

Consent to Participate in Research

Study Title: The Nutritarian Women's Health Study Pregnancy Arm

Principal Investigator: Jay Sutcliffe, PhD, RD

Summary of the research

This is a consent form for participation in a research study. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

Your participation involves an hour long phone interview about your experience of pregnancy while being enrolled in the Nutritarian Women's Health Study. The interview will be a series of open-ended questions. These questions will come from a number of topics:

- If you have had previous pregnancies, how pregnancy on the nutritarian diet compared.
- What your motivations and beliefs were that lead you to consume the nutritarian diet while pregnant.
- What barriers you may have faced consuming the nutritarian diet while pregnant.
- How you will feel about continuing the diet postpartum and post-study.

The interview itself will take approximately an hour. You will only be required to answer questions that you feel comfortable answering.

- **The purpose and expected duration:** This study is a branch or arm of the ongoing Nutritarian Women's Health Study. Specifically, this study aims to understand the motivations, experience, and barriers women faced following a Nutritarian diet while pregnant. The duration of the study of the study should take about one hour of your time.
- **Major requirements of the study:** The major requirements for this study will be access to a phone and a quiet place to perform an hour long phone interview.
- **The most important risks and/or benefits:** Although risks may be minimal, the interview may discuss sensitive topics. You are free to pass any question that may promote sensitivity. You may or may not benefit as a result of participating in this study, however, your participation will allow us to understand the experience of consuming a

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nutritarian diet while pregnant. This understanding may be utilized to inform future nutrition interventions for pregnant women.

- **Other alternatives to participating, if appropriate:** You may choose not to participate in this study without penalty or loss of benefits to which you are otherwise entitled.
- **Time commitment:** The phone interview will take approximately one hour.

Why is this study being done? This study is a branch or arm of the ongoing Nutritarian Women's Health Study. Specifically, this study aims to understand the motivations, experience, and barriers women faced following a Nutritarian diet while pregnant.

What will happen if I take part in this study?

If you decide you want to take part in the study, we will schedule a time to do a phone interview. This interview will take about one hour. This interview will be audio recorded and later transcribed. This will allow the researcher to analyze the similarities between the interviews.

How long will I be in this study?

The phone interview will take approximately one hour.

How many people will take part in this study?

This study will involve around 10-30 participants dependent on the number of women who decided to participate in the interviews.

What benefits can I expect from being in this study?

You may or may not benefit as a result of participating in this study, however, your participation will allow us to understand the experience of consuming a nutritarian diet while pregnant. This understanding may be utilized to inform future nutrition interventions for pregnant women.

If you decide to participate in the interview, you will receive a free copy of Dr. Furhman's best 100 recipes book. After the interviews for all the participants are complete we will raffle off three copies of Dr. Furhman's "eat to live" book. There will be around 30 participants and we will randomly choose who receives a copy of the "eat to live book" giving you 10% of receiving the "eat to live book".

What risks, side effects or discomforts can I expect from being in the study?

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Although risks may be minimal, the interview may discuss sensitive topics. You are free to pass any question that may promote sensitivity.

Additionally, depending on your current compliance to the Nutritarian diet, there may some risk of discomfort induced by dietary changes. Participants will be encouraged to follow a nutrient dense dietary pattern. Nutrient dense diets, such as the dietary pattern used for this program, have been proven to be safe and effective in clinical applications and have been associated with: weight reduction, lipid management, diabetes management, reduction of chronic inflammation, reduction of certain cancers, perceptions of hunger, and overall health and longevity. However, the dietary changes encouraged by this research may cause side effects, including digestive tract discomfort or bloating and increased intestinal gas and increased frequency of bowel movements. In addition, there is always the risk of very uncommon or previously unknown side effects occurring.

What other choices do I have if I do not take part in this study?

You may choose not to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

When may participation in the study be stopped?

You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with Northern Arizona University, the Nutritarian Women's Health Study, or the Nutritional Research Foundation. If you are a student or employee at Northern Arizona University, your decision will not affect your grades or employment status. If you withdraw from this portion of the study you will not be withdrawn from the primary Nutritarian Women's Health Study unless you wish to withdraw from both.

What are the costs of taking part in this study?

Although there are no financial costs for you to take part in this study there is a significant amount of time associated with participation.

Will I be paid for taking part in this study?

You will not be paid for your participation in this research study.

Will my data or specimens be stored for future research?

The data you share may be used in order to create future nutrition interventions for pregnant women. Your identity however will be removed from the information you share. The data will be stored in the form of transcribed interviews.

The identifiable information or biospecimen, even if identifiers are removed, will not be used or distributed for future research.

Will my study-related information be shared, disclosed, and kept confidential?

The highest efforts will be made to keep your study information confidential including de-identifying any electronic or written documents and utilizing only study ID numbers.

A research team member will transcribe the verbal narrative to text, but substitutions for identifying names or place names will be made on the transcription. We will code the data, and code keys will be kept in a lock-secured cabinet with the other identifying information and separate from the data. The phone interviews will be done from a private room to ensure confidentiality.

Your information may be shared or disclosed with others to conduct the study, for regulatory purposes, and to help ensure that the study has been done correctly. These other groups may include:

- Office for Human Research Protections
- Northern Arizona University Institutional Review Board

Who can answer my questions about this study?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the Principal Investigator at:

Jay Sutcliffe, PhD, RD

928-523-7450

Jay.Sutcliffe@nau.edu

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Research Protection Program at 928-523-9551 or online at <http://nau.edu/Research/Compliance/Human-Research/Welcome/>.

AGREEMENT TO PARTICIPATE

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I affirm I am at least 18 years old and voluntarily agree to

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participate in this study. I am not giving up any legal rights by signing this form. I will be given a signed copy of this form.

Printed name of subject

Signature of subject

Date

AGREEMENT TO BE AUDIO RECORDED

Printed name of subject

Signature of subject

Date