**Ingested Substances and Dietary Supplements Form**

Institutional Review Board Human Subjects Research

Northwest Missouri State University

**Submission Instructions:**

If you propose the use of any ingestible substance, this form must be completed and submitted, **along with your IRB application**, through email to IRBNWMS@nwmissouri.edu.

Some sections below only apply to certain types of substances. Only complete those sections that are relevant to your project. Further instructions are provided in each section to help explain when certain sections are required.

You must receive IRB approval for use of an ingestible substance in an experiment prior to collecting new research data or accessing existing data.

**SECTION 1: SUBSTANCE INFORMATION**

Please complete this section for **all** substances.

**1. Number of Substances Used**

State how many unique substances (foods, food components, and dietary supplements) will be used in your project.

Choose an item.

Note: If you will use more than one substance in this project, you will need to submit an additional Ingested Substances and Dietary Supplements Form for each additional substance. You should not submit the same form for multiple substances.

**2. What is the substance?**

Click or tap here to enter text.

**3. Substance Type**

Is this substance a food, food component, or dietary supplement?

[ ]  Food

[ ]  Food component

[ ]  Dietary supplement

**4. Substance Administration**

Explain in detail how the substance will be administered to participants (e.g., orally, intravenously, etc.).

Click or tap here to enter text.

**5. Substance Amount**

Explain how much of the substance will be administered in each experimental session, how much of the substance each participant will imbibe throughout the experiment, and how these values compare to the recommended daily amount. Use standard units (mg, oz, etc.).

Click or tap here to enter text.

**6. Source**

Explain where the substance has been sourced from (i.e., where you have/will acquire the substance from).

Click or tap here to enter text.

**7. Side Effects**

List all known allergic reactions to and potential harmful side effects of the substance.

Click or tap here to enter text.

**8. Storage and Disposal**

Describe in detail the storage and disposal protocols that will be followed with this substance.

Click or tap here to enter text.

**9. Required Components (all must be checked and present/true):**

 [ ]  I will administer a health screen to all participants prior to administration of this substance, so that I may ascertain if they have any pre-existing conditions or allergies to the substance indicated above or it’s components.

 [ ]  I have attached a copy of the health screen questionnaire I will use in my study to my IRB application.

 [ ]  I have indicated all known side effects and allergic reactions related to ingestion of this substance in my consent form.

 [ ]  I have included a liability statement in my consent form indicating myself nor the university are responsible for adverse reactions relating to ingesting the above substance.

 [ ]  I have included the following statement in my consent form (see below), followed by a space for the participant to initial they have read and agree to the liability statement.

 *Statement*: I have read and understood the potential side effects of ingesting this / (these) substance(s) and I understand that the researchers nor the university are liable for any adverse reaction I may experience. I have been provided contact information for the wellness clinic on campus in case I need medical attention.

[ ]  I have included contact information for the campus wellness clinic in case the participant experiences a negative reaction to the substance indicated above.

**SECTION 2: DIETARY SUPPLEMENTS**

If your substance is a dietary supplement, please complete this section.

**1. History of Previous Use in Humans**

Provide a brief (1-2 paragraph) overview detailing how the dietary supplement has been utilized in previous research involving human subjects.

Click or tap here to enter text.

**2. Potential Side Effects**

Please indicate all possible known side effects related to ingestion of the dietary supplement. Please use an asterisk (\*) to indicate serious side effects.

Click or tap here to enter text.

**3. Herbs**

If the dietary supplement is an herb, please indicate the following below: (1) potency, (2) consistency, (3) purity, and (4) method of cultivation of the supplement. These terms are defined below. If your dietary supplement is not an herb, please write, “My substance is not an herb.”

*Herb*: Part of a plant used for culinary purposes

*Potency*: the amount of herb required to produce an effect of given intensity

*Consistency*: the physical disposition of the substance. For example, it may be watery, powdery, pill form, etc.

*Purity*: the degree to which the dietary supplement contains other chemicals or biological entities not found naturally in the herb

*Method of cultivation*: origin of the herb

Click or tap here to enter text.

**SECTION 3: CONFIRMATION AND SIGNATURE**

All projects should complete this section.

**1. Is the item above the only food, food component, or dietary supplement used in your study?**

 [ ]  Yes

 [ ]  No

If no, please complete another Ingested Substances and Dietary Supplements Form for the additional substance. You should do this for each substance you plan to use in your study. You should not submit the same form for multiple substances.

**2. I have attached the Informed Consent with Ingested Substances Template, tailored to my project, detailing all substances that will be used in my study, with my application.**

[ ]  Yes

 [ ]  No

**Signatures**

All ingested substance forms must include an electronic or written signature on the application form. If you are a student researcher, you should also send the application form to your faculty advisor for review; they will also need to sign and date the form before you submit it.

I affirm that all materials submitted are accurate and represent the documents as they will be used in this project, and that the statements I have made herein are truthful to the best of my knowledge.

Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_

Faculty Advisor Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_

(if applicable)

All materials should be submitted electronically to the Northwest IRB email address (IRBNWMS@nwmissouri.edu). Any necessary supplementary documents should be included as attachments to your electronic submission.