A Phase One Study Investigating the Tolerability and Effects of AZD0530 on Functional Neuroimaging Response in Individuals With or Without a Family History of Alcoholism

NCT02262026

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Hartford HealthCare

Informed Consent for Research

6816

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You have been asked to participate in the research study, "Functional Neuroimaging of Alcoholism Vulnerability: Glutamate, Reward, Impulsivity, and Pavlovian-to-Instrumental Transfer (PIT), Part II-Saracatinib", because you have either previously participated in the "Brain and Alcohol Research on College Students" study or the study "Functional Neuroimaging of Alcoholism Vulnerability: Glutamate, Reward, Impulsivity, and Pavlovian-to-Instrumental Transfer (PIT)" or expressed interest in our study by responding to one of our advertisements. A total of 90 subjects will participate in this part of the study. This research study is expected to last 5 years.

In order to decide whether or not you wish to participate in this research study you should know enough about the risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, and possible benefits. You should understand that doing the Magnetic Resonance Imaging (MRI) and Electroencephalogram (EEG) are necessary for you to participate. An MRI is an imaging technique that uses a powerful magnet to create images of the brain without radiation. An EEG is a recording of electrical brain activity from the scalp. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

This research is funded by National Institute on Alcohol Abuse and Alcoholism (NIAAA). The NIAAA is paying Hartford Hospital, Yale, and Dr. Godfrey Pearlson to conduct this research.

A. The Purpose and procedures of this research

A.1. What is the purpose of this research?

The purpose of this research is to measure how Saracatinib, and family history of alcoholism affect (a) your performance on tasks related to making choices and (b) brain activity while performing these tasks. Saracatinib is an investigational medication cleared for use in this study by the United States Food and Drug Administration (FDA), but not currently approved for public use for any indication. Saracatinib is a type of medication called a kinase inhibitor (developed by Astra Zeneca) which is thought to help reset signaling in the reward system part of the brain, which is a part of the brain that has been linked to alcoholism.

A.2. What procedures are involved with participation in this research study?

Procedures: Your participation in this study will involve the following:

1. In this study, you will take part in: a screening visit (lasting about 7-8 hours), and two separate experimental sessions (lasting about 6 ½-7 hours each). Each experimental session will be scheduled approximately one week apart from each other. There are rest breaks and lunch is provided at the ONRC. You will need to stay at the ONRC until the doctors have determined that any drug effects have worn off.

2. Although you are allowed to drive to and from the study for the screening visit, you may not drive to or from the study on any of the 2 experimental session days; another person may drive you and/or pick you up or you can use a taxicab which the study will pay for.

3. In order to participate, you must use contraception from the start of the study until one week after completing the study.

4. We will also ask for a urine sample at the beginning of each visit to test for drug use and pregnancy. If you test positive for drugs, we will not be able to complete that visit and you will be sent home. If you are pregnant or breast-feeding you will not be able to participate in the study.

5. At each visit you will be given a breath screen for alcohol. A positive screen will result in rescheduling.

6. Also at each visit you will have an electrocardiogram (EKG), some blood tests, and an additional urine sample. These tests will be used to monitor your health and safety while participating in this study. The EKG takes about 5-10 minutes. During the EKG, small electrodes are attached to your arms, legs and chest to measure heart activity patterns. For the blood tests we will collect 2 tablespoons of blood from a vein in your arm by a needle stick. The blood tests measure a complete blood count that assesses the number of blood cells, liver function tests, electrolytes (salts and minerals normally present in the blood) and levels of vitamins.

7. Screening day visit:
   a. You will be invited to come to the Olin Neuropsychiatry Research Center (ONRC) and the study will be explained to you. If you agree to participate you will sign this **informed consent** form. The consenting process will take 30 minutes.

   b. During the screening visit, you will take part in a psychiatric interview section to determine eligibility, if not done in a previous study. You'll also be screened to make sure that you are suitable for an MRI study (i.e. can you lie in an MRI scanner for one hour, are you claustrophobic, etc.).

   c. During the screening visit, we will ask you about medications that you are taking currently, since some prescribed medicines can interact with the study drug. You are not able to participate in the study if you are taking any of the following medications: antipsychotics, narcotic pain medication, medications for Parkinson's disease, steroid pills or injections, anti-cholinergic medications, blood thinners such as warfarin, carbamazepine, colchicine, cyclosporine, disopyramide, fluticasone, quinidine, vinblastine, vincristine, nifedipine, sildenafil, tadalafil, vardenafil, cimetidine, danazol, fluconazole, HIV protease inhibitors, itraconazole, ketoconazole, macrolides, miconazole, nefazodone, omeprazole, ritoavir, docetaxel, aromatase inhibitors or verapamil. If you are not sure whether or not you're taking these medications, you can check with the investigator.

   d. You will also complete paper and pen tests including a short health screening questionnaire..

   e. Some parts of your participation will be audio recorded and we will tell you before we begin recording. This will include some memory recall tasks. The reason we use audio recording is so that another

research team member can check the notes your interviewer has made for accuracy. Recordings will be deleted once they have been verified (within 2 weeks). You can indicate later on if you agree to be audio recorded. If you do not wish to be audio recorded we will arrange for a second member of the research team to be present at the necessary moments only.

f. For the Pavlovian-to-Instrumental Transfer task (PIT) you will be asked to taste different stimuli. The stimuli will be delivered as liquids. Stimuli will be stored in a refrigerator and brought to room temperature before use. In brief, the liquid delivery consists of a computer running E-Prime, controlling a series of programmable syringe pumps with 60ml syringes and beverage tubing attached. New tubing and syringes are used for each subject. Our stimuli will contain either a taste (juice or bitter) or a neutral solution. The juice taste will be one of three different flavors of commercially available Gatorade that you will choose. The bitter and neutral solutions will be prepared in the laboratory using commercially available tastes such as: quinine sulfate, sodium bicarbonate and potassium chloride.

   You will also be asked to make ratings about your perceptions of these taste stimuli. For instance, you may be asked to judge the intensity of a taste. All stimuli are commercially available products, or made from commercially available products. You will then be asked to complete several tasks on the computer that require learning how abstract cues might predict the delivery of a bitter, neutral, or juice solution. The entire session should take approximately 1 hour and 15 minutes. The stimuli may be presented to you in several ways. For this study you will:

   - Sample tastes & beverages from small plastic pipettes.
   - Receive different tastes through plastic beverage tubing attached to 3, 60-mL syringes, which are connected to a computer-programmed pump system. New beverage tubing will be used for each subject. The placement of the beverage tubing in your mouth will not interfere with breathing or swallowing. However, you may be asked to refrain from swallowing during certain parts of the experiment (never longer than 15 seconds).
   - Look at abstract cues projected onto a computer screen, and at times respond to these projected cues by pressing specified computer keys. Your responses will sometimes be followed by the administration of pre-sampled tastes (bitter solution, neutral solution, or juice).

8. Experimental day visits:
   a. Heart rate and blood pressure will be taken prior to the placebo or medication dose, at hourly intervals during the course of the study day, and prior to discharge.
   b. During an experimental session, you will be given one of two possible doses of medication - **one 125 mg tablet of Saracatinib** or **one zero dose tablet (placebo)** 90 minutes prior to the MRI (which dose you receive first will be chosen at random, like flipping a coin). A placebo **is a non-active substance (like a sugar pill)** that is used in studies like this one to tell between actual effects of the drug versus what people expect the active substance will do. Saracatinib is an experimental medication currently undergoing clinical trials, but is the same type of drug expected to play a role in alcoholism therapy. During this 90-minute period, you will have time to complete the paper and pencil questionnaires, watch a movie, eat lunch, and relax in our library.

c. We will collect multiple computerized tests that measure impulse control and decision making. These tests are about 10 minutes each, and are like solving puzzles or tests of how fast you can react to a signal. In addition you will be asked questions about how you are currently feeling.

d. A magnet is used to take pictures of activation in your brain. The procedure is called magnetic resonance imaging (MRI). The procedure involves both structural and functional magnetic resonance imaging (MRI and fMRI respectively. You will change out of your street clothes into comfortable hospital scrubs, in a private changing room. You will be asked to remove any metal such as a watch or jewelry that you may have on prior to the scan. You are provided a locker where you can lock up your items. A magnetic wand may also be used to be sure that there are no superficial metal objects on you. For each MRI study, you will need to lie very still on a special table inside the scanner while pictures are taken of your head using a magnet. None of the measures we do are painful, but it may take several minutes to properly connect and test the monitors. The scan will take about 90 minutes. Tests given in the MRI scanner involve you listening to sounds and looking at images, and responding by pushing buttons. There will be times where you can relax and listen to music while data are being collected. After the scan you will change back into your street clothes.

e. An electroencephalograph (EEG) session will be conducted at each study day. These will last approximately 30 minutes each, and will be completed on separate days. During the EEG, electrodes attached to your head measure brain activity patterns. A cap is used with a saline solution gel to collect these brain waves while you complete tasks.

9. You will also be asked to give a **DNA sample** for some basic genetic testing, if not already given in a previous study. Providing us with a sample of your DNA is completely optional and will not affect your ability to participate in the main part of the study. Approximately one tablespoon of saliva will be collected for this sample. This is done by spitting several times into a small plastic container which collects skin cells from inside your mouth. These skin cells contain a chemical normally present in the cells of your body that contains your unique genetic code. You will not be allowed to eat, drink, smoke or chew gum for 30 minutes before giving their saliva sample so as to not contaminate it. Samples that you donate for this research will be sent to Dr. Joel Gelernter at Yale University in New Haven, CT. The genetic testing will be used to show whether certain genes have a role in substance use. Your name will not be on the sample, so the lab will not even know who you are. This sample will not be used for any diagnostic purpose. The major purpose of collecting the DNA from you is to identify genes influencing behaviors and other characteristics of brain structure and function. We will also use your DNA to study differences in genes between individuals. Some of the genetic markers we will study currently have no meaning, that is, they do not have any particular function – we will use these genetic markers to identify specific locations in all of your genes. We may also study specific genes that may relate to aspects of brain function (for example) or other physiological function (such as the rate at which your body breaks down alcohol). The DNA collection will each take approximately 5 minutes.

   The samples stored at Yale will be de-identified. This means that any information that could identify the sample as yours, such as name or birth date, will be removed. The only identifying information stored with

the samples is a random number that is only traceable to you through a secure, password-protected database located here at the Olin Research Center. These samples will be kept indefinitely.

The researchers at the Olin Research Center are responsible for entering and protecting your information in the database. Additionally, other outside researchers will have access to the de-identified DNA analysis results only if they are granted it by the NIAAA and are certified by their institution's research ethics committee, the IRB. The analysis results contain no identifying information. The physical DNA sample will not be sent to NIAAA.

10. One week after you complete the medication portion of the study, you will receive a telephone call from one of the study staff inquiring about possible side effects of the medication and asking a few brief health-related questions regarding the study.

A.3. Which of these procedures is experimental?

The entirety of this study is considered experimental which means that it is being conducted for research purposed only and it not a treatment study.

A.4. Where will participation take place?

The study will take place at the Olin Neuropsychiatry Research Center (ONRC) located in the Hartford Hospital's Institute of Living (IOL), 200 Retreat Avenue, Hartford, CT 06106.

A.5. How long will participation last?

The entire study from start to finish takes approximately 20-22 hours to complete, and will be broken up into the 7-8 hour screening session and an additional two approximately 6.5-7 hour sessions. The exact length of time depends on the amount of time it takes to complete the tasks and the symptoms you might experience. You will need to stay at the ONRC until doctors have determined that the Saracatinib effects have worn off. In extremely rare cases, the effects of Saracatinib can last longer in some individuals than expected. If this happens during your visit, you are still required to stay until the effects of Saracatinib have worn off. Overnight arrangements at Hartford Hospital have been made to accommodate you in this type of situation. A staff nurse will be overseeing your stay and will determine when you are able to be released.

B. The possible risks, discomforts and side effects of the procedures are described below, including safeguards to be used for your protection.

You are not charged for any tests in the study. Information gathered in the study will be kept strictly confidential, and stored in a locked file cabinet.

1. The main risks from this study are from the Saracatinib. The dose used may be sufficient enough to alter your mood or behavior. Possible side effects include mild skin rash, headache, or diarrhea. Additional side effects also include nausea, vomiting, feeling tired, flu-like symptoms, and abnormal liver function tests. Changes in cell counts in blood may occur as well as other bodily side effects. Although these side effects are more common with longer-term use of the drug, they are rare with single use, as in this study. We watch

over you closely until the Saracatinib wears off to minimize possible risks associated with any possible side effects. You should inform the experimenters of any symptoms you experience. You should not take the Saracatinib if you are pregnant.

Animal studies that have tested the effects of Saracatinib at higher doses than those used in the current project, or for longer periods of time, have shown that the drug can cause problems with the heart, liver, blood cells, and digestive system (including the stomach and intestines). These harmful effects have included irritation of the digestive system (which can lead to symptoms of vomiting and diarrhea). Other side effects include lower blood pressure, higher heart rate, lower white blood cell counts (infection-fighting cells), and higher liver enzymes (which can be a sign of damage to the liver). It is not known for sure if Saracatinib would produce the same harmful effects in humans that it has with long-term doses in animals. Also, the animal studies suggest that taking Saracatinib during pregnancy could result in eye defects in the developing baby.

2. As previously stated, you cannot drive home on completion of each part of the study because the Saracatinib you have been given may impair your driving ability. The investigators will pay for a cab, or you can arrange for a friend that you designate, to drive you.

3. **Cognitive Tests**: You may get tired or bored while completing the 2 computer tests and paper and pencil testing.

4. **Interview**: This interview will involve questions about your mental health. Such personal questions can make some people feel uncomfortable or anxious. Please know that if you feel uncomfortable during the interview. You are free to stop at any time.

5. **MRI**: The techniques of magnetic resonance imaging are thought to be completely safe and are approved by the FDA. Research has not found any negative effects of magnetic resonance imaging. No x-rays or radioactivity are involved. However, some people may get uncomfortable (feeling anxious or shut in) lying in the machine. These feelings are usually strongest when people first enter the MRI machine and generally go away as they get used to the situation.

Being inside the MRI scanner can also be noisy. You will wear special headphones that reduce the noise. We will be in communication with you throughout the whole MRI scan and will answer any questions you have. If you become too uncomfortable to continue at any point during the MRI scan, we will end the session and take you out of the magnet.

You cannot have the MRI scan if you are pregnant, or if you have any metal object (such as a heart pacemaker or artificial joint) inside your body. We will make sure we collect enough information about possible metal objects prior to beginning the study.

The MRI scan is not intended or designed to be a diagnostic and/or therapeutic examination. However, as part of the study your MRI scan will be read by a radiologist. While there is no guarantee that any and all abnormalities will be detected by the radiologist reading the scan, if any incidental findings are noted, one

of the physicians supervising the study will inform you by telephone. In addition, if incidental findings are noted and you provide us with written authorization for disclosure, the physician supervising the study will speak with your designated personal physician to relate these incidental findings, and upon request, provide copy of your radiology study report. Information about your participation in this particular study is not disclosed; the doctor will indicate that you have participated in a research study, but will not identify which study or where it was completed. Otherwise, all the testing performed during this trial will not be added to your clinical file.

Because the space inside the scanner is narrow, some people feel uncomfortable or anxious (claustrophobic) inside the MRI. The investigators will take steps to make you feel comfortable and relaxed inside the scanner. If you feel too uncomfortable to continue, you will be able to come out of the scanner whenever you need to.

6. **EEG**: The EEG is a recording of electrical brain activity across the scalp. The session is non-invasive, but requires us to maintain a clean contact between the electrode and your scalp. We will have to scrub your skin under each sensor placement. This procedure may be mildly uncomfortable, but not painful. This scrubbing may leave small red patches afterward that will disappear in a day or two. An additional risk lies in the possibility of transmission of infection. To minimize these risks, careful preparation of skin surfaces using sterile supplies is conducted before attachment of electrodes, and the elastic cap is sterilized after each use. There is a very low risk of developing an allergic reaction to the gel, which is essentially a thick salt-water. Some of the sounds you listen to in this part of the test may be loud or occasionally unexpected. You may discontinue the session at any time if it becomes uncomfortable.

7. If you give your consent, we will be testing your DNA or genes to determine if you have any of the genes known to be associated with alcohol related problems. Your genetic information will be kept confidential, but it is possible that someone could learn something about your genes. Some genes are known to be associated with the possibility of developing certain diseases. If it became known to you or others that you carried such genes, this could make you anxious and worried and even cause other people or insurance companies to treat you differently. This is a remote possibility, but could occur. We will make every effort to keep the results confidential (only scientists working on this research project will know the results). We will take your name off the sample and identify you by a random number that only the research staff knows is yours. We will not make any of our laboratory results available to you, nor will we add them to your medical record or release them to others.

8. **Urine Test/ Breath Screen**: There are minimal risks associated with giving the urine specimen and breath screen. However, the results of this test will be put on record in your research file and may prevent you from participating fully in the study.

9. **PIT**: You might experience some unpleasantness while tasting the bitter solutions. However, there are no known risks associated with drinking any of the liquids and beverages that are used in this research study. All are commercially available products. Additionally, researchers will keep in close communication with subjects while they are completing this study, and subjects experiencing discomfort can discontinue the study.

10. **Electrocardiogram (EKG)**: the EKG is a recording of the electrical activity generated by your heart. It involves small sticky electrodes being placed on the skin of your wrists, ankles and chest. Occasionally the gel used to make an electrical contact between your skin and the electrodes can be mildly irritating, but otherwise there is no risk to the procedure.

11. **Blood Draw**: about 2 tablespoons full of blood are collected by needle stick into tubes. These are sent to a laboratory to measure various vitamins, hormones and types of blood cells. Possible risks associated with your giving the blood sample include feeling mild discomfort when the needle is put into your vein, bleeding or bruising around the needle site, and rarely a skin infection at the site of the blood draw. If any of these events occur, they can be treated straightforwardly.

C. Possible benefits from your participation in this research.

There is no **benefit** to you or others to be expected from your participation in this research. However, information gained through this project will help researchers better understand the effects of alcohol on the brain so that more effective treatments for alcohol problems can be developed.

D. Alternatives to participation in this study that you should consider.

This research is not a **treatment.** You may choose not to participate in this study without any penalty to you.

E. Who can you call if you have questions about this study?

You do not have to sign this consent form until all the questions you have at this time are answered. The investigator is willing to answer any questions you may have about the study procedures. Below is a list of contacts if you should have any questions about the study.

Questions about:	Contact	Phone #
the research, research-related treatments, or a research related injury	Godfrey Pearlson, MD	860-545-7757
your rights as a research participant	An IRB Representative	(860) 972-2893
the research in general	Vice President, Research	(860) 972-2893
a confidential issue that you would like to discuss with someone not associated with research	Patient Advocates	(860) 972-1100

F. Your participation in the research is voluntary.

You may refuse to participate, or withdraw your consent and discontinue participation in the research at any time. You may do so without penalty or loss of benefits to which you are otherwise entitled. Your decision whether to participate will not affect your future medical care at Hartford Hospital.

To withdraw or revoke your consent or DNA sample at any time, you must submit a written request to Dr. Godfrey Pearlson here at the Olin Neuropsychiatry Research Center, 200 Retreat Ave., Hartford, CT 06106. Your data will be anonymized or destroyed according to your wishes.

G. You will receive financial compensation for your participation in this research.

There is no monetary cost to you for participating in this study.

You will be compensated for the time required to participate in the study. On the study day you earn **$25 per hour** for participation (total payment will vary depending on the number of hours completed). You will be fully compensated if you participate in any part of the research. If it is decided that overnight accommodations are necessary, you will neither be paid nor charged for this time. The cost of overnight accommodations will be covered by the study. In addition to the money for participating in the study, you may also win extra small amounts of money by scoring well on some of the tasks given to you in the scanner, and for performing well on certain computerized tasks (up to $65).

Payments are on a prepaid debit card and are reportable as income to the IRS. We will give you separate instructions on how to use the card. Payments will be loaded onto the card by the beginning of the next business day following the study visit.

In addition to the hourly compensation for participating in this study, participants who complete the study and who are able to keep their scheduled appointments without cancellations, with exceptions made upon the research staffs discretion, (i.e. bad weather) will be given a $50 gift card at the end of the study.

A note about the Internal Revenue Service (IRS): Hartford Hospital is required to report payments of $600 or more to the IRS. This means that if you receive $600 or more from Hartford Hospital during the calendar year, your compensation will be reported to the IRS and you will receive an IRS 1099 Form.

H. Your confidentiality will be guarded to the greatest extent possible.

Hartford Hospital will protect all the information about you and your part in this study, just as is done for all patients at Hartford Hospital. Your records will be maintained in accordance with applicable state and federal laws. However, private identifiable information about you may be used or disclosed for purposes of this research project as described in the study's authorization form (HIPAA). HIPAA laws protect confidentiality about your personal health information which includes your doctor visits, hospitalizations, and any outpatient clinic services. Protections under HIPAA are not absolute, and records can be subpoenaed by insurance companies or the government.

Please note that your research files are not placed in your medical records, nor are medical records placed in your research files unless medical records have been created as a part of your participation (i.e. radiology reads, blood labs, etc.).

AstraZeneca LP, the manufacturer of the study drug, will receive your health information as a result of your participation in this study.

Clinical research relies on truthful data collected from you without the fear of disclosure of your sensitive information. Congress authorized the Secretary of Health and Human Services to issue Certificates of Confidentiality (CoCs) which allows research investigators to refuse to disclose identifiable information about you even under a subpoena. This study has been issued a CoC from the National Institute on Alcohol Abuse and Alcoholism (NIAAA). As a subject, you must also do your part in protecting your identity and your sensitive information linked specifically to this study: The CoC remains protective if you do not disclose your participation in this study to others. Once disclosure is in the public domain, it's possible that the CoC can be challenged.

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 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. This protection will not apply until we have obtained the CoC, which may take a few weeks.

Also, because this research is sponsored by NIAAA, staff from that and other DHHS agencies may review records that identify you only for audit or program evaluation. They can't report anything that would harm the research subjects. This Certificate, however, does not imply that the Secretary, DHHS, approves or disapproves of the project.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from **voluntarily releasing information** about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

*A Federal law, called the **Genetic Information Nondiscrimination Act (GINA)**, generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:*

- *Health insurance companies and group health plans may not request your genetic information that we get from this research.*
- *Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.*

- *Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.*

I. What happens if you are injured as a direct result of your participation in this research project?

In the event that you are injured as a direct result of taking part in this research, you will receive help in the following way:

If you have medical insurance, Hartford Hospital will collect fees for medical treatment at Hartford Hospital from your insurance company. If you are not fully covered by insurance or uninsured, Hartford Hospital will cover these expenses.

There is no plan for Hartford Hospital to pay for your medical expenses at other hospitals or for pain and suffering, travel, lost wages, or other indirect costs of taking part in this research. You do not waive any of your legal rights by signing this informed consent document.

AstraZeneca does not provide financial assistance for injury, medical or other costs. Additionally, Astra Zeneca will not pay for lost wages. All losses for medical expenses that have been covered by medical or hospital insurance or by third-party or governmental programs providing such coverage, you do not give up any legal rights by signing this form and may have other legal options.

J. Contact Preferences

While we will make every effort to protect your privacy we also realize the importance of being able to contact you about your participation in this research study. This can sometimes mean exchanging information by phone or email. We'd like you to tell us what way is best for reaching you and what information is permitted to be exchanged. Text messages will be sent from an encrypted and password protected study phone.
Please indicate below your preferred method(s) to be contacted:
Mark all that apply.

YES / NO

☐ ☐ Home phone:

- (_____)_____-_____
- Is it ok to leave voice mail appointment reminders? ***YES / NO***

YES / NO

☐ ☐ Cell phone:

- (_____)_____-_____
- Is it ok to leave voice mail appointment reminders? ***YES / NO***
- Is it ok to send text messages about your appointment to this number? ***YES / NO***

Can we contact you by email?

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- Appointment reminders
- Information related to this research project

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact our office at 860-545-7800.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your protected health information via email?

_____**Yes** _____**No**
(Initials) **(Initials)**

- Patient email address (please use all capital letters):_____

K. Signatures

You will be given a copy of this informed consent document to keep. By signing below, it means that you have read it, that you voluntarily agree to participate in this research, "Functional Neuroimaging of Alcoholism Vulnerability: Glutamate, Reward, Impulsivity, and Pavlovian-to-Instrumental Transfer (PIT), Part II- Saracatinib" and that you consent to the performance of the procedures listed above.

Participant's Signature	Printed Name	Date
Legally Authorized Healthcare Representative	*Printed Name*	*Date*
Person Obtaining Consenter's Signature	Printed Name	Date
Witness signature	*Printed Name*	*Date*

(A witness is the person observing the explanation of the above information to the participant. A witness to the informed consent process is optional unless presented orally.)

Please indicate below if you give us a permission to collect a saliva sample from you for genetic testing:

☐ I agree ☐ I do not agree Initials: _____

Please indicate below if you agree to be audio recorded for various portions of the study visit (please know that you will never be audio recorded without being notified first):

☐ I agree ☐ I do not agree Initials: _____