BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

"Probenecid as a Pharmacotherapy for Alcohol Use Disorder"

Version #4; 01/12/2022

KEY INFORMATION:

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

- PURPOSE: The purpose of the study is to evaluate the safety and success of probenecid when administered with alcohol
- PROCEDURES: You will receive either probenecid (or placebo) on two laboratory visits while being exposed to a craving/urge procedure in which you drink alcohol and undergo computer based tasks. The visits will involve questions about your medical history, alcohol/tobacco/marijuana use, alcohol craving and desires to drink, and will include a psychiatric evaluation. The medical procedures include a physical exam, an electrocardiogram, and three blood draws.
- TIME INVOLVED: There will be 4 visits total over the course of about 2 weeks
- COMPENSATION: Total maximum possible compensation is $300.
- RISKS: Answering questions about your alcohol use may cause you discomfort and/or put you at risk for loss of confidentiality. You may notify a researcher if you feel discomfort and we will protect your information in locked filing cabinets and computer password-protected computers.
- BENEFITS: There are no benefits to be expected by your participation in this study
- ALTERNATIVES TO PARTICIPATION: This research study is not a treatment study for alcohol use disorder (AUD) and your participation is completely voluntary

1. Researcher(s):

Principle Investigator: Carolina Haass-Koffler (401) 863-6646
Contact information for research staff: (401) 863-6646

2. What is this study about?

The goal of this study is to determine if probenecid reduces the pleasurable effects of alcohol drinking.

You are being asked to take part in this study because you have stated that you consume amounts of alcohol that are considered unhealthy. This study is being done to determine if a drug called probenecid (also called "Probalan") reduces your desire to drink alcohol. Probenecid is an FDA-approved medication for the treatment of gout caused by hyperuricemia (too much uric acid in the blood). Probenecid has been given to many research participants,

including healthy individuals and individuals affected by chronic or serious medical conditions (i.e. gout, skin and soft tissue infections, heart failure, HIV patients, etc.).

3. What will I be asked to do?

While probenecid is an FDA-approved medication, it is NOT approved for alcohol use disorder treatment and is used ONLY as an investigational drug in this study. However, research from human and animal studies supports the hypothesis that probenecid affects alcohol drinking.

After an initial screening visit to confirm your eligibility and ability to safely enroll in the study, we will ask you to come in for visit 2, laboratory session 1. At this visit, we will administer 2 g of probenecid or placebo and you will undergo a lab procedure on the computer in which we ask you to consume alcohol. There are a total of 4 visits over a period of about 2 weeks. Placebo pills are not able to affect your desire for alcohol craving and consumption. We wish to see if probenecid reduces your desire to drink alcohol compared to the placebo.

Which medication that you receive will be determined by a process called randomization (like flipping of a coin) and gives each participant in the study an equal chance to receive probenecid or placebo. We will also contact you either by phone, email, or text to assess alcohol-related behaviors and monitor adverse events. We will also ask you to report any negative symptoms during your study visits.

This study is called a double-blind study. This means that neither you nor the study staff will know which medication (probenecid or placebo) you are taking. In case of an emergency, the study staff can find out which group you are in. Neither you nor the study staff will know what you received until all the participants have completed the study. At that time, you may be told which week you took probenecid and which week you took the placebo.

In order for you to decide whether or not you wish to be a part of this research study, you should consider the risks and benefits so that you can make an informed decision. This consent form gives you important information about the research study and a member of the research team will discuss the information with you. This discussion will go over all parts of this research: its purpose, the procedures that will be done, and possible benefits and risks. Once you understand what this study is about, you will then be asked if you wish to participate. If so, you will be asked to read and initial each page and sign this informed consent form.

This study is expected to last about 2 weeks and will consist of a total of 4 visits. You will be assigned a specific number for the study to protect your privacy. We will use your number rather than your name on all study documents. All information collected during each visit will be kept in a locked cabinet in our locked office here at Brown University. Your data will be entered into a password protected computer.

A portion of your blood sample, using your study number, will be sent to a local laboratory in Providence, and will be used to test for possible important clinical conditions (e.g. liver and kidney damage, altered blood analysis, etc.). The results of this could prevent you from participation in the study. Additional blood samples collected will be used for analysis of

genetic biomarkers- we will examine individual chromosome sequencing (i.e. DNA and RNA). Please note, you will not receive the results of these tests.

You can stop your participation in this study at any time. If the blood and urine samples have not yet been analyzed, we will destroy them at your request. However, if we have already analyzed the samples, you can tell us whether we may keep the information about the results or should destroy them. Below is a Table that briefly describes what will occur at each visit and compensation.

STUDY PLAN

Visit	Procedures and Estimated Time	Compensation
1 (screening)	You will sign an informed consent document, and undergo assessments of demographics, medical history, psychological/behavioral tests, a physical exam, vitals, drug screen and ECG. Alcohol, tobacco and marijuana use will be assessed using the time line follow back (TLFB). A practitioner will draw your blood using a butterfly needle to test for eligibility. (2-3 hours). The next visit is roughly 3 days later.	$25
2 (lab session I)	You will fill out questionnaires regarding alcohol withdraw symptoms. We will administer either probenecid or placebo. We will begin the lab computer task. After 1 hour, you will fill out baseline assessments measuring alcohol craving. After 2 hours, you will consume alcohol (within a set time frame) and again fill out questionnaires related to craving. We will measure your breath alcohol level (BrAC) while you are consuming the alcohol. We will draw 5-8 mL of blood for clinical analysis. The visit should last about 5 hours.	$120
3 (lab session II)	You will fill out questionnaires regarding alcohol withdraw symptoms. We will administer either probenecid or placebo. We will begin the lab computer task. After 1 hour, you will fill out baseline assessments measuring alcohol craving. After 2 hours, you will consume alcohol (within a set time frame) and again fill out questionnaires related to craving. We will measure your breath alcohol level (BrAC) while you are consuming the alcohol. We will draw 5-8 mL of blood for clinical analysis. The visit should last about 5 hours.	$120
4 (follow-up)	You will be asked to come in to monitor any negative reactions and will fill out questionnaires. (1 hour). **This is the end of the study.**	$25 + a bonus of $10 for completion
In order to determine if you are eligible to participate in the study, you must have a breath alcohol (BrAC) = 0.00% at each visit when you arrive in our office. We will perform a urine test to check for possible pregnancy (if applicable) and perform a drug screen at the initial visit and other visits if necessary. We will also measure your vitals: blood pressure, heart rate and temperature at the start of every visit.		

No information from this study will become part of any permanent medical record.
You will be also reimbursed for travel (parking, public transportation or taxi).

VISIT#1 Screening Notes

- Before starting any study procedure, a breath alcohol test will be performed and must be 0.00%. Breath alcohol is measured by blowing into a machine called a breathalyzer.
- If your breath alcohol is above 0.00% you may wait until it is 0.00% or return another day.
- Depending on how high your alcohol level is, it may take some time to return to zero. For example, if your breath alcohol is .08% it will take about 5 hours. If you choose not to wait until it is 0.00% transportation home will be arranged.
- If your breath alcohol is 0.00%**,** the study will be discussed with you, and you will have an opportunity to ask questions about the study. If you agree to participate, you will be asked to sign this consent form. You will receive a copy of the signed consent form to take home with you.
- You will be asked to provide your contact information, as well as an alternate contact person's name and phone number who will be called in case you miss a study visit appointment and if we cannot contact you directly.
- You will have a physical exam and your blood pressure, pulse, weight, height, and temperature will be recorded. You will also have an electrocardiogram (ECG) that measures the electrical activity of your heart.
- You will be asked about any medications that you are taking. For your safety, it is **IMPORTANT to discuss all medications that you are taking with the study staff**. This includes over the counter medications and vitamins. Drug interactions are serious and could cause harm. Some medications interact with probenecid and alcohol, so please discuss all medication that you are taking.
- We will collect blood for screening and genetic tests at visit 1 (approximately 2 teaspoons, three small tubes) to confirm eligibility in the study. You will be examined to determine if you are having any alcohol withdrawal symptoms.
- You will complete a number of questionnaires asking you about your alcohol use, family history of alcoholism, mood, urge and craving for alcohol.
- If applicable, you will be asked about your periods or menopausal status and tested for pregnancy at each visit.
- You will be asked about your medical history as well as about your traumatic and psychiatric history, including previous substance abuse.

Visit 1 (screening, day 1): You will be asked to sign an Informed Consent Document. You will be assessed on demographics, medical history, physical examination, vital signs and an electrocardiogram (ECG) will be conducted to monitor your heart's condition. At this visit, we will draw your blood using a butterfly needle to screen for eligibility criteria. Alcohol, tobacco and marijuana (not exclusionary criteria) use will be assessed using the time line follow back (TLFB) at each visit. Psychological/behavioral assessments are given by trained medical personnel. After a study medical provider reviews and approves the medical history and lab results, you will be called with the results and scheduled for Visit 2.

Visit 2 (randomization, laboratory session I): You will be asked to not consume alcohol for 24 hours prior to the session. We will measure your breath alcohol level (BrAC) which must read

(0.00). We will administer (orally) 2 g of either probenecid or placebo. You will fill out a couple of assessments regarding alcohol withdraw symptoms. Next, we will begin the lab procedure which is completed on the computer. After two hours, we will ask you to drink alcohol which must be completed within a set time frame. We will give you enough alcohol to raise your blood alcohol level to 0.08. The exact amount is determined by a calculation on the computer and is found by using your weight, height, and the percent of alcohol within the alcoholic beverage. We will then give you additional assessments to fill out regarding your alcohol craving, and will collect breath alcohol samples using a breathalyzer. We will draw 5-8 mL of blood for clinical analysis at the end of the visit.

Visit 3 (laboratory session II): You will be asked to not consume alcohol for 24 hours prior to the session. We will measure your breath alcohol level (BrAC) which must read (0.00). We will administer (orally) 2 g of either probenecid or placebo. You will fit out a couple of assessments regarding alcohol withdraw symptoms. Next, we will begin the lab procedure which is completed on the computer. After two hours, we will ask you to drink alcohol which must be completed within a set time frame. We will give you enough alcohol to raise your blood alcohol level to 0.08. The exact amount is determined by a calculation on the computer and is found by using your weight, height, and the percent of alcohol within the alcoholic beverage. We will then give you additional assessments to fill out regarding your alcohol craving, and will collect breath alcohol samples. We will draw 5-8 mL of blood for clinical analysis at the end of the visit. The final visit will be scheduled for one week later.

Visit 4 (follow up, week 2): You will be asked to return after 1 week to undergo a follow-up and complete the final assessments. The research staff will provide you materials for alcohol use disorder treatment services. This is the **END OF THE STUDY.**

4. Will I be paid?

The study medications and all procedures that are required for the study, will be provided to you. If eligible for the study, you will be compensated for your time and travel costs. The amounts of compensation that can be received are described in the study table on page 3. The maximum amount of compensation that can be received in all study procedures is $300.

However, this amount can vary depending on whether or not you complete all the visits.
NOTE: In the event that research staff are unable to give cash, you will be compensated the full amount via a ClinCard, or an Amazon e-giftcard (sent to the email address of your choice).

ClinCard Information:
We will mail you the card. You will be given one card for the entire time of your participation and this card may be used to pay you in any future Brown University studies that uses ClinCard. You will also get information about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

Money will be added to your card based on the study's payment schedule. You may use this card online or at any store that accepts Mastercard. Please read the FAQ information sheet from

your study coordinator for details about the ways you can use the card, some of which may involve fees that will reduce the amount of money on the card. This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating. If your card is lost or stolen, please call the study coordinator for a free replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

5. What are the risks?

The following complications or risks have been reported, are known, or may occur:
Please take your time with this section and feel free to discuss any words you may not understand with the research staff.

Answering questions about your alcohol use may cause you discomfort and/or put you at risk for loss of confidentiality. You may notify a researcher if you feel discomfort and we will protect your information in locked filing cabinets and computer password-protected computers.

A needle is inserted through the skin and into an accessible blood vessel. After the initial needle insertion, there is minimal risk and discomfort related to needle puncture.

Inflammation of a blood vessel, or hematoma (a visible bruise or lump) may occur.

Most Common Side-Effects of Probenecid:

- headache, anorexia, nausea, and vomiting, joint pain, redness or swelling

Uncommon Side Effects of Probenecid:

- dizziness, flushing or redness of the face, frequent urge to urinate, hair loss and sore gums

Rare Side-Effects:

- cloudy urine, cough or hoarseness, fast or irregular breathing, fever, pain in back and/or ribs, sores, upper stomach pain, white spots on lips or in mouth, sore throat, sudden decrease in the amount of urine, swollen and/or painful glands, unusual bleeding or bruising, unusual tiredness, yellow eyes or skin, and weight gain

You will take all medication (either probenecid or placebo) while at the CAAS laboratory. You will be instructed to stop taking the medication and the research assistant will call the PI if any side effects as a result of the medication occur. The PI will then contact Dr. Swift who will recommend next steps. You may withdraw from the study at any time if you do not feel comfortable taking the medication and will be compensated for sessions that you have completed.

To protect against or minimize any risk associated with alcohol craving after the alcohol task, your vital signs and alcohol craving with behavioral assessments will be monitored. If a

significant increase in craving were to occur, you may require the help of a doctor. Dr. Swift will be immediately called and will evaluate each participant on a case-by-case scenario.

With your copy of the informed consent, you are given a list of mental health resources available in the State of Rhode Island. Some participants may have suicidal thoughts or actions. Should you have thoughts of suicide for any reason before the second visit, the study physician will be notified and he will assess the best course of action to take including coming here to talk with you, or referring you to receive appropriate medical or psychiatric intervention. For your safety, we will monitor your mood or any thoughts of suicide closely during the entire course of the study.

Between visits, however, if you feel a change in your mood or if you feel depressed or feel you may harm yourself, please contact us, or one of the resources provided to you (**please see Attachment #1**).

Should you develop any medical or psychiatric problems that require clinical attention, the study physician will refer you to receive appropriate medical or psychiatric help. However, you will not be compensated for any medical treatment you receive in the event of physical or psychological injury resulting from these research procedures. Brown University does not routinely provide any compensation

6. What are the benefits?

There are no benefits to be expected by your participation in this study. You will have the chance to contribute to research that may prove beneficial to you or to others in the future.

7. Additional Considerations

- We may learn things about your health as part of the research. If this happens, this information will be provided to you. For example if you become pregnant, or if your blood test results or ECG reveal any abnormalities, you may meet with professionals to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.
- The blood samples (biospecimens) collected from you for this research may be used to develop new tests, drugs, or devices. Researchers, their organizations, and others, including companies, may potentially profit from the use of the data, biospecimens or discoveries from this research. You will not have rights to these discoveries or benefit financially from them.
  If you give us your permission, by signing this document, information (including biospecimens) which do not identify you by name, may be used for medical and scientific purposes including teaching and/or publication. No one at Brown University who is unaffiliated with this research project will have access to information that identifies you.
  By signing this document you give Dr. Haass-Koffler permission to share your data collected (including biospecimens) during this study. The results of the study will be analyzed, and the results of this study may be used for other research purposes, including:
    - reviewing the safety or effectiveness of the study drug and other products or therapies
    - developing a better understanding of disease
    - improving the design of future clinical trials

- Should any problems arise or you experience any side effects during the study, contact us by calling our lab at (401) 836-6646, Dr. Haass-Koffler at (401) 863-6624 or Dr. Swift at (401) 457-3057 during normal business hours. After hours, you may call (401) 273-7100 and ask to have Dr. Swift paged.

8. How will my information be protected?

This study will ask potentially sensitive information about your alcohol and drug use. Every attempt will be made to keep this information confidential. All reasonable efforts will be made to protect the confidentiality of your participation in the study. However, it is possible that your confidentiality may be violated.

In order to protect your confidentiality, all your records collected during the study will be kept in a locked file by a code number, rather than your name. None of the information, including this consent form, will become part of your medical record. Your name will not be publicly disclosed at any time, and the records will be strictly maintained according to current legal requirements. However, please note that state law mandates reporting of any incidents of child or elder abuse (age 60 or older).

Certificate of Confidentiality from the National Institutes of Health (NIH)

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH, which is funding this project 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child or elder abuse and neglect, or harm to self or others. Because this research involves articles regulated by the Food and Drug Administration (FDA), the FDA may

choose to inspect and copy medical or research records that identify individual research subjects.

9. What if I want to stop?

Your participation in this study is voluntary. Your decision whether or not to participate will not hurt your future relationship with Brown University. If you decide to participate, you are free to withdraw your consent and to discontinue your participation without prejudice. If you choose not to participate or if you withdraw from this study, it will not negatively affect your relationship with the doctors and staff at Brown University. If you so choose, you may also withdraw your permission for Dr. Haass-Koffler to use and share your collected research data.

If it is in your best interest medically, or if you do not follow the study procedures required of the study, the study doctors, the PI and her staff can stop your participation in the study without your consent. This could be because you have had an unexpected reaction, have not followed instructions, or because the entire study has been stopped. Regardless of whether you choose to withdraw or if your participation in the study is terminated, certain procedures must be followed in ending your participation in the study in order to protect your safety. You may be asked questions about any reactions you may have had during this study, and may be asked to cooperate in certain tasks such as a physical examination in-person.

If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the study doctor would not be able to collect the information needed to evaluate the goals of the study.

10. 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 the research staff at (401) 863-6646

11. 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.

12. Consent to Participate

You have read and understand the preceding information describing this medical research study. It has been explained you in detail by the study doctor or the study staff and all of your questions have been answered to your satisfaction. You voluntarily consent to participate in this study.

You have read this informed consent and agree to participate in the study. You will receive a copy of this consent form.

A description of this clinical trial is available on http://www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

1. May we contact you for future studies? Yes No Initial_____

2. May we store your blood samples (biospecimens) for testing additional hormone levels for future studies? Examples of future hormone level testing include, but are not limited to, stress, adrenaline levels, increase of appetite (ghrelin), loss of appetite (leptin) etc. *If you agree to allow us to use your blood samples for future study testing, you will not be able to withdraw this consent once the data has been de-identified. Yes No Initial_____

THIS EVIDENCE OF INFORMED CONSENT MUST BE SIGNED BY THE SUBJECT

Participant's Signature and Date / PRINTED NAME

Research Staff Signature and Date / PRINTED NAME

Brown University IRB Original Approval: 09/19/2019
Brown University IRB Amendment Approval 10/20/2020
Brown University IRB Amendment Approval: 11/06/2020
Brown University IRB Amendment Approval: 02/23/2021
Brown University IRB Amendment Approval: 02/02/2022

Attachment #1

Substance Use & Mental Health

- Services for Adults: BH Link at (401) 414-LINK (5465)
- Services for children: Kids Link at (855) 543-5465
- RI's Hope & Recovery Support Line: (401) 942-STOP (7867)
- National Suicide Prevention Lifeline: (800) 273-TALK (8255)
- The Disaster Distress Helpline: 800-985-5990 or text TalkWithUs to 66746

Employment Related Issues

- The Rhode Island Department of Labor and Training COVID-19 Assistance Line and email address (401-462-2020; dlt.covid19@dlt.ri.gov) to provide support regarding employment issues. The phone line is staffed Monday to Friday during business hours.

Resources for Food Access

- Rhode Islanders seeking food assistance may locate their local food pantry online through the RI Community Food Bank or call (401) 942-6325 for a pantry near you.

Resources for People Experiencing Homelessness

- For those in our community experiencing homelessness, you can call the Rhode Island Coalition for the Homeless coordinated entry system hotline at (401) 277-4316.

Domestic Violence

- The Rhode Island Coalition Against Domestic Violence and all of its member agencies are open, as are domestic violence shelters. Rhode Islanders seeking help can call 1-800-494-8100.

Health Insurance Information

- If you have lost your employer-sponsored coverage due to job loss, or if you have experienced another qualifying life-changing event, you may qualify to sign up for coverage through Health Source RI. You must sign up within 60 days of your qualifying life event. Please call 1-855-840-4774 for assistance.

BROWN UNIVERSITY
CONSENT ADDENDUM FOR OPTIONAL DATA SHARING WITH A NATIONAL INSTITUTE OF HEALTH (NIH) DATA REPOSITORY

"Probenecid as a Pharmacotherapy for Alcohol Use Disorder"
Addendum
Version #4; 01/12/2022

- **WHAT IS A DATA REPOSITORY?**
  A data repository holds research data and makes that data available for future use by the broader research community. Data repositories may have specific requirements about the research topic, data re-use and access, file format, and data structure that can be used. Many data repositories have restrictions on who can add and access data.

- **WHAT IS RESEARCH DATA?**
  Research data is any information or biospecimens (identifiable or anonymous) you provide to the research team for the purposes of conducting this research study.

- **WHAT IS PERSONALLY IDENTIFIABLE INFORMATION (PII)?**
  Personally Identifiable Information (PII) is the information that can be used to recognize or trace your identity, such as your name, social security number, finger prints, and DNA sequence.

- **WHAT WILL HAPPEN TO MY RESEARCH DATA?**
  If you allow us to share your research data with an NIH data repository, we will need to collect your personal information as it appears on your birth certificate (first name, middle name [if applicable], last name, date of birth, sex, and town/city/municipality of birth). This PII will be used to create a Global Unique Identifier (GUID), so your research data can be properly catalogued in the data repository. Your PII will never be shared with the data repository.
  Other researchers can apply to the data repository to receive a copy of your GUID and research data for their own research. Your PII will never be shared with these researchers.

- **WHAT ARE THE RISKS?**
  Your research data could be accidentally shared with someone who may attempt to learn your identity.

- **WHAT ARE THE BENEFITS?**
  You will likely not benefit directly from allowing your research data to be shared with the data repository.

- **DO I HAVE TO DECIDE NOW?**
  You may decide to share or stop sharing your research data with the data repository at any time by contacting the research team (email and phone number) and asking them to start or stop sharing your research data with the data repository.

Brown University IRB Original Approval: 09/19/2019
Brown University IRB Amendment Approval 10/20/2020
Brown University IRB Amendment Approval: 11/06/2020
Brown University IRB Amendment Approval: 02/23/2021
Brown University IRB Amendment Approval: 02/02/2022

Creating a GUID and sharing your data with the data repository are optional and not required to participate in this study.

- **CAN INFORMATION ABOUT ME BE DESTROYED?**

  Your GUID and your research data *in the repository* will be destroyed upon your request.

  However, *once shared with other researchers*, the shared copy of your GUID and your research data cannot be destroyed.

DECLINE TO SHARE DATA:

☐ I do not want the research team to share my research data with an NIH data repository.

PERMISSION TO SHARE DATA:

☐ I give permission for the research team to use my personal information as it appears on my birth certificate (first name, middle name [if applicable], last name, date of birth, sex, and town/city/municipality of birth) to create a GUID and share my research data with an NIH data repository.

Participant's Signature and Date / PRINTED NAME