***This document is a template for informed consent developed by the Northwest Missouri State University Institutional Review Board for use with human subjects research involving ingested substances.***

***To use this form, replace all sections written in red brackets below with information related to your project. All sections are required with the exception of sections labeled [OPTIONAL], but note that “optional” sections must be included if they apply to your project. Delete any optional sections that do not apply to your project.***

***All information should be a single font color, and all instructions (indicated in red font) should be deleted prior to submitting your ingested substances consent statement to the IRB.***

**Informed Consent Statement with Ingested Substances**

Please review each statement below, and initial next to lines provided. By initialing, you are indicating that you understand and consent to the information provided.

**Project Title:** [insert project title]

**Background and Purpose:** The purpose of this study is [insert justification for research. This should explain why you are conducting the study.]

**Subject Participation:** Approximately [insert estimated number of subjects] will participate in this study. In this study, you will [insert detailed description of everything subjects will be asked to do during the study.] Your participation in this study will take approximately [insert estimated amount of time and number of sessions in which subjects will participate.]

**Acknowledgment of Ingested Substance(s):** In this study, I will be asked to ingest the following substances: [insert detailed description of all substances the subject will be asked to ingest and how much of the substance they will ingest during an experimental session.]

**\_\_\_\_\_\_** I understand that I may be asked to ingest [insert substances and their amounts] as part of my participation in this study.

**Compensation:** [If subjects will be compensated for their participation, either monetarily or through course credit, explain the details of that compensation including the amount, where the compensation may be used (e.g., a gift card to Amazon; course credit for psychology courses), and any steps that must be completed to qualify for compensation beyond simply completing the study. If subjects will not be compensated, write, “There is no compensation for participation in this study.”]

**Risks:** [Insert a description of all foreseeable risks that subjects may encounter through their participation. If there are no foreseeable risks, write, “There are no foreseeable risks or discomforts associated with this project beyond those encountered in daily life.”] In addition to foreseeable risks, your participation in this study may also involve risks that are currently unforeseeable.

**Acknowledgment of Risk & Liability:**

**\_\_\_\_\_\_** I understand that there are risks or adverse reactions associated with the ingestion of the aforementioned substances. I know that these risks include [Insert a description of all foreseeable risks that subjects may encounter through their participation related to ingesting the substances indicated above.] In addition to foreseeable risks, my participation in this study may also involve risks that are currently unforeseeable.

**\_\_\_\_\_\_** I understand that the experimenter nor the university are liable for any adverse reactions I may experience.

**Information In Case of Adverse Reaction:** If you experience any adverse reactions to the substances aforementioned, you should seek medical attention at University Wellness Services, located on 800 University Drive, Maryville, MO 64468. You can call University Wellness at 660-562-1348. You should be aware that Northwest students can schedule clinic appointments by phone, in person, or online using the Wellness Portal at http://wellness.nwmissouri.edu.

If you require medical attention outside of regular business hours, you should contact my own healthcare provider, call 911, or go to the Mosaic Medical Center Emergency Department.

If you require immediate medical attention, you should call 911.

**\_\_\_\_\_\_** I have received information on what I should do in case of adverse reactions to the ingested substance, and I understand where I may seek medical attention if necessary.

**Benefits:** [Insert a description of any benefits that subjects may expect from their participation, or any benefits that others may incur due to the subjects’ participation. This can include benefits gained for society as a whole from learning more about the research topic. Note that compensation is not considered a benefit.]

**[OPTIONAL] Compensation Information In Case of Injury:** [If your research involves more than minimal risk, explain whether any compensation or treatment will be provided if injury occurs during the study and, if so, what that compensation/treatment consists of.]

**[OPTIONAL] Alternative Procedures or Courses of Treatment:** [If your project involves treating subjects for something in which other treatments already exist, list all treatments which would be advantageous for subjects to be aware of.

**Confidentiality:** Any information obtained during this study that could identify you will be kept strictly confidential and will be accessible only to those on the research team. [Insert one of the following: “Other than this consent form, your responses will be collected anonymously, and consent forms will be stored separately from the rest of your data.” “Your responses will be collected anonymously.” “Although data collection links your name to your responses, your name will be kept confidential and, if your data is shared with anyone outside the research team, your name will be removed prior to sharing your data.”] Your data will be stored by [Insert details about storage, including how storage will ensure responses remain confidential.] Your data will be stored for [insert amount of time of at least three years], after which time it will be [insert one: shredded, permanently deleted, archived.]

**Voluntary Participation:** Your participation in this study is completely voluntary, and you may refuse to participate without penalty or loss of benefits you are otherwise entitled to. You also have the right to skip any questions you do not wish to answer. You may also remove yourself from the study at any time without penalty or loss of benefits, even if you have previously agreed to participate. Your participation may also be terminated by the researcher without your consent if [insert any circumstances in which the subject’s participation may be terminated, **such as not passing the required wellness screen.**] [OPTIONAL: If there are any consequences for a subject’s withdrawal from the study, list them here. If there are specific steps that will need to be followed to ensure orderly termination from the study, list them here.] If any significant findings arise during the course of the research that may affect your willingness to continue participating in the study, you will be notified of these findings.

**Use with Future Research Studies:** [Insert one of the following statements:

“Your data may be used for future research studies by our research team, or by another investigator without the need for additional consent from you. If your data is used in this way, any information that may identify you will be removed from the data prior to its use in future research.”

“Your data will not be used or distributed for future research studies conducted by the research team or by another investigator.”]

**[OPTIONAL] Information on Biospecimens:** It is important for you to know that the biospecimens ([explain in parentheses specifically what data you are referring to as ‘biospecimens’]) collected for this study may be used for commercial profit. If they are used in this way, you [will/will not] share in the commercial profit. It is also important for you to understand that this research [will/will not] include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

**Contact Information:** You may have questions or concerns about the research study, subjects’ rights, or wish to contact someone in the event of a research-related injury. If so, please contact the principal investigator, [insert name here]. You can reach them by [insert your contact information here, including at least an email address.] [If you have a faculty advisor, write, “You may also contact the faculty advisor associated with this project with questions or concerns.” Then, include the same information for them.] You may also wish to contact the Northwest Institutional Review Board. They can be reached through email at IRBNWMS@nwmissouri.edu.

***[All projects involved ingested substances should assume that signatures are required on informed consent statements. If you feel that signed consent should not be required for your project, see the exceptions to signed consent outlined on the* Informed Consent, Assent, and Permission Information *webpage, and send an email to the IRB Committee to discuss the matter.]***

**Signature:** I am voluntarily making a decision whether or not to participate in this research study. By signing this, I agree that I have read and understand the above information and have no further questions for the researcher. If requested, a copy of this consent can be provided to me to keep.

Subject Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_

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