 2 – 200 mg/day
If you are randomized to Group 2, you will receive Immulina™ capsules that delivers a 200 mg/day dose.

Study capsule group 3 – 400 mg/day
If you are randomized to Group 3, you will receive Immulina™ capsules that delivers a 400 mg/day dose.

Study capsule group 4 – 800 mg/day
If you are randomized to Group 4, you will receive Immulina™ capsules that delivers an 800 mg/day dose.

You will take 2 capsules in the morning and 2 capsules in the evening every day for sixteen weeks.

You may receive email, phone call, and/or text reminders (12 times total) from the study team to encourage you to continue to take your study capsules.

You may also receive a phone call, email and/or text reminder before each study visit to remind you of your upcoming study appointment and other visit-specific reminders.

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With Schedule Option 1 - **12 Visits**

	Start study supplement				Dispense capsules	Dispense capsules	Stop study supplement				
	↓				↓	↓	↓				
Visit 1	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**V8**	**V9**	**V10**	**V11**	**V12**
Baseline	Day 1	Day 4	Day 7	Wk2	WK4	WK8	WK16	WK16	WK17	WK18	WK20
Day0	Day 1	Day 4	Day 7	Day 14	Day 28	Day 56	Day 112	Day 116	Day 119	Day 126	Day 140

(Table key: V = Visit; WK = Week)

Study Visit 2

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will ask you about your experience with taking the capsules, including if you noted any side effects or other concerns while taking the capsules.

Study Visit 3

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will ask you about your experience with taking the capsules, including whether you note any side effects or other concerns while taking the capsules.

Study Visit 4

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will ask you about your experience with taking the capsules, including whether you note any side effects or other concerns while taking the capsules.

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Study Visit 5

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will ask you about your experience with taking the capsules, including whether you note any side effects or other concerns while taking the capsules.

Study Visit 6

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will ask you about your experience with taking the capsules, including whether you note any side effects or other concerns while taking the capsules.

- We will give you 1 container with capsules.

Study Visit 7

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will remind you to bring all capsule containers, remaining capsules, and daily logs to the next study visit.
- We will ask you about your experience with taking the capsules, including whether you note any side effects or other concerns while taking the capsules.

- We will give you 2 containers with capsules

Study Visit 8

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will collect all capsule containers and all remaining capsules from you.

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- We will collect the completed daily logs from you.
- We will ask you about your experience with taking the capsules, including whether you note any side effects or other concerns while taking the capsules.

Study Visit 9

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will ask you about your experience without taking the capsules, including if you noted any side effects or other concerns.

Study Visit 10

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will ask you about your experience without taking the capsules, including if you noted any side effects or other concerns.

Study Visit 11

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will ask you about your experience without taking the capsules, including if you noted any side effects or other concerns.

Study Visit 12

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will ask you about your experience without taking the capsules, including if you noted any side effects or other concerns.

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With Schedule Option 2 - **7 Visits**

	Start Study supplement	Dispense capsules	Dispense capsules	Stop study supplement		
	↓	↓	↓	↓		
Visit 1	**V 2**	**V 3**	**V 4**	**V 5**	**V 6**	**V 7**
Baseline	Wk2	WK4	WK8	WK16	WK18	WK20
Day0	Day 14	Day 28	Day 56	Day 112	Day 126	Day 140

(Table key: V = Visit; WK = Week)

Study Visit 2

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will ask you about your experience with taking the capsules, including if you noted any side effects or other concerns while taking the capsules.

Study Visit 3

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will ask you about your experience with taking the capsules, including whether you note any side effects or other concerns while taking the capsules.
- We will give you 1 container with capsules.

Study Visit 4

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will remind you to bring all capsule containers, remaining capsules, and daily logs to the next study visit.

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- We will ask you about your experience with taking the capsules, including whether you note any side effects or other concerns while taking the capsules.
- We will give you 2 containers with capsules.

Study Visit 5

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will collect all capsule containers and all remaining capsules from you.
- We will collect the completed daily logs from you.
- We will ask you about your experience with taking the capsules, including whether you note any side effects or other concerns while taking the capsules.

Study Visit 6

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will ask you about your experience with taking the capsules, including whether you note any side effects or other concerns while taking the capsules.

Study Visit 7

- We will draw about 3 tablespoons of blood to check the effects of the study capsule on specific cells of your immune system and measure the cell's activities.
- We will remind you to bring all capsule containers, remaining capsules, and daily logs to the next study visit.
- We will ask you about your experience with taking the capsules, including whether you note any side effects or other concerns while taking the capsules.

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Risks

Blood Draw
The risks of drawing blood are pain, bruising, or infections at the site where the needle is placed in your arm. On occasion, persons have been known to faint when having the blood drawn. Precautions will be taken to prevent these things from happening.

Placebo
Placebo has no known side effects.

Immulina™
The risks of taking Immulina™, which is derived from Spirulina are as follows:

- Rare, but minor side effects are nausea (the most common side effect), vomiting, diarrhea, stomach pain, dry mouth, fever, chest pain or discomfort, back pain, drowsiness, headache or skin rash or itching.
- Rare, but severe side effect is allergic reaction.

We do not know how your body might respond to Immulina™, placebo or blood collection procedure used in this study. We will discuss the risks identified above with you and the chances that they will happen. There may be risks that we do not know about at this time. Unknown problems, ranging from a mild inconvenience to some severe enough to result in a rapid need for medical attention, may occur. If you experience any problems, you should report them immediately to the study doctor, Dr. Gailen D. Marshall, Jr., at (601) 815-1078. This phone line is available 24hours a day. If you experience symptoms requiring emergency assistance, please dial 911 immediately.

Benefits

You may or may not receive a direct benefit from being in this research study. If you take Immulina™, it is unknown if you will experience any

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effects on your immune system. We hope to learn information from this study that may help others in the future.

Alternatives

The only alternative is not to participate.

Costs

There will not be additional costs to you if you participate in this study.

The study capsules will be supplied by the study at no cost to you. The lab tests performed on your blood are done solely for research purposes and will be paid for by the study. Insurance companies and other third party payers will not be billed for research procedures.

Research-related injury

In the case of injury or illness resulting from your participation in this study, medical treatment is available to you at the University of Mississippi Medical Center. You will be charged the usual and customary charges for any such treatment you receive.

Compensation

You will receive a $50 for each study visit you complete. You will receive this compensation in the form of a check, mailed to the address provided on the reimbursement form completed at each study visit.

Voluntary Participation

Your participation is voluntary. If you decide not to participate in this study you will not suffer a penalty of loss of benefits to which you are otherwise entitled.

You may choose to stop your participation in this study at any time. If you decide to withdraw the information already collected about you may still be used in this study, but additional information will not be collected. Your decision to stop your participation will have no effect on the quality of medical care you receive at the University of Mississippi Medical Center.

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There may be a small possibility that the study doctor may have to terminate your participation from the study without regard to your agreement to participate in the study. It may possibly be due to unforeseen side effects that may randomly occur. The study doctor will consider each event on a case-by-case basis.

Confidentiality

Every effort will be made to keep the information we learn about you private. Study personnel, the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Office for Human Research Protections
(OHRP) and the University of Mississippi Medical Center's Institutional Review Board (IRB) and Office of Integrity and Compliance, and Grants and Contracts may review the study records. If study results are published your name will not be used.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Protected Health Information

Protected health information is any personal health information through which you can be identified. The information collected in this study includes: Your name, gender, race, age, height, weight, BMI, phone numbers, email address, medical history, and medication history.

By signing this consent document, you authorize Dr. Marshall and his study staff to collect this information for this study. Dr. Marshall will use your information to investigate whether there are age, gender, and race differences in the research lab test results. The study team will use your contact information for appointment scheduling and reminders.

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The information collected for this study will be kept until the study is complete and may be combined with information collected through other research studies or used in other studies but no information will identify you. While this study is ongoing you may not have access to the research information, but you may request it after the research is completed.

Your medical information and records, once disclosed, may be re-disclosed and may no longer be protected by the Privacy Standards of the Health Insurance Portability and Accountability Act (HIPAA), which is a federal regulation designed to protect medical information, including medical information and records created through research.

You have the right to cancel this authorization at any time by providing Dr. Marshall with a written request to cancel the authorization. If you cancel this authorization, medical information and records about you that were created before the authorization was cancelled will still be used and disclosed as needed to preserve the integrity of the study.

This authorization has no expiration date. If you do not sign this consent document, you will not be allowed to participate in this study.

Number of Participants

We expect 236 participants to enroll in Group 1 of this study.

Questions

If you have questions about this study or need to report any problems, side effects, or injuries, please call Dr. Gailen D. Marshall, Jr. at (601) 815-1078. This phone line is available 24-hours a day.

You may discuss your rights as a research participant with the Chairman of the University of Mississippi Medical Center's Institutional Review Board, 2500 N. State Street, Jackson, Mississippi 39216; telephone, (601) 984-2815; facsimile, (601) 984-2961. The Institutional Review Board is a group of people not involved with this study who have reviewed the study to protect your rights.

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You will be given a copy of this consent document to take home for your records.

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Schedule Option Selection:

For my study participation, I choose the:

- ☐ 12 visit Schedule (**Option 1**)
- ☐ 7 visit Schedule (**Option 2**)

Statement of Participation

I have been told about this study, including the experimental natural supplement I may receive, and the possible risks and benefits. I agree to participate in this study, to follow instructions, and to report any side effects to my study doctor. My participation is voluntary and I may withdraw at any time without any penalty or loss of benefits to which I am entitled, including medical care at the University of Mississippi Medical Center.

By signing this form, I am not giving up any legal rights I may have.

_____
Participant's Printed Name

_____
Participant's Signature

_____
Date

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_____

Printed Name of Person Obtaining Consent

_____

Signature of Person Obtaining Consent

_____

Date

I acknowledge that the participant identified above has been entered into this study, with properly obtained informed consent.

_____

Signature of Investigator

_____

Date

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ADDENDUM TO MAIN STUDY CONSENT

CONSENT FOR STORAGE AND FUTURE USE OF SAMPLES

We would like to keep and store left over samples of your blood to use in future research. The samples of blood will be coded and stored in a freezer located in the Clinical Immunology and Allergy laboratory at UMMC. Your name will not be on the sample, but a separate list will be created with your name and an identification code that is placed on the sample. The list of names and codes will be kept in a separate, password protected electronic file that is only accessible by the researchers.

We may use the samples to help us:

- Learn how the supplement Immulina™ affects the immune system

It is your choice. You do not have to let us do this and there will be no penalty if you do not let us keep the left-over samples. This part of the study is **optional** and you can be in the study no matter what you decide.

Please initial by your choice below.

_____ You may keep, store, and use samples of my blood for future research studies to learn more about Immulina effects on the immune system.

_____ You may keep, store, and use samples of my blood for future research studies conducted by Dr. Marshall, the study doctor. The studies do not have to be related to Immulina effects on the immune system.

_____ You may not keep, store, and use samples of my blood for any future research studies.

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_____

Printed name of Participant

_____ _____

Signature of Participant Date

Future Studies: We may be doing more research studies like this one in the future. If we do, may we contact you by phone or email to see if you might be interested in participating?

Please initial your choice below and complete the contact information.

Phone: _____Yes _____No

Phone Number: _____

Email: _____Yes _____No

Email address: _____

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