BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

Probiotics, Immune Function, and the Brain in Alcohol Consumers
[Version 2, 9/16/2022]

KEY INFORMATION:

You are invited to take part in a Brown University research study. Your participation is voluntary.

- PURPOSE: The study looks at the effects of probiotics on immune function and the brain in people who consume alcohol.
- PROCEDURES: You will be asked to complete a 30-day trial of a probiotic supplement. If you are eligible, you will be asked to attend two visits at the start of the study, one midpoint visit, a visit at the end of the probiotic course, and a final visit one or more months later. The research team will ask you questions about your alcohol use, health, medical history, adherence to the probiotic trial, and any possible side effects. Samples of your blood, breath, and urine will be taken. The initial and final visits include MRI scans of the brain.
- TIME INVOLVED: The study will take several hours of your time. Today's visit will take about 2.5 hours. The initial MRI will take about 1.75 hours. The midpoint visit will take about 1.5 hours. At the end of the probiotic course, there will be a visit, including MRI, that takes about 3 hours. In between visits, you will be asked to respond to a short daily email or phone call about whether you took the probiotic each day. We will ask you to return 1-10 months after completing the probiotic for a visit lasting up to 1.5 hours.
- COMPENSATION: You may receive up to $280 for completing all study procedures. If you are not eligible to complete the study at today's visit, you will receive compensation prorated at $20 per hour for your time.
- RISKS: Probiotics have an excellent safety and tolerability profile, but some individuals may experience mild side effects. There is a risk to the privacy of your personal information. Risks of having your blood drawn include infection, pain, bleeding, and fainting. Risks of MRI scan include injury if there is metal in the body or from pre-existing health conditions.
- BENEFITS: Some people experience health benefits from probiotics, such as better gut function. However, you may not benefit personally from this research. The outcome may increase scientific knowledge and help people in the future.

- ALTERNATIVES TO PARTICIPATION: The research team has no other alternatives to offer at this time. To learn about treatment options or obtain medical care, it is recommended that you contact your primary care provider.

1. Researcher(s):

The principal investigator is Mollie Monnig, PhD (phone: 401-863-3491). Dr. Monnig is not affiliated with the company that makes the probiotic supplement and has no financial interest in the research. Seraphina Negash is the Research Assistant and the point of contact for the study. She can be reached at **probiotic_study@brown.edu**.

1. **What is this study about?**

The purpose of the study is to explore whether probiotics have beneficial effects on immunity and brain health in people who consume alcohol. Probiotics are defined by the World Health Organization as "live microorganisms which when administered in adequate amounts confer a health benefit on the host."

You are being asked to be in this study because you are between the ages of 18-64 and consume alcohol.

2. **What will I be asked to do?**

Today's visit (2.5 hours): Today's visit will see whether you are eligible to continue in the study. You will be asked questions about your social history, medical history, and alcohol use. You may skip any question that you do not wish to answer. Your height, weight, and breath alcohol will be measured. A urine sample will be taken for drug testing. For people who may become pregnant, the urine sample will be tested for pregnancy hormones.

Blood samples will be taken in a volume up to 50 ml, or about 3.5 tablespoons. A licensed nurse will draw blood from a vein in your arm using sterile procedures.

You will be paid $50 for completion, or $20 per hour if not eligible to complete the visit. If you are eligible for the study, we will schedule an MRI as the next step.

Initial MRI (1.75 hours): You will undergo a one-hour MRI scan of the brain at Brown University's MRI Research Facility. People who may become pregnant will undergo a urine pregnancy test prior to the scan. You will be paid $50 for completion.

To study how the brain works, we use Magnetic Resonance Imaging (MRI). This is a non-invasive method of imaging, which means there are no injections, drugs or radioactive tracers

used while a person is in the scanner. The brain images collected are used to answer research questions about how the brain works.

Before MRI, you will need to fill out a questionnaire about your health. You will be screened for "MR Safety" by answering questions about surgeries you had, and any medical devices or metal you may have on or in your body.

The MRI session will last 1.5 hours, which includes up to 30 minutes of screening and set-up outside of the scanner and up to 1 hour of physically being in the MRI scanner.

You will be asked to return for 1 more MRI scan during the end of probiotic visit (see below).

Between visits (daily for 30 days): After the MRI scan, you will be given a 30-day supply of probiotic capsules. You will be asked to take two capsules each day. The research team will email or call on a daily basis to confirm that you have taken the probiotic capsule. You will be paid $1 for every day that you respond. Compensation is for responding, not for taking the probiotic. You will be scheduled to return to the lab in about 15 days.

Midpoint visit (1.5 hours): Halfway through the probiotic trial (about 15 days after the start), you will return to the lab for more questionnaires. Blood samples will be taken in a volume up to 50 ml, or about 3.5 tablespoons. You will be paid $30 for completion.

End of probiotic visit (3 hours): At the end of the probiotic trial (about 30 days after the start), you will return to the lab to answer questions about adherence, possible side effects, and alcohol use. Blood samples will be taken in a volume up to 50 ml, or about 3.5 tablespoons. You will undergo another one-hour MRI scan of the brain. You will be paid $80 for completion.

Final visit (1.5 hours): You will be asked to return for a brief assessment and blood draw at least one month after finishing the probiotic. You will be asked questions about recent substance use. Blood samples will be taken in a volume up to 50 ml, or about 3.5 tablespoons. You will be paid $40 for completion.

Results provided to you: You will be informed if you have a positive pregnancy test. A positive test will exclude participation. You will not receive feedback on other tests or procedures.

Length of participation: Your participation in this study may last up to 10.25 hours total.

3. **Will I be paid?**

Yes. You will receive $50 for today's visit, $50 for the initial MRI scan, $30 for the midpoint visit, $80 for the end of probiotic visit, and $40 for the final visit. Payment will be made at the completion of each visit. Also, you will receive $1 for every day that you respond to the daily email or phone call about whether you took the probiotic supplement (up to $30). Payment for the daily response will be made at the end of the 30-day period for the total number of responses. The total compensation is $280. You also can be reimbursed for parking at our center or for other transportation (e.g., bus, rideshare). Payment will be made in the form of an electronic Amazon gift card.

4. **What are the risks?**

There are risks of being in this study. If you experience a study-related injury, illness, or distress, call the Principal Investigator, Dr. Monnig, at 401-863-3491.

- **Sensitive information:** This study asks questions about sensitive subjects, including medical problems and substance use. We take many precautions to protect the confidentiality of your information, but no system is 100% guaranteed.
- **Side effects of probiotics:** Probiotics have an excellent safety and tolerability profile. However, some people experience side effects like gas or bloating. These side effects usually go away after a few days.
- **Blood draw:** Risks of blood draw include infection, pain or discomfort, bruising (which could vary in size), and fainting. Serious risks are not common when best practices are used. In this study, a licensed professional will use sterile instruments, disinfecting agents, and non-latex materials for all blood draws.
- **MRI scan:** There may be some discomfort from being in the MRI scanner because you will be asked to lie down and be very still for one hour. The research team will try to make you as comfortable as possible. If you feel claustrophobic or anxious, let the researcher know immediately. MRI scanning risks and discomforts are discussed in further detail in the MRI addendum to this consent form.

The study can be stopped at any time if you tell us that you do not want to continue.

5. **What are the benefits?**

You may not directly benefit from being in this research study. Some people experience health benefits from probiotics, such as better gut function.

6. **How will my information be protected?**

Your study data, including biological samples, will be coded with an ID number so that it cannot be linked directly to you without knowing the code. Coded study data and your personal information are kept in separate, locked filing cabinets. The file linking the code to personal information is password-protected and accessible only to study staff. This file will be

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destroyed after primary data analysis is complete so that there will no longer be a link between coded data and your personal information.

The consent process and all study procedures are conducted in private locations. Paper files and computer files are accessible only to study staff. Computer files are stored on Brown University's encrypted, secure servers. Your information is kept confidential, meaning that it is not shared with anyone outside of the study except under the circumstances below:

- Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.
- The National Institutes of Health, which sponsors this study, may review records for quality assurance purposes.
- The FDA may inspect study records as part of their regulatory duties.
- If you report imminent risk of harming yourself or others, or abuse or neglect of a child or elderly person, these events will be reported to the appropriate authorities.

We may share your anonymized data and biospecimens with researchers at Brown or other institutions. Once your data is anonymized, we will no longer be able to identify you and you will not be able to withdraw it from storage.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of such as child abuse and neglect, or harm to self or others.

A description of this clinical trial will be available on http://www.Clinical Trials.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.

7. Are there any alternatives to this study?

The research team has no other alternatives to offer at this time. The standard of care is no intervention.

What if I want to stop?

You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.

If you refuse to participate in or leave the study, your current or future relationship with Brown University will not be affected.

8. Who can I talk to if I have questions about this study?

If you have any questions about your participation in this study, you can call Dr. Mollie Monnig at 401-863-3491 or email the Research Assistant at probiotic_study@brown.edu.

9. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

10. Consent to Participate

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

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Participant's Signature and Date / PRINTED NAME

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Research Staff Signature and Date / PRINTED NAME