Consent for Research Participation

Title: **Gut health and the effect on substance and alcohol cravings**
Investigator/Researcher(s): **Anna Marie McCarthy, MD MPH, Karen McCarthy, MD**
Investigator/Researcher Contact Information: **9049554247**
Sponsor: **Anna Marie MCCarthy, MD MPH**

KEY INFORMATION FOR YOU TO CONSIDER:

We (the researchers) are asking if you would like to be in a research study. Some key information is provided in the boxes below to help you decide if you want to participate or not. Read the entire form and ask questions before you decide. The researchers will go over this form with you and you can ask any questions.

What is the purpose of this research?	This main purpose of this study is to learn whether improving gut health with probiotics and prebiotics can help decrease cravings for alcohol and drugs.
What will happen to you during the study?	You are being asked to be in this research study to evaluate if taking a probiotic and prebiotic to help with gut health have an effect on decreasing substance and alcohol cravings. When enrolled in this study, you will receive a probiotic/prebiotic and pickle daily for 30 days. You will take a survey prior to starting the probiotic/prebiotic and pickle and then take the same survey after the 30 days of taking the probiotic/prebiotic and pickle. The survey will take around 5-10 minutes. You will be asked to complete surveys about cravings.
How long will you be in the research?	You will be in this study for just 30 days. We will collect the surveys from before and after.
Could being in this research harm you?	*There are no foreseeable risks in participating, the most common side effects of probiotic can be bloating/diarrhea.* You should understand the risks of this research study before you decide to participate. If you participate in this study, you might experience some risks and discomforts that might include the following: • bloating

	• Increased gas • diarrhea This research is no more than minimal risk. The level of risk is expected to about the same as risks of daily life or a physical exam.
Will being in this study help you in any way?	No benefits are promised. Some benefits might include digestive health, weight loss, improved immune function, decrease diarrhea, mental health improvement, decrease bad cholesterol levels, decrease severity of eczema, and decrease symptoms of some digestive disorders.
Are there any costs to participate?	It does not cost anything to be in the study.
How do researchers protect your information?	Researchers keep your personal information confidential and stored securely. Only the researchers approved to be on this study may see your information.

ADDITIONAL DETAILED INFORMATION:

How many people will participate in this research study?

30-40 participants

Who can you talk to about the research?

Contact the researcher listed on the first page if you have questions, concerns, complaints, or get hurt.

Pearl Institutional Review Board (IRB) oversees this research. You may call (317) 899-9341 to speak to the IRB for any reason, such as:

- You have questions about your rights.
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get more information.
- You want to provide your input about this research.

How do researchers protect your information?

The researchers will keep information about you in a secure location with limited access. If the results of this study are made public, information that identifies you will not be used.

(2) the research participant's information and surveys, even if identifiers are removed, will not be used or distributed for future research studies.

The researchers will not use or share your identifiable information or surveys collected for this research study for any future research studies, even after your identifiers are removed.

What Protected Health Information will be used or disclosed?

Federal law protects your right to privacy concerning PHI. There are certain things you need to know. PHI is any information from your medical record or obtained from the study linked to you and that refers to your mental or health conditions in the past, the present or the future.

Researchers include Dr. Anna Marie McCarthy, Dr. Karen MCCarthy and Montana Wells B.S. who will have access to PHI during the study.

By signing this form, you give permission to the researchers approved on this study to use or disclose (release) your Health Information that identifies you for the research described within this form.

This authorization is valid on the date the form is signed until the research is complete.

The PHI that we may create, use, report, or disclose (release) for this research includes:

- Health information collected during the research
- Medical records
- Results of surveys
- Medical history
- Alcohol/drug abuse treatment

This information will be used and/or given to others to:

- Do the research,
- To study the results and surveys
- To see if the research was done right.

The **PHI** listed above may be used by and/or disclosed (released) to:

- The Institutional Review Board(s) (IRB) that have oversight of this research.
- The researchers and their staff approved by the IRB.
- Other administrative staff who supervise the way research is done, such as auditors or monitors.
- The sponsor(s) of this study, including monitors and auditors.
- The Federal agencies that supervise the way research is conducted, such as the Department of Health and Human Services (DHHS) Office for Human Research

Protections (OHRP), the Food and Drug Administration (FDA), the National Institute of Health (NIH) or other government agencies.

You may change your mind and revoke (take back) this authorization in writing at any time. To withdraw, please write to Anna Marie McCarthy Your PHI collected before you withdraw your authorization will still be used and reported to the extent that those noted above have taken action in reliance of this authorization, including as necessary to maintain the integrity of the research or to conduct investigations or to report adverse events (bad effects).

You have a right to refuse to sign this form. If you do not sign this form, your health care treatment are not affected. However, you will not be able to participate in the research described in this consent form if you do not sign this form.

You need to know that some of the individuals or groups mentioned above who may receive your health information may not be required by federal privacy laws to protect your PHI. They may share your information with others without your permission if permitted by the laws governing them

If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

What information about this study is available to the public?

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. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your participation in the research study may end for any of the following reasons:

- Whenever it is determined that it is not in your best interest to continue
- If you do not follow the instructions or adhere to the research requirements given to you by the study doctor or study staff
- You do not take probiotics/prebiotics pickle as instructed
- You do not keep study appointments

What additional information should I know?

The researchers will inform you of any significant new information that may affect you in a timely manner. Such information may help you decide if you want to stay in the study. The researchers will share any new information with you if it affects your ability to stay in the study.

Will you receive anything for being in the research?

You will NOT receive any gifts, rewards, compensation, or reimbursement for your participation in this research study.

SIGNATURES:

You have read this document and were told of the risks and benefits and a member of the research team answered questions to your satisfaction. A member of the research team will answer any future questions. You voluntarily agree to join the study and know that you can withdraw from the study at any time without penalty. You do not waive any legal rights by signing this form.

You will receive a signed copy of this document.

_____ ***Print the Name of the Adult Research Participant*** *(18 years of age or older)*	_____ ***Signature of the Adult Research Participant***	_____ ***Date Signed***
Completed by the Investigator obtaining informed consent: ☐ In addition to advising the person authorizing the research about any appropriate alternatives to research participation, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be, associated with this research, and to answer any further questions. ☐ Check to confirm participant agreed to participate in the study and signed the informed consent form(s) and all questions were answered. *Check options pertaining to remote consent if applicable:* ☐ Check if remote consent (conference call or video conference). ☐ Check if the informed consent document was not retained, due to contamination of the document by infectious material. ☐ Check to confirm participant was asked to mail, fax, or e-mail a copy of the signed consent to the research team.		
_____ **Print Name of Investigator Obtaining Informed Consent**	_____ **Signature of Investigator Obtaining Informed Consent**	_____ **Date Signed**

Contact Info:
Pearl IRB Monday through Friday 9-5 EST/EDT
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