INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**National Institute on Alcohol Abuse and Alcoholism / "Human Laboratory Study of ASP8062 for Alcohol Use Disorder"**
Protocol Number:	**HLAB-003**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

KEY INFORMATION

You are invited to take part in a research study and your participation is voluntary. This research study is studying a drug named ASP8062 as a possible treatment for Alcohol Use Disorder. One tablet of ASP8062 taken every day for 6 weeks will be compared to taking a placebo tablet (like a sugar pill, with no active study drug) every day for 6 weeks. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) is sponsoring this research study.

- You are being invited to participate in this study because you have an interest in reducing your alcohol consumption.
- The purpose of this study is to determine if the study drug, ASP8062, decreases craving for alcohol and helps people with Alcohol Use Disorder to reduce drinking.
- The study drug has never been tested for this purpose before and is considered "investigational". This means that it has not been approved by the United States Food and Drug Administration (FDA).
- About 60 people aged 21 and over with moderate to severe alcohol use disorder will participate in this study.
- A total of about 76 mL (about 15 teaspoons or 5 tablespoons) of blood will be collected for tests during the study.
- This research study should take up to 11 weeks of your time. You will be asked to visit the clinic about 7 times (possibly a few more) and there is a follow-up phone call at the end of the study.
- You will be given an alcohol breathalyzer test at each clinic visit to ensure you are able to provide consent and participate in the study assessments.

- You will be asked to give blood for testing how your liver, kidney and body are functioning.
- You will be asked about your cravings for alcohol and about your alcohol drinking.
- You will watch some computerized presentations about the benefits of controlling your drinking.
- This study uses a smartphone to check to make sure you took your study drug.
- You will be asked lots of questions about you and how you are feeling.
- You may become tired of answering questions.
- The main benefit to you (or others) for taking part in this study is your drinking habits may change.
- There are several alternative treatments that may be effective for treating alcohol use disorder, including other medications and/or counseling. These other treatments are not offered to you as part of this research study, but if you decide not to participate, or are not eligible, study personnel will give you contact information for existing treatment programs in your area.

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you would like to change how much alcohol you drink. This study will look at how your craving for alcohol changes with the study drug and if you cut down or stop drinking alcohol while taking the study drug.

WHAT WILL HAPPEN DURING THE STUDY?

Screening:

Before any study-related tests and procedures are performed, you will be asked to read, sign, and date this consent document. The screening phase will be completed within 14 days and will involve one clinic visit. Additional visits may be requested if laboratory tests need to be repeated.

If you decide to volunteer for this study, your first visit will take approximately 2 1/2 to 3 hours to complete. This involves a number of tests to make sure that you meet all of the requirements for participation and that you can safely take the study drug. You will not be given study drug during this first screening visit.

At the beginning of the Screening Visit, your blood alcohol level will be measured using an alcohol breathalyzer. If your blood alcohol is greater than 0.000%, you may not be able to complete your visit as scheduled. If your blood alcohol level is very slightly higher than 0.000%, study staff may give you the option of waiting until it reaches 0.000% to continue with your first visit. If your blood alcohol level is 0.080%, that is above the legal limit for driving, or higher and

you drove to your visit, study staff will ask you to remain in the clinic until you are capable of leaving without risking your (or others) safety. The following screening tests and procedures will then be performed to determine if you qualify to take part in this study:

- Provide a valid form of identification (ID). Acceptable forms of ID are as follows: Driver's License, Passport, Military ID, State or National ID, or Medicare or Medicaid card.
- Provide contact information of friends and/or family in case we cannot contact you.
- Provide your age, race, ethnicity, and sex at birth.
- Provide a urine sample to test for drug use and to assess how your kidney is working.
- Undergo a physical exam to assess your overall health and wellness and have an electrocardiogram (ECG) to measure the electrical activity of your heart.
- Give your medical history and have your weight measured.
- Have vital signs taken (blood pressure and heart rate).
- Answer questions about your mental health and desire to quit drinking.
- Provide a blood sample to assess how your liver, kidneys, and immune system are working.
- If you are a female, provide a urine sample to test for pregnancy.
- You will be asked about birth control method(s).
- Provide your daily alcohol use for the past 28 days.
- Provide the names of any prescription and "over-the-counter" drugs you may be taking now or in the recent past.
- Answer a question about use of cocaine, amphetamines, methamphetamine or MDMA – also known as ecstasy or Molly in the past two months
- Answer questions about any withdrawal symptoms from alcohol.
- Participate in an exercise (called a cue session) where you will be shown beverages (including your favorite alcoholic beverage) and complete computerized questions about your craving for the beverages.

This study will use competitive enrollment. This means that when a target number of participants begin the study, all further enrollment will be closed. Therefore, it is possible that you could be in the screening phase, ready to begin the study, and be discontinued without your consent if the target number of participants has already begun the study.

Employees of the study doctor, sponsor, or study drug manufacturer are not allowed to participate in this study.

Students of this institution are allowed to participate in this study. If you are a student:

- The decision to participate or not will not affect your grade, recommendations, employment or the like.
- Failure to participate will not have a negative effect on your relationship with the study doctor or the faculty.

If you qualify to take part in this study and go on to receive the study treatment, then the following will happen:

Study Treatment:
You will be randomly assigned by chance (like the flip of a coin) to receive either ASP8062 or placebo (inactive substance). You will have a 50% (1 in 2) chance of receiving ASP8062 and a 50% (1 in 2) chance of receiving placebo. This is a double-blind study, which means neither you nor the study doctor will know to which of these study drug groups you are assigned. In case of an emergency, however, the study doctor can get this information.

You will take your assigned study drug tablet orally (swallowed with water) at bedtime at home.

You will have the following study visits and other procedures:

Study Phase	**Screening**	**Study Treatment**					**End of Study**	**Follow-up Call**
Clinic Visit #	**1**	**2**	**3**	**4**	**5**	**6**	**7**	
Study Week	**Pre-study**	**1**	**2**	**3**	**4**	**5**	**7**	**9**
Urine Drug Test	X	X	X	X	X	X	X	
Medical History	X	X						
Physical Exam	X	X						
Body Weight	X				X		X	
Questionnaires	X	X	X	X	X	X	X	
Vital signs	X	X	X	X	X	X	X	
Blood tests + ECG	X				X		X	
Pregnancy test (if female)	X	X					X	
Cue session	X			X				
Side effects + medications	X	X	X	X	X	X	X	X
Take control video		X	X	X	X (2 videos at this visit)	X	X	

The blood sample will be used to measure study drug levels in your blood and to check how your liver, kidneys, and immune system are working. Questionnaires include asking about your cravings for alcohol and alcohol withdrawal symptoms, mood, desire to quit drinking, sleep, drinking urges, smoking cigarettes, and use of other nicotine products, and about your daily alcohol use since your last visit. You will view an alcohol education program called Take Control**.** You will participate in a cue session (like the one done at the screening visit) where you will be shown beverages (including your favorite alcoholic beverage) and complete computerized questions about your craving for the beverages. You will be asked how you are feeling (side effects of taking the study drug or any new problems) and about any medications that you are taking. You will be reminded about using appropriate birth control methods.

During this study, you will use a smartphone provided by a company called AiCure, LLC, with its primary place of business at 19 West 24th Street, 11th floor, New York, NY 10010, USA ("AiCure"). Before starting use of this smartphone, you will be instructed on how to set up the smartphone so that it can confirm your identity and register your preferred settings. You will also practice several times to learn how to use it.

You may use your personal smartphone by downloading a computer program with assistance from the study staff. If you do not have a suitable smartphone, one will be provided by the study site. If you are provided with a smartphone, you will not be able to make general phone calls, respond to text messages, or use it to access the Internet. You are required to return the provided smartphone at the end of the Study.

How you will interact with the smartphone:

- The smartphone will help remind you when it is time to take your study drug. You will be required to use the smartphone to monitor each dose of study drug while you are enrolled in the study. The smartphone is used to visually confirm that the same person uses the smartphone each time, and that the study drug is correct and administered properly. It is important that you remember to use the smartphone every time you take your study drug.
- The smartphone will NOT be used to collect and report any emergencies, side effects, or adverse events you may experience during the study. If there is something that you need to discuss with the site, you should contact them directly or follow procedures for reporting a medical emergency.

You will be reimbursed for your additional time when successfully using the smartphone at $1 United States Dollar (USD) every time you take your study drug. This is a maximum payment of $42. The study staff will provide you with a debit card for you to receive the compensation for using the smartphone. You will be required to register your payment cards with the company providing the payment cards by entering personal information including your name, date of birth and home address. Neither AiCure nor Sponsor will have any access to the information you provide.

During the registration process in the smartphone, you will be given the option to enter your personal telephone number(s), which is voluntary. By submitting your number, you grant the study site and AiCure permission to contact you at this number by text messaging or by phone if:

- You are not responding to the prompts or reminders in the application
- The study staff needs to reach you in regards to the study
- The study device requires updates or alterations

Information that will be collected by the smartphone: your study ID, cell phone number if provided, phone IMEI (unique phone ID), the video and audio of you using the smartphone, and the date and time the video was taken.

All of your video recordings and data are encrypted (converted to a code to prevent unauthorized access) and will be automatically forwarded to a secure server. The encrypted recordings are only accessible by authorized staff of AiCure. The data excluding the video recording are securely stored and only accessible to AiCure, healthcare providers and sponsor through a website password protected.

The smartphone will be used only for the purpose of making sure you are taking your dose. If you are provided with a smartphone, you will not be able to make general phone calls, respond to text messages, or use the smartphone to access the Internet. This smartphone uses a very sophisticated computer program to confirm that the same person uses the device, and that the study drug is correct and taken properly. The smartphone will send a message to a secure server, confirming that you took the study drug. The smartphone will record the date and time that you took the study drug so that the study site can confirm it was taken for that day.

Before starting use of the smartphone, the study site staff will assist you in set up so that the smartphone can confirm your identity and register your preferred settings. Through prompts, the smartphone will assist you to practice recording yourself taking the study drug.

The study staff will help you set the smartphone so that it will remind you to take the study drug in the evening before bedtime. It is important that you remember to use the smartphone every time you take your study drug.

<u>End of Study Visit</u>:
Because this is a research study, the study drug will be given to you only during this study and not after the study is over. Besides the tests described above and in the table above you will be given a treatment referral

<u>Follow-up Contact: (2 weeks after last in-clinic visit)</u>
Two weeks after you complete the study, a study staff member will contact you by telephone to ask you questions about your alcohol use and any side effects you may have had since you stopped taking the study drug. If study staff is not able to reach you by telephone, they may contact friends or family members you provided at screening to get your new contact information. Please be aware that if you tell others that you are in this study, this could be a risk of your confidentiality. In order to maintain your confidentiality when attempting to contact you or a contact person by telephone, the research staff will not say that you are a participant in this research study. Once we have contacted you and/or the contacts you gave us, your participation in the study will end.

EXPECTATIONS
If you participate in this study, you will be expected to:

- Not give the study drug to other people and keep it out of the reach of children
- Be willing and able to follow the study directions and procedures
- Tell the study staff about any side effects or problems
- Ask questions as you think of them

- Tell the study doctor or the study staff if you change your mind about staying in the study
- Not participate in any other research studies during this time
- Participate in all study procedures as instructed

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

In clinical studies of ASP8062 conducted so far, 195 healthy volunteers were given single or multiple doses from 0.3 milligrams (mg) to 60 mg. If assigned to the study drug, you will be given daily doses of 25 mg per day for 6 weeks in this study. Also, 95 participants with fibromyalgia (a medical condition that causes muscle and bone pain, fatigue (tiredness), sleep, memory and mood issues), received 30 mg doses over 8 weeks.

You may be required to seek proper medical attention if your blood pressure is above normal limits during the study.

Taking part in this research study involves some inconveniences and risks. The main risks are discussed below.

For ASP8062:

Common (greater than or equal to 1/100 to less than 1/10 people)

- Dizziness and headache
- Dizziness, vomiting, nausea, loss of coordination, and sleepiness occurs at a higher rate when taking the study drug with alcohol

Uncommon (greater than or equal to 1/1,000 to less than 1/100 people)

- Lightheaded when standing
- Ear pain
- Feeling hot
- Nausea
- Neck pain
- Vomiting

Effects during cocaine use

- Animals exposed to cocaine and ASP8062 at the same time had increases in blood pressure. This may occur in humans. Cocaine use can cause a stroke. If you use ASP8062 with cocaine you may have a greater risk for a stroke (bleeding in your brain or loss of blood to your brain). You are expected to not use cocaine in this study. Other drugs such as amphetamines, methamphetamine or MDMA that are considered stimulants like cocaine may also increase blood pressure when taken with ASP8062. You are expected to not use these drugs either during the study.

RISKS OF STUDY PROCEDURES

- Blood samples: Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.
- Electrocardiogram (ECG): Skin irritation is rare but could occur during an ECG from the electrodes or gel that is used.
- Questionnaires: Some of the questions about your personal habits, lifestyle, emotional state and drug and alcohol use may embarrass you. If any question makes you feel uncomfortable you may discuss its importance and the need to answer it with the specially trained interviewer. You may refuse to answer a question if it is upsetting to you.
- If you are having suicidal thoughts call the study doctor at the telephone number listed on the first page of this form. If you feel in crisis, you can call 911 and/or a Nationwide Suicide Hotline that is answered 24 hours a day with a skilled, trained counselor. One example is the National Suicide Prevention Lifeline at 1-800-273-TALK (8255).
- You may become bored with answering questionnaires.
- As part of this research, you may be required to use one or more of the following: a phone or web app/ site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data includes your study ID, cell phone number if provided, phone IMEI (unique phone ID), the video and audio of you using the smartphone, and the date and time the video was taken. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor. While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app, eDiary, or device in this study, you do not release the investigator, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

If you receive placebo (the inactive substance) as part of this study, your symptoms of Alcohol Use Disorder may not improve or may get worse.

RISKS FROM ALCOHOL WITHDRAWAL

Some people may experience symptoms of alcohol withdrawal if they stop drinking suddenly. At your screening visit, you will be given information to help you recognize the symptoms of withdrawal. You will be monitored carefully throughout the study in case you begin to have symptoms of alcohol withdrawal. If you experience any of these symptoms, you will be instructed to call the clinical site using the 24-hour phone number provided to you. If you have serious withdrawal, you should go to the nearest emergency room.

UNFORESEEN RISKS
Since the study drug ASP8062 is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you or your female partner becomes pregnant.

BIRTH CONTROL RESTRICTIONS
Taking the study drug may involve risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. Therefore, if you are pregnant, planning to become pregnant, planning to father a child, or are breastfeeding a child, you cannot participate in this study.

Females:
In order to reduce the risk of pregnancy, you should use an effective method of birth control while you are participating in this study and for 30 days after your last dose of the study drug. Acceptable methods of birth control for use in this study are

- Oral contraceptives,
- Contraceptive sponge,
- Patch,
- Double barrier (diaphragm/spermicidal or condom/spermicidal),
- Intrauterine contraceptive system (such as an IUD),
- Etonogestrel implant,
- Medroxyprogesterone acetate contraceptive injection,
- True abstinence: when this is in line with your preferred and usual lifestyle,
- And/or hormonal vaginal contraceptive ring.

You must not donate ova for at least 30 days following the last dose of ASP8062.

The study doctor or study staff will discuss this with you.

If you become pregnant while you are participating in this study, or within 30 days (one month), tell your study doctor or study staff immediately. The study drug will be stopped and your participation in this study will be ended. You will be asked to provide information about the health of your new born child.

Males:
In order to reduce the risk of pregnancy, you should use an effective method of birth control while you are participating in this study and for 90 days (three months) after your last dose of the study drug. Acceptable methods of birth control for use in this study are

- Surgical sterilization (vasectomy);
- Your female partner uses oral contraceptives (combination estrogen/progesterone pills), injectable progesterone or sub dermal implants (started at least 14 days prior to study drug administration to the male participant)
- Your female partner uses a medically prescribed topically applied transdermal contraceptive patch (started at least 14 days prior to study drug administration to the male participant);

- Your female partner has undergone tubal ligation (female sterilization) or is postmenopausal (one year);
- Your female partner has undergone placement of an intrauterine device or intrauterine system; and,
- True abstinence: when this is in line with your preferred and usual lifestyle

The study doctor or study staff will discuss this with you.

If your female partner becomes pregnant while you are participating in this study or within 90 days (three months) after you have stopped taking the study drug, tell your study doctor or study staff immediately.

You must not donate sperm for 90 days after the last dose of ASP8062.

ALTERNATIVES TO PARTICIPATION

You do not have to be in this study to receive treatment for your Alcohol Use Disorder**.** There are other options including:

- Seeking care for your alcohol use disorder from a licensed therapist, psychiatrist, or medical doctor
- Participation in another study
- Referral to other available treatment programs in your area

Please talk to the study doctor about your options before you decide whether or not you will take part in this study.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

BENEFITS

You may benefit by viewing Take Control alcohol education modules and learning how much you drink and the risks associated with drinking this amount. Participation in this study may or may not help you cut back or quit drinking. However, by participating in this study you will receive information and advice about reducing your drinking, as well as close medical attention and monitoring of your overall well-being. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

COMPENSATION FOR PARTICIPATION

«Compensation»

You will be paid up to a total of up to $595.00 if you complete this study. You will be paid for the visits you complete according to the following schedule:

- $30 for the Screening Visit
- $50 for the Randomization Visit
- $65 for the Week 2 Visit
- $100 for the Week 3 Cue Reactivity Session
- $75 for Week 4
- $80 for Week 5
- $85 for Week 7, the Final Clinic Visit, and
- $110 for the Final Telephone Follow-Up

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid _____ ***[“after each visit,” “annually,” “bi-weekly,” etc.]***

If you have any questions regarding your compensation for participation, please contact the study staff.

CONFIDENTIALITY

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.

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. Some people and organizations may inspect and copy confidential study-related records and review your identifiable information. They may need to see these records in order to monitor the research, verify the accuracy of the study data, or to analyze data or samples. These groups include:

- Research study staff at your study site,
- A limited number of representatives from Astellas Pharma Global Development, the drug company providing the study drug,
- The National Institute on Alcohol Abuse and Alcoholism, who is sponsoring this research,
- The research ethics review board – Advarra IRB (an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants),
- Fast Track Drugs & Biologics, the group that is monitoring the study data,
- Government regulatory authorities including the FDA.

This means that absolute confidentiality cannot be guaranteed. Your study records including confidential information about you collected during the study will be kept at a secure location.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

By signing and dating this information and consent form, you consent to the collection, access, use and disclosure of your information as described above.

COMPENSATION FOR INJURY

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need.

No medical care, evaluations or financial compensation for research-related injuries or illness will be provided. The costs of such additional treatment will be paid by you or by your health insurance carrier. You also have the right to pursue legal remedy if you believe that your injuries justify such action. Compensation for injury/illness may be payable under the Federal Tort Claims Act. The availability of this compensation may vary depending upon the circumstances involved and there are certain limitations.

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information

By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

COSTS

There will be no charge to you for your participation in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company. You may be responsible for care related to injury or complications that could arise from participation in the study.

DATA SHARING AND RESEARCH RESULTS

Your study data will be shared with the study sponsor, NIAAA, and the company that is developing the study drug, Astellas Pharma Global Development. Direct identifiers (such as your name, address, or date of birth) will be removed from your private information when sharing the study data with NIAAA and Astellas.

If you agree, NIAAA may share your data without direct identifiers as part of the combined study database through controlled access without additional informed consent. This means the data are made available for other research only after the researcher has obtained approval from NIAAA to use the requested data for a particular project. The data will not include direct identifiers like your name, medical record number or date of birth. To use your data, researchers must promise not to try to re-identify you. You can tell us at the end of this form whether you will allow is to share your data in this way.

Researchers are required to publish the results of this study. These results will be based on outcomes for the entire group of participants and will not identify you as a participant. No individual information about you or your participation in this research will be made public without your express written permission. You will not be told directly the results of this research; however, after the end of the study, you may request and be provided with the name of the study drug that you received, ASP8062 or placebo. A research article may be published that may be available to the public at the end of the study. Research results that are clinically relevant, including individual research results, will not be disclosed to you.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will not expire.

CERTIFICATE OF 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 or biological samples are covered by a CoC.

The CoC is issued to protect the study doctors on this study from being forced to tell people that are not connected with this study about your participation in this study, even under a subpoena. This protection, however, is not absolute. The protection offered by the CoC does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a participant's threats of violence to self or others.

If any member of the research team is given such information, he or she will make a report to the appropriate authorities If you participate in this study, you are protected permanently during any time the Certificate is in effect - even if you gave the researcher data before the Certificate is issued. Also, because this research is sponsored by NIAAA, staff from NIAAA and other DHHS agencies may review records that identify you but only for the purposes of audit for quality and accuracy or program evaluation.

Even when a CoC is in place, you must still continue to actively protect your own privacy. If you voluntarily give your written consent to anyone to receive information about your participation in the research or freely volunteer information to anyone other than the study staff that you are a research participant in this study, then we may not use the CoC to withhold this information.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participant. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Participant Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Participant Adviser: Pro00057799.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

To withdraw from the study, please contact the study doctor (in writing is preferred).

The study doctor, the sponsor, Advarra IRB, or the FDA can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If you or your partner become pregnant
- You start to drink more alcohol at a level deemed harmful by study staff
- You are confined in a controlled environment
- You have a psychiatric crisis
- You have a physical illness that prevents you from taking the study drug
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests for your safety.

ADDITIONAL REQUIRED PRIVACY LANGUAGE

By submitting my personal telephone number(s), I grant the Study site and AiCure permission to contact me at this number by SMS (text) messaging or by phone if:

- Study drug is not taken or not taken correctly; or
- The Study smartphone or app requires updates or alterations.

Additionally, I grant the Study site and AiCure permission to contact me on the smartphone-like device if my personal telephone number(s) cannot be reached.

AGREEMENT TO BE IN THE STUDY

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer **YES** or **NO** to the following questions:

A. Is this document in a language you understand? _____

B. Do you understand the information in this consent form? _____

C. Have you been given enough time to ask questions and talk about the study? _____

D. Have all of your questions been answered to your satisfaction? _____

E. Do you think you received enough information about the study? _____

F. Do you volunteer to be in this study of your own free will and without being pressured by the study doctor or study staff? _____

G. Do you know that you can leave the study at any time without giving a reason and without affecting your health care? _____

H. Do you know that your health records from this study may be reviewed by the study sponsor and by government authorities? _____

I. Do you know that you cannot be in another study while you are in this study? _____

IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS,
OR YOU ARE UNABLE TO ANSWER ANY OF THE ABOVE QUESTIONS,
YOU SHOULD NOT SIGN AND DATE THIS CONSENT FORM.

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____

Participant's Printed Name

_____	_____	_____
Participant's Signature	Date	Time

_____

Printed Name of the Person Conducting the Consent Discussion

_____	_____	_____
Signature of the Person Conducting the Consent Discussion	Date	Time

I agree to allow NIAAA to share my data as part of the combined study database through controlled access (circle yes or no): Yes / No.

_____

Initials / Date

You will receive a signed and dated copy of this consent form to keep.

CONSENT FORM QUESTIONS

ASP8062 for Alcohol Use Disorder

Check the appropriate response:	**TRUE**	**FALSE**
1) If a study participant becomes pregnant while participating in this study, she will be taken off the study drug.		
2) ASP8062 has already been approved by the Food and Drug Administration (FDA) as a treatment for alcohol use disorder.		
3) You will take two pills per day of ASP8062 or placebo.		
4) You are expected to give truthful answers about your drinking.		
5) You will be told whether you are receiving ASP8062 or placebo.		
6) You will have to give blood and urine samples during the course of the study.		
7) The study staff may end your participation in this study if they feel that it is in your best interest.		
8) You will be compensated for your time and travel.		
9) You must bring your study drug blister packs to every visit.		
10) You will never be contacted by telephone during the study.		
11) You must inform the study staff of starting any new medications that you take during the study.		
12) The research data I provide in this study may be made available to the general research community, but will be de-identified so that any personally identifiable data will removed.		

The correct answers to the questions above have been discussed with me.

_____

Participant Signature

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name
- Address
- Phone number
- Age
- Medical history
- Information from your study visits, including all test results

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of NIAAA
- Representatives of Fast-Track Drugs and Biologics, LLC, the company hired by NIAAA to monitor the study
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- Representatives of Astellas Pharma Global Development (the company that makes the study drug)
- Representatives AiCure (the company that provides the smart phone application)
- The Food and Drug Administration (FDA) and other US federal and state agencies
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study drug works and is safe
- To compare the study drug to other drugs
- For other research activities related to the study drug

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date