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COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
200 FR. 4 (2014-3)
YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: A Pilot Study on the Safety and Efficacy of Mavoglurant in Alcohol Drinking
Principal Investigator: Suchitra Krishnan- Sarin, Ph.D., Professor of Psychiatry
Funding Source: National Institutes of Health

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to examine the interactions between alcohol and a drug called mavoglurant.
- Study procedures will include initial intake, remote psychological examination, PE/In-person intake, lab session 1, medication period, lab session 2, morning after lab session 2 lab work and 1 week follow up.
- 13 (some will be remote) visits are required.
- These visits will take approximately 25 hours total.
- There are some risks from participating in this study. Side effects from the study medication, mavoglurant. Risks of alcohol consumption. Possible interactions of alcohol and mavoglurant. Possible discomfort in answering certain items on questionnaires. Bruising, blood clots or light-headedness from blood draw. Irritation of the skin from adhesive used for EKG. Risk for hematoma at the site of the venous puncture from Intravenous catheter. Very rarely, venous puncture can also result in a blood clot or infection.
- You will not directly benefit from participating in this study. You may benefit by receiving, at no charge, a thorough screening and diagnostic evaluation, the results of which may be shared with you and, if you wish, with your physicians. This research will benefit scientific knowledge and may lead to the development of a potential therapy for alcoholism.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Invitation to Participate and Description of Project

You are invited to participate in a small study to examine the interactions between alcohol and a drug called mavoglurant. Mavoglurant is an investigational medication that has been studied in a variety of disorders, including Obsessive Compulsive Disorder, Parkinson's and Fragile X Syndrome (genetic condition causing intellectual disability, behavioral, and learning difficulties). Since mavoglurant targets a neurochemical system, called the glutamate system, which is involved in alcohol's effects, we want to examine if this drug alters an individual's responses to alcohol. In this project, we will explore the effects of mavoglurant on responses to alcohol, including stimulation, sedation, intoxication, and physiological reactions (e.g. blood pressure, heart rate, steadiness) You have been chosen to participate because you drink alcoholic beverages socially and are not seeking treatment for your alcohol use. You may smoke cigarettes but use no other street drugs. 28 participants will complete this project.

APPROVED BY THE YALE UNIVERSITY IRB 6/30/2023

The study is funded by the National Institutes of Health. In order to decide whether you wish to be a part of this research study, you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the research study, which a member of the research team will discuss with you. This form will be completed as a hard copy on paper or online through REDCap. This discussion will go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures and any possible benefits. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

COVID-19 related procedures

We care about your safety as a research participant. Because participating in this study may involve travel outside of your home and exposure to others, we will discuss ways to minimize risks related to COVID-19. All study participants must be fully vaccinated against COVID-19 (as defined by CDC guidelines). If you are eligible for the study, we will ask that you fill out a COVID symptom online prior to each in person appointment. This questionnaire will be sent to you via an online link to your cell phone or email (your preference). Depending on symptoms, we may need to call you to follow up on your symptoms. You will not be allowed to attend in-person visits until your COVID symptom questionnaires are completed. If you are not able to fill out the online questionnaire, study staff can administer the questionnaire via phone.

At all in-person appointments, participants will be asked to wear masks and study staff will wear masks. If you do not have a mask, one will be provided to you by study staff. Further safety information for the sessions is described below. During in-person appointments, you will again be asked about COVID symptoms, and a temperature check will be conducted. Participants who report symptoms or have a temperature of >100 will be asked to reschedule their visit and instructed to immediately contact their primary health care provide or call the Campus COVID Resource line (203-432-6604).

Description of Procedures

This study consists of five parts: 1) An evaluation period during which we will determine your eligibility for the study, physical exam/in-person intake, and your medical history in your medical record may be reviewed for eligibility by the study physician and study psychologist 2) Lab Session 1, during which you will be randomly assigned (like flipping a coin) to receive mavoglurant or a placebo (like a sugar pill). 3) Medication Period, in which you will attend via video chat daily for 6-9 days, where you will be observed taking the study medication. 4) a fourth part in which you will be asked to come in for Lab Session 2 followed by a blood draw/urine collection the morning after. 5) The last part is the follow-up appointments. We will call to see how you are doing and check on any remaining side effects. You will return for a brief visit two weeks after you Lab Session 2 to have a blood draw, urine collection and your blood pressure evaluated.

1) Remote Evaluation: For the health and safety of everyone, much of the intake will be conducted remotely via phone call or videoconferencing. During this appointment, you will provide personal information, including your psychological history and your history and current use of alcohol. Information will be collected by you filling out questionnaires via a website and the researcher administering questionnaires. The researcher will be on the phone and/or video chat with you for the entirety of this collection period. Additionally, portions of the clinical examination and physical examination (see below) will be collected during this remote visit. It should take approximately 3 hours to complete all parts of the remote intake, remote physical, and remote psychological examination.

   Following this, at your convenience, we will schedule an in-person physical examination/intake at 1 Long Wharf Drive, New Haven, that will include an electrocardiogram, along with blood and urine tests. This will require about 2 hours of your time. You will be asked to not use any drugs while you are

participating in this study. If you test positive for any drugs or alcohol, you may not be paid for your appointment and may be asked to reschedule. Females will have a pregnancy test and will only be allowed to participate if the result is negative. The blood tests are routine safety laboratory chemistry tests and the urine test will be used for routine lab screening and use of drugs.

2) Lab Session 1: If you are found to be eligible, you will enter the second part of the study, lab session 1. This appointment will be conducted at the HRU at YNHH, CSRU at 2 Church Street South, New Haven or Masonicare, 22 Masonic Ave, Wallingford. Since we are giving you alcohol you cannot drive to the appointment. You will be provided with transportation to and from the appointment or can choose to be dropped off. You will come in at 8:15 am. When you arrive, you will be asked questions about your use of alcohol, drugs, and any prescribed medications. We will also collect a urine sample to screen for use of drugs (e.g., cocaine, opiates, marijuana, benzodiazepines); this test will have to be negative for you to continue in the study. If the drug test is positive, you will need to be rescheduled.

   If you are a smoker, prior to entering the lab you will be given time to smoke a cigarette. You will be given breakfast at 9am, complete questionnaires and computer tasks. At approximately 11:00 am, an IV will be placed in your non-dominant arm and will be used to draw blood during the session. This is done to avoid having to stick you more than once for the blood collections. A blood pressure cuff will be placed on your other arm to monitor your vital signs (e.g., blood pressure, pulse).

   We will provide you with alcohol to drink from 12:00 pm to 1:30 pm in the form of 6 drinks. These drinks will contain 80-proof vodka with a non-carbonated mixer of your choice (based on your selection at intake). You will drink beverages containing an amount of alcohol corresponding to moderate drinking (approximately 3 drinks for women and 4 drinks for men). The exact amount of alcohol given to you will depend upon your body size (height and weight); however, you will not be given an amount of alcohol greater than that which you have previously ingested on at least one occasion during the past twelve months. We will ask you to consume a drink every 15 minutes. If you are unable to consume all of the drinks, you have the right to stop drinking. If you are a smoker, you cannot smoke during this session but once it is over you can use nicotine lozenges or gum.

   Blood samples will be obtained to measure blood chemistry before the alcohol drinking session. Blood alcohol concentrations will be drawn every 15 minutes for 90 minutes and hourly thereafter. Breath alcohol levels will be performed every 30 minutes until the alcohol level has dropped below 0.02 or until 6pm.

   We will ask you to complete some questionnaires on how alcohol makes you feel and about your mood during each session; these assessments will be completed multiple times during each session. We will also assess your balance by having you stand on a balance board as steadily as possible for 30 seconds before and after drinking.

   Your IV catheter will be removed at approximately 5:00 pm. You will be allowed to rest in your room, watch movies, listen to music, and have a snack. You will stay until your BAC falls to below 0.02 or until 6pm. At that point you will be provided with transportation home (Uber, Lyft, or Taxi).

3) Medication Period: You will be randomized to receive either mavoglurant or placebo (sugar pill) and will receive your supply of study medication upon completion of Lab Session 1. During the next 6-9 days, we will video chat with you daily while you take your study medication (200mg of mavoglurant/day or a placebo). You will be monitored for any side effects. If you are experiencing

excessive side effects, you may be scheduled to meet with the study physician and may be asked to discontinue your participation. We will ask you not to drink any alcohol during this medication period. Midway through the medication period you will be required to provide a negative drug test (females will also need a negative pregnancy test). An additional test/s will be administered if your first day of medication does not take place the day after your first lab session.

4) Lab Session 2: The second laboratory session will be scheduled approximately one week after the first lab session, depending on your schedule and room availability. It will be similar to the first lab session as far as blood draws, questionnaires, and computer assessments. The main difference will be that you will take your final dose of study medication that morning. As with lab session 1, we will be giving you alcohol therefore, you cannot drive to the appointment. You can be dropped off or we can arrange transportation to the appointment. Your IV catheter will be placed at 11:00 am and alcohol will be given to you from 12:00 pm - 1:30 pm. You will stay until your breath alcohol level falls to below 0.02 or 6pm. You will be provided you with transportation home (Uber, Lyft, or Taxi). You will be asked to go to Quest Diagnostics the following morning for a urine collection and blood draw.

5) Follow Up: We will call you on the two days following the second lab session to briefly check on how you are doing and to record any remaining side effects.

One week after you complete the second lab session, we will video chat with you for a 30-minute follow-up interview. We will record any remaining side effects of the medication and ask a few brief health-related questions. You will be asked to come in for a brief blood draw, urine collection, and blood pressure reading.

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 website at any time.

Risks and Inconveniences

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

Risks Associated with Study Drug, Mavoglurant: Mavoglurant, or AFQ056, has been studied in a total of 1863 study subjects. Overall, the adverse events observed in the various human studies were of mild to moderate severity. Dizziness (11%), visual hallucinations (11.1%), uncontrolled, involuntary movement (12%), headaches (8.3%), falls (8%), impaired voluntary movement (8%), and lack of energy (8%) were the most common. Other adverse events (5.6%) were anxiety, back pain, confusion, constipation, decreased hemoglobin (protein in red blood cells), insomnia, muscle spasms, nasopharyngitis (common cold), nausea, peripheral edema (swelling in legs), orthostatic hypotension (decrease in blood pressure when standing), blurred vision, have also been observed. The safety of AFQ056 was also assessed in 50 patients with moderate to severe Obsessive Compulsive Disorder. Patients in this study received 200 mg BID (twice the dose being used in the current project) of mavoglurant for up to 18 weeks and the results indicate that this dose was safe and well tolerated.

Risks associated with alcohol: Several medical conditions could potentially be worsened by acute alcohol administration (e.g., liver disease, cardiac abnormality, pancreatitis, diabetes, neurological problems, and

gastrointestinal disorders). Therefore, subjects with evidence of these condition, as revealed by physical exam and/or laboratory findings, will be excluded from the study.

Alcohol may also cause nausea in high doses; however, nausea is not expected at the dose being used in this sample of healthy volunteers who will report prior experience of consuming alcohol levels similar to the quantity used in this study. Alcohol dosing will be calculated using published gender specific algorithms based on estimated body water determined from height, weight, and age and the amount of alcohol provided will raise your blood alcohol level to 80 mg/dl, which is the legal limit of intoxication.

Another area of potential risk to subjects under the influence of alcohol involves their safety during the experimental procedures. Although impairment of gross motor coordination may occur after alcohol administration at the doses being used in this study, all experimental procedures will be conducted under the supervision of the experimenters to prevent possible accidents such as falls. Further on the day of alcohol administration, you will also be observed and questioned until your BAC drops below 0.02 or at 6pm. You will be provided with a ride home.

Interaction of alcohol and mavoglurant: There are no data currently available on the interaction of alcohol with mavoglurant. We are studying this interaction in the current study.

Risks associated with urine collections: Screening urine collections are performed primarily as safeguards to subjects and should add no risks other than those normally associated with these procedures.

Risks associated with rating scales and questionnaires: These are all noninvasive and should add no risk. The major disadvantages are the time taken to complete them or possible discomfort in answering certain items.

Risks Associated with Blood Drawing: Drawing blood is a safe and standard medical procedure. Sometimes a bruise will occur at the puncture site and rarely a blood clot or infection will occur in the vein. Certain individuals may feel light-headed during venipuncture.
You will have approximately 3.4 tbsps. of blood drawn at the PE appointment to determine liver and kidney functioning. We will draw approximately 4.8 tbsps. of blood during the first lab session and 5.8 tbsps. of blood at the second lab session for BALs and health profile and PK samples. The morning after lab session 2, 3.4 tbsps. of blood is drawn. At the 1 week follow up 3.4 tbsps. will be drawn again for health profile. Therefore, the total amount of blood drawn during the study (20.8 tbsps.) is well within the HIC guidelines of 30.5 tbsps. within 8 research weeks, and the blood loss poses minimal risk in healthy subjects. We will advise subjects against donating blood for 6 weeks following study participation.

Risks Associated with Electrocardiograms (EKG/ECGs): There is no pain or discomfort during an EKG/ECG; however, removing the pads may cause some irritation to the skin.

Risks Associated with Intravenous Access: Insertion of an intravenous catheter involves risk for hematoma at the site of the venous puncture. Very rarely, venous puncture can also result in a blood clot or infection.

Pregnant women: Since alcohol drinking is harmful to an unborn child, pregnant women may not participate in this study. As a result, the following precautions are necessary if you are female: 1) Repeated pregnancy test will be performed using a urine sample. A positive pregnancy test will result in your being excluded from the study, 2) you must agree to use a reliable method of birth control during the study and 3) if you are a nursing mother, you will be excluded from the study.

Benefits

You will not directly benefit from participating in this study. You may benefit by receiving, at no charge, a thorough screening and diagnostic evaluation, the results of which may be shared with you and, if you wish, with your physicians. This research will benefit scientific knowledge and may lead to the development of a potential therapy for alcoholism.

Economic Considerations

You will not be charged for any of the tests or procedures conducted to determine eligibility for the study. Payment for the remote intake interview will be $50. You will also receive an additional $65 for the physical examination/in-person intake and up to $20 for the MSDM task. You will also receive $140 for participating in the 1st laboratory session and $200 for completing the 2nd laboratory session. The morning after lab session 2 we'll have you come in-person to Quest Diagnostics for blood and urine collection $25 payment. Additionally, you will receive $10 for calling in via video chat to take your study medication (7-10 days), for up to a total of $100. You will be paid $30 for completing the one-week follow-up appointment.

Appointment	e-gift card (or cash)	Cash	Check
Intake	$50		
Physical Exam and in-person intake		$65	
MSDM Computer Task at In-Person Intake		Up to $20	
Lab Session #1			$140
Medication ($10/day for 7-10 days)			$70- $100
Lab Session #2			$200
Morning after Lab Session 2 blood and urine collection			$25
1 Week Follow Up			$30

This a total of up to $50 e-gift card (or cash at in-person), up to $85 in cash and up to $495 in the form of a check which will be mailed to you within 3-5 weeks of study completion for a grand total of up to $630. If you must drop out of the study, then you will be paid for the portions that you complete.

*If you are asked to come back in for a repeat lab appointment (blood work, or EKG/ECG), we will compensate you $25 in cash for your time.

According to the rules of the Internal Revenue Service (IRS), payments that are made to you because of your participation in a study may be considered taxable income.

Subject Obligation

We ask that you do not use any medicines except mavoglurant or participate in any other research study without discussing this with us first while you are in our study. Please let us know if you do use any other medications or drugs during this time since we may need to reschedule your study sessions. You could be dismissed from the study if you repeatedly do not show up or lie about your alcohol and drug use. We will be monitoring your urine periodically for use of other drugs and your breath to assess alcohol level.

Treatment Alternatives/Alternatives

This is not a treatment study. If you are currently interested in changing your drinking behavior, we will provide you with a treatment referral and you will not be eligible to participate in this study.

Confidentiality and Privacy

When you participate in a research study, your identity as a research participant—and all the identifiers that could lead to your identity will be held confidentially. The investigator cannot be forced to release your identifiers to anyone outside of the research team if a Certificate of Confidentiality is issued. Thus, to protect your sensitive information, we have a Certificate of Confidentiality (CoC) from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) which is part of the National Institutes of Health (NIH).
The CoC protects the identity of individuals in a study and protects the investigators 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 subject'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. Individuals who participate as research subjects (i.e., about whom the investigator maintains identifying information) in the specified research project are protected permanently during any time the Certificate is in effect. 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.

If you decide that you will be in this study, and you will be visiting the Connecticut Mental Health Center (CMHC) as part of your study procedures, some information about your participation in this research study will become part of your CMHC medical record that identifies you. If you do not already have a medical record at CMHC, one will be made for your visit. This chart will say you are/were a research participant and had an EKG and lab work at the CMHC.

As a participant in a clinical research study involving the Yale-New Haven Hospital (YNHH) Research Unit (HRU), it is important for you to know that if you do not already have a medical record at YNHH, one will be made for your admission. In addition, you need to know that if you have ever been a patient at YNHH at any time, your previous medical records of other visits or admissions will become available to the researchers and to the staff of the HRU/CSRU when today's information is added into the medical record.

Information about your study participation will be entered into your Electronic Medical Record (EMR). This information will only indicate that you've participated in a research study and will not give details of the type of study. Once placed in your EMR, this information is accessible to all of your providers who participate in the EMR system. Information within your EMR may also be shared with others who are appropriate to have access to your EMR (e.g. health insurance company, disability provider) including the study physicians and study psychologist which may check your medical history, to ensure eligibility and safety for your research participation.

Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. There are certain circumstances when medical records can be demanded without your written permission. In some cases, medical records can be requested, for example, by an insurance company, the government, or an attorney representing another person. When the results of the research are published, or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. Documents that contain your name, such as this consent form signed by you, will be securely stored separately from your research data. All research data will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. All identifiable data will be kept in a locked file cabinet, separate from your research data. The data will be kept in this anonymous form at least seven years after the end of the study and will be shredded.

You should understand that there is a risk that you will be recognized by other patients or staff involved in the laboratory or hospital ward and it could be known that you are participating in this study. If you find this to be an unacceptable condition you should not sign this consent form.

You will be given and encouraged to carry a wallet card that identifies the research study by a designated number, states that you are taking either Mavoglurant or placebo, but does not identify you as a participant in alcohol research. This card provides the name and phone number of the main study doctor who can provide information to other doctors in the event of an emergency. The card also instructs the emergency room, or other doctor treating you to provide information to the study doctor about your care.

The information about your health that will be collected in this study includes:

- Name
- Address
- Telephone number
- Information from a brief psychiatric examination
- Emergency contact information
- Initial telephone screening information
- Healthcare, Social Functioning, and Addiction Questionnaires/Forms
- Medical and laboratory records of only those services provided in connection with this Study.
- Records about phone calls made as part of this research
- Research study records about your study visits
- Hepatitis infection
- Other reportable infectious diseases
- Physical exams, Laboratory, EKG, and other test results
- Questionnaires
- The diagnosis and treatment of a mental health condition
- Use of illegal drugs or the study of illegal behavior
- Records about any study drug you received

Information about you and your health which might identify you may be used by or given to:

- The U.S. Department of Health and Human Services (DHHS) agencies
- The FDA
- Yale New Haven Hospital
- Masonicare, Church Street Research Unit
- Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on

human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.

- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- Those providers who are participants in the Electronic Medical Record (EMR) system.
- The Principal Investigator, Suchitra Krishnan-Sarin, PhD and the Center Principal Investigator, John Krystal, MD.
- The study sponsor or manufacturer of study drug
- Health care providers who provide services to you in connection with this study.
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards
- Novartis, the supplier of the study medication, will also have access to your data however, they will only have access to your data that is un-identifiable. They will not have any of your personal/identifying information so there will be no way for them to link you to your data. Similarly, your de-identified data may also be provided to the FDA.

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and Yale-New Haven Hospital and the Connecticut Mental Health Center and Masonicare are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies. However, by deciding to take part in a single or double blinded treatment study and sign this permission form, you will not be allowed to look at or copy your study related information until after the research is completed.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

Voluntary Participation and Withdrawal

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

Withdrawing from the Study

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. If you should choose to end the experimental session after you have consumed alcohol, we would ask you to stay

in the laboratory until your breath alcohol level falls to below 0.02 in order to ensure your safety. In addition, we may insist that you accept transportation to your home.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with Yale-New Haven Hospital, or the Connecticut Mental Health Center.

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to the study doctor, Dr. Krishnan-Sarin, Yale University, 34 Park Street, Ste S-208, New Haven, CT 06519.

If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight.

If the Principal Investigator decides to discontinue your participation in the research study, you will receive payment for all completed appointments.

In Case of Injury

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able Dr. Julia Shi (203) 781-4640 or the Principal Investigator: Suchitra Krishnan-Sarin, PhD (203) 974-7595.

Yale School of Medicine, Yale-New Haven Hospital, the Connecticut Mental Health Center, Masonicare Church Street Research Unit, and Novartis do not provide financial assistance for injury, medical or other costs and will not pay for lost wages or losses or 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.

If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment.

Data Archive:

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many NIH studies are stored and managed. Sharing your deidentified study data helps researchers learn new and important things about brain science more quickly than before.

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. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you. The study researchers will never send your personal information to NDA.

It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your deidentified data from each study. This data matching helps researchers who use NDA data to count you only one time. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for different research projects. Every researcher (and the institution 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 NDA. The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to NDA. You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in NDA, 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 NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, 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 NDA, it is available on-line at http://nda.nih.gov.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you decide.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject: _____

Signature: _____

Date: _____

_____ _____

Signature of Principal Investigator Date

or

_____ _____

Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Suchitra Krishnan-Sarin, Ph.D. at 203-974-7595 or the study physician, Julia Shi, M.D. at (203)781-4640. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at 203-785-4688.