General Informed Consent Form (v2023-08-31)
NSU Consent to be in a Research Study Entitled
Effects of magnesium supplementation on body composition in physically active individuals: A pilot study

Who is doing this research study?

College: Dr. Kiran C. Patel College of Osteopathic Medicine in the Department of Nutrition

Principal Investigator: Madison Doten, BS

Faculty Advisor/Dissertation Chair: Cassandra Evans, BS, MS

Co-Investigator(s): Sarah Franco, BS

Site Information: HPD Annex Building – Exercise and Sport Science Laboratory (Room Number 131)

Funding: This study is funded by Life Extension®

Introduction:

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to decide about participating. You can discuss your decision with your family, friends and other trusted people.

What is this study about?

This is a research study, designed to test and create new ideas that other people can use. The purpose of this research study is to provide evidence of the effects of Magnesium supplementation on body composition in an active population. We are specifically looking to see if the supplement is capable of causing changes to lean body mass (muscle mass) with no other changes to lifestyle factors.

This research involves a dietary supplement, and it is to be noted that supplements are not approved by the U.S. Food and Drug Administration or has not been approved for the purpose being used in this research study.

Why are you asking me to be in this research study?

You are being asked to be in this research study because you are an active individual looking to improve body composition and muscle mass through different supplementation strategies. You may previously have read about potential benefits of magnesium and are looking to view its effects on your body measurements or composition data.

This study will include about 32 people.

What will I be doing if I agree to be in this research study?

While you are taking part in this research study, you will continue your typical diet and exercise regime. You will attend 3 checkpoints in which baseline, midpoint, and end-point measurements will be taken to review any possible changes. In between this time, you will complete a food log at least 3 days a week and take 1 magnesium supplement capsule every morning.

You will be in this study about 8 weeks. You may have to come back to the HPD Annex Building – Exercise and Sport Science Laboratory every 4 weeks.

Research Study Procedures – If you choose to be in this study:

- Eligibility will be determined by an initial meeting for screening that will include verbal questions based on the necessary participation criteria and subsequent paperwork for consent purposes. This meeting will range from 1-2 hours based on your questions, concerns, and responses.
- There will be 3 additional visits you are required to attend. These include baseline, midpoint, and endpoint measurements. These will have 4 weeks spaced between and will include an InBody scan, pill-counting, and dietary recall (1st visit) or shared diet journal records at each visit. You will be evaluated for a maximum of 60 minutes at each visit to account for any additional concerns. These visits are solely for research purposes.
- A text message, phone call, or email will be sent to you biweekly to discuss any concerns, adverse effects, or other commentary.

Could I be removed from the study early by the research team?

There are several reasons why the researchers may need to remove you from the study early. Some reasons are if you no longer meet inclusion criteria or fail to follow the studies intervention.

Are there possible risks and discomforts to me?

This research study involves little risk to you. To the best of our knowledge, the things you will be doing have no more risk of harm than you would have in everyday life.

Some of the most likely risks of being in this study include:

- Side effects of magnesium supplementation such as: diarrhea, facial flushing, nausea, stomach cramps, vomiting, lethargy.
- Psychological effects associated with InBody measurements such as lower self-esteem and reduced self-confidence if measurements are not personally “desirable”.
- Emotional effects associated with discussing and sharing dietary habits such as guilt, stress, and discomfort.

You may find some questions we ask you (or some things we ask you to do) to be upsetting or stressful.

If so, we can refer you to someone who may be able to help you with these feelings.

What other options are there to being in this research study?

If you do not want to be in the study, there are no other choices except not to take part in the study.

What happens if I am injured because I took part in this study?

The researchers have taken steps to minimize the known or expected risks. You may still have problems or get side effects even though the researchers were careful to avoid them. Contact Principal Investigator right away if you think you have suffered a research-related injury or a bad reaction. Their contact information can be found in the contact section at the end of this form.

Nova Southeastern University does not have a program to pay you if you are hurt or have other bad results from being in this study. Medical care at Nova Southeastern University is open to you as it is to all sick or injured people. The cost for such care will be billed to you or your insurance company.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed because of participation in this study.

What happens if I do not want to be in this research study

You can leave this research study at any time, or not be in it. There will be no penalty or loss of services. Any information collected about you **before** the date you leave the study will be kept in the research records for 36 months from the end of the study. You may request that it not be used.

Are there risks if I leave the study early?

Tell the study investigator if you are thinking about stopping or have decided to stop. They will tell you how to stop your participation safely.
There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

What if there is new information learned during the study that may affect my decision to remain in the study?

Any information that may impact your decision to remain in this study will be given to you by the investigators. You may be asked to sign a new Informed Consent Form if the information is given to you after you have joined the study.

Are there any benefits for taking part in this research study?

The possible benefit of your being in this research study is changes in body composition, specifically an increase in lean body mass (muscle mass). There is no guarantee or promise that you will receive any

benefit from this study. We hope the information learned from this research study will benefit other people with similar conditions in the future.

Will I be paid or otherwise compensated for being in the study?

You will not be given any payments for being in this research study.

Will it cost me anything?

There are no costs to you for being in this research study.

Ask the researchers if you have any questions about what it will cost you to take part in this research study. This could include bills, fees, or other costs related to the research.

Will clinically relevant research results be shared with me?

The study investigators plan to share some research results with certain people who are in the study. These results will only be shared if they think they are important for you to know. The results will be shared with you in an individualized format, meaning that the results apply only to you. The study team will share these results with a copy of body composition via InBody results either scanned and emailed or a printed copy, as preferred by you. These results will only include your own body composition measurements.

How will you keep my information private?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Physical paper copies will be kept in a locked filing cabinet (in the Department of Nutrition offices at 7600 SW 36th Street, bldg. 200, room 2280 in Fort Lauderdale, FL, 33328), while all digital copies will be kept in a password protected folder through OneDrive.

Only people who need to review your information will have access to study files. Organizations or people that may review and copy your information include:

- Members of the research team
- NSU Institutional Review Board and other representatives of this institution responsible for overseeing the research

Your personal information may also be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. All confidential data will be kept in a filing cabinet at 7600 SW 36th Street, Bldg 200, Room 2280 in Fort Lauderdale, FL, 33328 as well as in a password protected OneDrive folder. All data will be kept for 36 months from the end of the study. They will be destroyed after that time by shredding the physical copies and deleting all digital copies.

INSTITUTIONAL REVIEW BOARD
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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. The Web site will include a summary of the results. You can search this Web site at any time.

Whom can I contact if I have questions, concerns, comments, or complaints?

If you have questions now, feel free to ask us. If you have more questions about the research, your research rights, or have a research-related injury, please contact:

Primary contact:
Madison Doten, BS can be reached at 518-225-8013.

If primary is not available, contact:
Sarah Franco, BS can be reached at 954-329-6655.

Research Participants Rights
For questions/concerns regarding your research rights, please contact:

Institutional Review Board
Nova Southeastern University
(954) 262-5369 / Toll Free: 1-866-499-0790
IRB@nova.edu

You may also visit the NSU IRB website at www.nova.edu/irb/information-for-research-participants for further information regarding your rights as a research participant.

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Research Consent & Authorization Signature Section

Voluntary Participation - You are not required to participate in this study. In the event you do participate, you may leave this research study at any time. If you leave this research study before it is completed, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

If you agree to participate in this research study, sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction about the research.

Adult Signature Section

I have voluntarily decided to take part in this research study.

Printed Name of Participant	Signature of Participant	Date
Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent & Authorization	Date