RESEARCH CONSENT FORM

Basic Information

Title of Project: THE EFFECTS OF THE HISTAMINE-3 RECEPTOR INVERSE AGONIST PITOLISANT ON ALCOHOL SELF-ADMINISTRATION IN HEAVY DRINKERS

NCT04596267

IRB Number: H-40959

Sponsor: National Institute on Alcohol Abuse and Alcoholism
Study medication provided by: Harmony Biosciences

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Robinson Building, C5 (5th floor)
72 E. Concord St., Boston, MA 02118

Study Phone Number: 617-414-1990 (business hours and 24-hour emergency contact)

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

You are being asked to participate in this research study because you consume alcohol regularly and are not seeking treatment to change your drinking. It is your decision whether or not to join the study. We are doing the research to evaluate the effects of a drug called pitolisant (also known as Wakix) on alcohol craving and consumption. If you agree, you will be asked to take the pitolisant medication and consume alcohol in a laboratory setting. You will be in the study for up to 66 days if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are experiencing side effects of pitolisant, discomfort with study procedures, overconsumption of alcohol, and loss of confidentiality. You will find more information about risks later in this form.

Purpose

We are conducting this study to see if taking pitolisant will have an impact on alcohol craving and alcohol consumption. If pitolisant has an effect of reducing alcohol cravings or drinking, researchers may want to test this medication with people who are trying to cut back or stop drinking alcohol. The

results of this study will help researchers decide if pitolisant should be tested as a treatment for alcohol misuse.

What Will Happen in This Research Study

Participants in this study will be asked to come into the Robinson Building 5th floor for 5-6 visits over a period of up to 66 days. Prior to each study visit, participants will be asked to complete a COVID-19 symptom screening questionnaire. Each part of the study is described below.

1. Screening Visit (Today)

If you decide to volunteer for this study, your first visit will take approximately 3 hours to complete. You may complete all of this today, or your visit may be split up. In this visit, you will be evaluated to make sure that you meet the requirements for participation and that you can safely take the study medication.

During this visit you will be asked to:

- Blow into a small device (Breathalyzer) that will measure the amount of alcohol in your blood.
- Undergo a physical exam and review of your medical history to assess your overall health and wellness.
- Have an electrocardiogram (ECG). This is a test that measures the electrical activity of your heart. It involves placement of leads on your chest, arms and legs for about 15 minutes.
- Have vital signs (blood pressure, heart rate, and temperature) and weight taken.
- Provide a blood sample to assess how your liver and kidneys are working.
- Provide a urine sample to test for recreational drug use.
- Provide basic demographic information (e.g. age, occupation, and income).
- Provide the names of any prescription and "over-the-counter" medications you are taking.
- Answer questions about your mental health, substance use and alcohol withdrawal symptoms.
- Describe your daily alcohol use over the past 28 days.
- If you are a female, provide a urine sample to test for pregnancy and answer questions about your birth control method(s).

You will provide addresses and telephone numbers for yourself and other people, such as family members or friends who will know how to contact you if you fail to show up for clinic visits, or if study personnel have problems getting in touch with you. In doing so, you give study personnel permission to contact these people to find out how to contact you. Please be aware that telling others you are in this study could jeopardize your privacy.

If you test positive for any recreational drugs other than marijuana during this screening visit, you will be excluded from this study and will not be reimbursed. If we encounter anything else during the screening that would disqualify you from taking part in this study, we will end the visit and provide you will a pro-rated payment for the time you have spent in screening. You will receive a percentage of the payment based on the amount of the screening you completed. If your laboratory results disqualify you from taking part in the study, you will receive a telephone call from study staff prior to medication visit #1 informing you of these results.

If you decide at any time during this study that you would like to seek treatment for drinking, please inform study staff immediately. Drinking alcohol in a laboratory could interfere with any effort you are

making to change your drinking. If you purposefully abstain from alcohol for 7 consecutive days, we will view this as you making an effort to change your drinking and you will be excluded from study participation.

2. Medication visit #1 (This visit takes place within 14 days after the screening visit.)
The medication visit #1 is expected to take 60 minutes.

During this visit you will be asked to:

- Blow into a small device (Breathalyzer) that will measure the amount of alcohol in your blood.
- Have vital signs (blood pressure, heart rate, and temperature) and weight taken.
- Provide a urine sample to test for drug use.
- Provide the names of any prescription and "over-the-counter" medications you are taking.
- Describe your daily alcohol use since your last study visit.
- If you are a female, provide a urine sample to test for pregnancy and answer questions about your birth control method(s).
- Answer questions about alcohol craving.

During the medication visit #1 you will receive two bottles of study pills. One bottle will contain either 4.45 mg of pitolisant or placebo (an inactive pill) and the other bottle will contain either 17.8 mg of pitolisant or placebo. Both pills look the same and each contains a small about of vitamin B2 (riboflavin). This helps us determine if you have taken the study medication. A random process will be used, like the flip of a coin, to determine whether you receive the pitolisant pills or placebo pills. This is a blinded study, which means that neither you nor the study staff will not know which pills you receive. This blinding process is necessary to study the true effects of pitolisant on your alcohol use. If a concern for your safety arises, the study doctor will be able to find out immediately which study pills you are receiving and tell it to any doctors treating you. You will be instructed to start taking the study pills the morning twelve days prior to the visit in which you will consume alcohol in the laboratory. You may be instructed to delay beginning to take the medication for up to 7 days after the medication visit #1 to accommodate scheduling for the next visit (drinking session #1). Once the next visit is scheduled, the study physician will instruct you on which day you should begin taking the medication so that your last dose occurs on the day of your next visit. You will receive a reminder call to begin taking the medication on that day. Please do not begin taking the study medication until instructed to do so.

The study team will ask you to start taking the medication on the day that is exactly 12 days before your next study visit. The study team will contact you to remind what day to start the medication on. You will take two pills of pitolisant (4.45 mg each) or placebo once per day on days 1 through 7. You will then take one pill of pitolisant (17.8 mg) or placebo once per day on days 8 through 12. The study team will contact you by telephone three times while you take the study medication to ask you how you are feeling 3-4 days, 6-7 days, and 9-10 days after starting medication. If you are unable to tolerate this increase in dose while taking the study medication, you will be instructed to stop taking the study medication immediately and will no longer be able to participate in the study. Each day that you take study medication, the team will send you a link by email or text message for you to complete a survey. The link will open a web-based survey that can be accessed on your smartphone. The survey will ask you questions about your level of alcohol craving and quality of sleep for each day you are taking the study medication.

3. Drinking session #1 (after 12 days of taking the study medication)

The drinking session #1 is expected to take at least 4 hours. For safety reasons, we ask that you arrange for transportation that does not involve you driving a motorized vehicle on the day of the drinking sessions. You will not be permitted to use nicotine during the drinking session. If you are unable to abstain from nicotine for periods of up to 8 hours, then you may not take part in this study.

During this visit you will be asked to:

- Blow into a small device (Breathalyzer) that will measure the amount of alcohol in your blood.
- Have vital signs (blood pressure, heart rate, and temperature) and weight taken.
- Provide a urine sample to test for recreational drug use.
- Provide the names of any prescription and "over-the-counter" medications you are taking.
- Describe your daily alcohol use since your last study visit.
- If you are a female, provide a urine sample to test for pregnancy and answer questions about your birth control method(s).
- Answer questions about alcohol craving.
- Take your last dose of study medication with study staff observing you.

You may be excluded from continuing in the study if you have become pregnant, if you test positive for recreational drug use, or if you have started a new medication that would make participation unsafe for you. You may also be excluded from continuing in the study if we determine that you have not been taking the study medication. We will test your urine to confirm that you have been taking study medication.

After completing surveys and interviews, you will be brought to a room that is furnished with a comfortable chair, side table, and television. You will choose your alcohol of choice that exceeds 24% alcohol by volume. The study staff will pour you a drink of this alcohol that is measured to raise your blood alcohol level to 0.03 g/dl. You will consume this first drink in five minutes. You will complete a 1-item alcohol craving questionnaire, an alcohol effects survey and alcohol breath test every 10 minutes for a period of 40 minutes.

After 40 minutes have passed since your first drink, study staff will bring you an additional 4 drinks that are measured to raise your blood alcohol level by 0.0125 g/dl each. It is up to you whether you consume these additional 4 drinks over the next 60 minutes. If you choose to not consume them, you will receive $3.00 for every drink you do not consume. You will complete two alcohol craving questionnaires, an alcohol effects survey, and alcohol breath test twice over the 60 minutes.

After the 60 minutes have passed since receiving your first 4 drinks, study staff will remove these drinks and bring you an additional 4 drinks. It is up to you whether you consume these additional 4 drinks over the next 60 minutes. If you choose to not consume them, you will receive $3.00 for every drink you do not consume. You will complete the same two craving alcohol questionnaires, alcohol effects survey and alcohol breath test. When the two 60-minute drinking sessions are complete, study staff will provide you with a meal (e.g., sandwich and chips).

During the entire duration of the drinking session you will have access to Netflix, HBOgo and YouTube. You will be asked to limit your use personal electronics to entertainment only (i.e., no working). The estimated maximum BAC you might achieve if you consumed every drink is in the range of 0.09 g/dl to 0.13 g/dl. For reference, the legal limit in Massachusetts for driving is 0.08 g/dl. You will be asked to

remain in the drinking room until your blood alcohol level reaches 0.04 g/dl or less. If you consume all of the drinks available to you during the session, it could take up to 5 hours for you to reach a blood alcohol level of 0.04 g/dl or less. During this time you will continue to have access to entertainment. You will have a choice of snacks and non-alcoholic beverages.

Your drinking session will be observed by study staff using a small video camera in the room where you are drinking. This drinking session will be recorded. The video will be stored on an encrypted hard drive with password protection. The video recording will be deleted upon completion of the study.

4. Medication visit #2 (This visit takes place 7-14 days after Drinking Session #1)
The medication visit #2 will take about 60 minutes.

During this visit you will:

- Blow into a small device (Breathalyzer) that will measure the amount of alcohol in your blood.
- Have vital signs (blood pressure, heart rate, and temperature) and weight taken.
- Provide a urine sample to test for recreational drug use.
- Provide the names of any prescription and "over-the-counter" medications you may be taking.
- Describe your daily alcohol use since your last study visit.
- If you are a female, provide a urine sample to test for pregnancy and answer questions about your birth control method(s).
- Answer questions about alcohol craving.

You may be excluded from continuing in the study if you have become pregnant, if you test positive for recreational drug use, or if you have started a new medication that would make participation unsafe for you. During this visit, you will receive two bottles of study pills containing either pitolisant or placebo. If you received the placebo at medication visit #1, then you will receive the pitolisant at medication visit #2. If you received the pitolisant at medication visit #1, then you will receive the placebo at medication visit #2. You will start taking the study pills on the day that is exactly 12 days before the drinking session #2. The study team will call you on the day you need to start taking the medication to remind you. The study team will contact you by telephone three times while you take the study medication to ask you how you are feeling 3-4 days, 6-7 days, and 9-10 days after starting medication. If you are unable to tolerate this increase in dose while taking the study medication, you will be instructed to stop taking the study medication immediately and will no longer be able to participate in the study. You will use your smartphone to report your medication taking each day. You will also report your alcohol craving and quality of sleep each day using your smartphone.

5. Drinking session #2 (after 12 days of taking the study medication)
You may be excluded from continuing in the study if you have become pregnant, if you test positive for recreational drug use, or if you have started a new medication that would make participation unsafe for you. You may also be excluded from continuing in the study if we determine that you have not been taking the study medication. We will test your urine to confirm that you have been taking study medication.

The drinking session #2 is expected to take at least 4 hours hours and you will complete the same procedures described above in drinking session #1. Both drinking sessions are identical.

At the end of drinking session #2 study staff will provide you with some alcohol education materials.

Telephone Follow-up
If you experience any physical complaints during the study that have not gone away by the end of the study, study staff will contact you by telephone after the study is over to ask you about the physical symptoms.

If you participate in this study, all visits will be completed within 66 days of your first visit.

The laboratory testing and ECG you will have in this study is for research purposes only. However, we might see something that could be important to your health. If we do, we will ask you if you want us to explain what we noticed. If you would like, we will also tell your doctor. You or your doctor should not rely on the research measurements to make any diagnosis, treatment, or health planning decisions. If you or your doctor decides that follow-up tests and treatments are necessary, then you or your insurance will be billed for the costs.

The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

You will be one of approximately 72 subjects who will be asked to be in the study.

Risks and Discomforts

RISKS OF PITOLISANT
Most common side effects
Headache is the most commonly reported side effect of taking pitolisant. Headache occurs in about 18% of people taking pitolisant compared to 15% of people taking a placebo. About 6% of people who take pitolisant experience insomnia, 6% experience nausea, and 5% experience anxiety. Upper respiratory tract infection occurs in about 5% of people taking pitolisant. About 5% of people taking pitolisant report musculoskeletal pain.

Less common side effects
About 3% of people taking pitolisant report an increase in heart rate, 3% report hallucinations, 3% experience irritability, 3% report abdominal pain, 3% report sleep disturbance, and 3% report decreased appetite. About 2% of people taking pitolisant experience sudden muscle weakness, 2% experience dry mouth, and 2% experience rash.

OTHER STUDY RISKS
Physical discomforts of participating in this study
The drawing of blood may cause pain, bruising, lightheadedness, and on rare occasions, infection. You may briefly feel the prick of the needle when it is inserted into your vein. You may feel dizzy or faint when your blood is drawn. Precautions will be taken to minimize these risks.

ECGs may cause discomfort and/or irritation of the skin (redness and itching) from the adhesive electrodes. Hair on your chest may need to be removed in order to obtain the best electrical contact between the adhesive electrodes and your skin.

Risks of pregnancy

If you get pregnant while you are in this study, it could be bad for the fetus. You must use birth control if you are a woman having sex with men while you are in this study. Only some birth control methods work well enough to be safe while you are in this study. These methods are oral contraceptives (the pill), intrauterine devices (IUDs), contraceptive implants under the skin, contraceptive rings or patches or injections, diaphragms with spermicide, and condoms with foam. You should not be in this study if you are a woman who has sex with men and cannot use one of these birth control methods. Pitolisant may make oral contraceptives (the pill) less effective. If this is your chosen birth control method, you will be required to use an approved back-up birth control method beginning with your first dose of study medication and continuing for 21 days after your last dose of study medication.

Risks of riboflavin

Riboflavin is a B vitamin that is added to the study medication and the placebo. During this study you may notice that your urine will have a bright yellow appearance. This is a harmless side effect of taking riboflavin.

Risk of overconsumption

There is a risk that your drinking could be more than what is comfortable for you. If you decide to be in this study you will drink the entire first drink given to you, but after that you are free to drink as much or little as you choose. Study staff will be monitoring your participation and if you become intoxicated to a point of presenting some risk to yourself or others, your participation will be stopped. The study team will ask you to stay in the laboratory until your blood alcohol level reaches 0.04 g/dl or less. During this time you will have snacks, access to your personal electronic devices, and access to streaming electronic entertainment.

Discomfort with study procedures

You may feel uncomfortable answering some of the questions we ask you about your medical history and mental health history. You may also feel some discomfort with the study procedures. You are free to stop participation and discontinue at any time. If you feel uncomfortable with any part of the study you can let staff know.

There may be unknown risks or discomforts involved with taking part in this study.

Potential Benefits

You will receive no direct benefit from being in this study. Your being in this study may help the investigators learn if pitolisant may be helpful for future patients who misuse alcohol.

Costs

There are no costs to you for being in this research study. The medication in this study is being provided at no cost by Harmony Biosciences.

Payment

You may be compensated up to $543 for completion of all study activities. During this study you will receive the following payments for completion of study tasks:

Screening visit - $50 (split payment if visit is split)
Medication visit #1 - $20
Drinking session #1 - $100
Medication visit #2 - $20
Drinking session #2 - $100
Answering surveys on your smartphone - Up to $130

You will receive $5 compensation for each day you report your pill taking and craving on your smartphone. If you report your pill taking and craving all 11 days after medication visit #1, you will receive a $10 bonus. If you report your pill taking and craving all 11 days after medication visit #2, you will receive a $10 bonus.

Completion bonus - $75

In addition to the payments described above, you will receive a $75 bonus payment if you complete both drinking sessions.

Drink incentive - up to $48

You will receive $3.00 for each drink you do not consume during this study.

In addition to this $543 of compensation for completion of all study tasks, you may also be reimbursed up to an additional $60 for distributing study recruitment materials to other people who may want to take part in this study. Distributing recruitment materials is completely optional. You may take part in the study and decline to hand out flyers to people you know. Study staff will provide additional information about this after you have enrolled in the study.

Confidentiality

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC**.** The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in the study and sign this form, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Any people who you give us separate permission to share your information

- The sponsor(s) of the research study, listed on the first page, and people or groups they hire to help them do the research; see below information about the NIAAA$_{DA}$ database. Note that we will not share information that includes your identity with Harmony Biosciences.

Data from this study will be submitted to the National Institute on Alcohol Abuse and Alcoholism Database (NIAAA$_{DA}$) at the National Institutes of Health (NIH). NIAAA$_{DA}$ is a large database where deidentified study data from many NIAAA studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about alcohol problems more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NIAAA$_{DA}$. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NIAAA$_{DA}$. The study data provided to NIAAA$_{DA}$ may help researchers around the world learn more about alcohol problems and how to help others who have problems with alcohol. NIAAA will also report to Congress and on its website about the different studies using NIAAA$_{DA}$ data. You will not be contacted directly about the study data you contributed to NIAAA$_{DA}$.

You may decide now or later that you do not want your study data to be added to the NIAAA$_{DA}$. You can still participate in this research study even if you decide that you do not want your data to be added to the NIAAA$_{DA}$. If you know now that you do not want your data in the NIAAA$_{DA}$, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to the NIAAA$_{DA}$, call or email the study staff who conducted this study, and they will tell NIAAA$_{DA}$ to stop sharing your study data. Once your data is part of the NIAAA$_{DA}$, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NIAAA$_{DA}$, this is available on-line at https://nda.nih.gov/niaaa.

If you are in immediate danger of hurting yourself at any time in the study, the study team will try to work with you on a plan to keep you safe. Because study staff will be trying to protect you, it is possible that your information will be shared with others as part of a plan for safety.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

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.

Use and Sharing of Your Health Information

The research team has to use and share your health information to do this study, including information that may identify you. By agreeing to be in this study and signing this form, you are giving us your permission where needed to use and share your health information as described in this form.

Health information that might be used or shared during this research includes:

- Information that is in your hospital or office health records. The records we will use or share are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The reasons that your health information might be used or shared with others are:

- To do the research described here.
- To make sure we do the research according to certain standards set by ethics, law, and quality groups.
- To protect you. As we explained above, if you are in immediate danger of hurting yourself, it is possible that your information will be shared with others as part of a plan for safety.

The people and groups that may use or share your health information are:

- Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations
- Other people within Boston Medical Center and Boston University who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study
- The sponsor(s) of the research study, listed on the first page, and people or groups they hire to help them do the research
- Other care providers and public safety authorities who may be involved in helping to protect you if you express thoughts about hurting yourself.

We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.

The time period for using or sharing your health information:

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and share your health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.
- You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.
- When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at Boston Medical Center at DG-privacyofficer@bmc.org.

Compensation for Injury

If you think that you have been injured by being in this study, please let the investigator know right away. Use the phone number on the first page of this form. You can get treatment for the injury at Boston Medical Center or at any healthcare facility you choose. There is no program to provide compensation for the cost of care for research related injury or for other expenses. Other expenses might be lost wages, disability, pain, or discomfort. You or your insurance will be billed for the medical care you receive for a research injury. You are not giving up any of your legal rights by signing this form.

Re-Contact

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

____Yes_____No You may contact me again to ask for additional information related to this study

____Yes_____No You may contact me again to let me know about a different research study

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

During this study, we may find out something that might make you not want to stay in the study. If this happens, we will tell you as soon as possible.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Eric Devine at 617-638-7888. Also call if you need to report an injury while being in this research. Contact our 24/7 answering service at 617-414-1990 if there is no answer at that phone number or if you are calling after normal business hours.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Project Title: The effects of the histamine H-3 inverse agonist pitolisant on alcohol self-administration in heavy drinkers
Principal Investigator: Eric Devine, Ph.D.

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that

- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and sharing of information that may identify you as described, including your health information.

_____ _____
Signature of subject Date

Researcher: _____
Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

_____ _____
Signature of person conducting consent discussion Date