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COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
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YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: The role of neuroactive steroids in stress, alcohol and drug craving and alcohol and drug use in alcohol use disorders

Principal Investigator: Rajita Sinha, PhD, 2 Church Street South Suite 209, New Haven, CT 06519

Funding Source: National Institute of Health, NIAAA

Invitation to Participate and Description of Project

You are invited to take part in a research study that will examine urges to use alcohol in women and men. We hope in the future to develop better treatments to reduce alcohol craving and use. You have been asked to take part because we understand that you are seeking treatment for alcohol use disorders and are interested in participating in a research study examining alcohol craving and alcohol use. Approximately 90 persons will be recruited for this study.

The goal of this study is to look at how pregnenolone, a naturally occurring hormone and a precursor to many other hormones, affects the body's response to different stressful situations and if there are any differences in response between men and women. You may or may not experience craving for alcohol or other drugs when you are in stressful, neutral or alcohol-related situations. We will check your craving and mood to see the effect that these situations may have on your alcohol craving and motivation. We are also trying to see if pregnenolone will affect your daily alcohol and drug use. These findings may also help us understand the physical and mental effects of stress, so as to better understand the factors that lead to alcohol use and relapse.

In order to decide whether or not 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 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, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to take part in this study, you will participate in an initial screening and intake session, followed by physical examination and blood work to determine eligibility. Eligible participants will be assigned to receive one of two doses of pregnenolone or placebo (a dummy pill that does not contain any medicine but is used for the purposes of providing a comparison in this study to the study medication) for eight weeks. You will also be provided with behavioral counseling and allowed to win monetary prizes for attending treatment for eight

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weeks. In week 2, there will be an experimental laboratory component that involves imagining your own stressful, relaxing and alcohol- related situations for very brief 5 minute periods on three separate days.

All the study procedures and appointments will be conducted at the Yale Stress Center on 2 Church Street South, New Haven, CT.

You will meet with a psychiatrist who will explain the risks and benefits associated with taking pregnenolone/placebo. If you are willing to participate in the study, you will be asked to sign this consent form after which you will be interviewed and be asked to complete some questionnaires.

Intake procedures:

If you agree to take part in this study, you will be asked to complete 2-3 intake appointments. Intake appointments take approximately 1.5 hours to complete. During these appointments we will ask questions about your alcohol use, demographics and health history. You will also complete a physical examination and blood work to ensure that all inclusion and exclusion criteria for the study are met. You may also attend a number of these appointments via the Internet or phone if needed, and visit a Quest Diagnostics location to provide a urine and blood sample instead of visiting the Center.

If you decide to take part in this study, you must be free of major medical illnesses as determined by the physical examination, laboratory tests, urine analysis and EKG. For women, you will be given a pregnancy screening test and scheduled to start pregnenolone/placebo medication in the week of the expected beginning of menstruation. You will be randomly assigned to either placebo or pregnenolone. You will take pregnenolone or placebo twice daily as provided in weekly packs by the study staff. However, you will not know whether you are taking placebo or the pregnenolone. You will come to the Yale Stress Center twice per week and we will check your heart rate, blood pressure and ask you about your alcohol craving, use and mood.

The assignment to pregnenolone doses or placebo will be done by random selection, which means that it will be decided by the "chance" of the draw, and not selected deliberately because of any special characteristics or problems you have. After taking the first dose of study medication, we will check your pulse, blood pressure and other physical and psychological symptoms. If you have any side effects from the study drugs, you will meet with the research nurse or doctor who will check your symptoms.

We will communicate with you using the smartphone using an application called MetricWire and eMocha. The apps will remind you daily to take your study medication, and make ratings on your mood and, craving, and tell us about your alcohol use. To check that you are taking your study medication, we will be collecting urines, and doing a blood draw at weeks 2, 5, and 7. The study medication will have riboflavin added as a marker. Riboflavin produces a bright yellow discoloration of the urine when the medication is taken 2 to 8 hours prior, so study staff will be able to visually inspect whether you have taken the medication. You will also use the eMocha app to video yourself taking your medication. You will receive random prompts to complete a brief 1-minute survey of questions and a third time for a 5-10 minute survey to be completed at night before bedtime. The surveys are set up with standard automated questions and prompts and you will use the phone key pad to answer the prompts. All data will be encrypted and sent to a secure server where data is identified by subject ID only. You will be trained to use the phones in this way at the start of the study and if you don't have a smartphone one will be provided to you at no cost for the duration of the study.

Imagery testing development session:

We will also ask you to tell us about specific events from your personal life, events that were stressful for you and those that are associated with alcohol drinking. Brief stories about these situations will be put together with you. These stories will be later played back to you during the laboratory sessions and you will be asked to briefly imagine these situations on different days. In addition to these stories we will ask you to select some situations that are neutral and relaxing from your own experiences. The neutral relaxing events that you select will also be described to you in a laboratory session and you will be asked to briefly imagine that situation as well.

Imagery training and practice session
After completing the interview and testing sessions, you will have a training session in week 2 on the morning of DAY 1 of the laboratory sessions starting at 11 AM. The research assistant will meet with you and train you on how to generate and hold an image in your mind's eye. We will guide you through imagining some common scenes such as reading a popular magazine and doing sit-ups in gym class, and coach you on how to focus and keep the image in your mind.

We will also train you on how to get your body to relax by using relaxation procedures. The purpose of this training will be so you can clearly imagine the scenes that we will describe to you in the three imagery response laboratory sessions and can get yourself to become completely relaxed after imagining the scenes. In this session, we will once again describe the laboratory procedures to you and show you around the testing room. We will insert an intravenous (IV) catheter at this time so you can be familiar with having an IV in your arm. No blood samples will be drawn at this time. In addition, we will provide you with clear instructions on how to fill out questionnaires on your feelings and craving. After this session, you will be able to leave the Yale Stress Center. The relaxation and imagery training session will last for one hour, while the 3 full laboratory sessions will last for three hours scheduled from 2:00 PM to 5:00 PM for each of three afternoons.

Laboratory Sessions:

After the training session you will take part in the first of three laboratory sessions (also on DAY 1). The second and third lab session will be conducted on separate and days as close together as possible (identified as DAY 2 and DAY 3). The laboratory sessions will begin at 2:00 PM at the Yale Stress Center. When you come into the testing room with the research assistant we will first set you up to draw blood samples. An IV will be put into the vein in one of your arms so that we can draw blood at regular intervals. About four ounces of blood will be taken during each session, an amount less than a blood donation, which your body can tolerate. Over the three lab days, this will amount to 12 ounces of blood or the amount of a 12 ounce can of soda and somewhat less than then amount of blood drawn during a blood donation. While your body can tolerate this level of blood draw, you should not donate blood for a period of 8 weeks after you finish the study. You also will not be admitted to the study if you have donated blood within a period of 5 weeks prior to admission to the research program.

The blood samples will be analyzed for naturally occurring chemicals that your body produces regularly. At various times during the session we will place a small cotton ball in your mouth for you to hold on the side against your cheek for 2-3 minutes. This cotton ball will soak up saliva. We will collect the cotton ball in 3 minutes and place another one in your mouth every 10-15 minutes. Your saliva will then be analyzed for naturally occurring chemicals that your body produces regularly.

Next, we will attach a sensor (like a clothespin) to your finger to check your heart rate, and place a blood pressure cuff on your arm to measure blood pressure. These are painless procedures. You will remain seated and relax for an additional 45 minutes. After this, we will place headphones and prepare you for the imagery session. After a brief relaxation period, you will be given instructions on the imagery task and you will then hear a story over the

headphones. Your task will be to imagine yourself in the situation being described and relive it 'as if' it were happening to you at that moment.

The story you will hear will be a description of one of your personal situations that you described to us during the intake or a description of the neutral situation that you selected. The order of stories in the three sessions will be selected randomly; you will not be told of the order of the stories presentation. After the imagery period, you will remain seated. From time to time, the nurse will enter to draw some blood and you will also be asked to make some ratings of your feelings and alcohol craving. You will also be asked to complete some brief mental tests. Following the imagery period, we will ask you to remain in the testing room for an additional hour. during which time we will be collecting blood samples and asking you to rate your feelings and craving.

During the course of the imagery session you may have some alcohol craving and changes in feelings due to your recall of personal events that were stressful or alcohol-related. Each laboratory imagery session will last for about three hours. You will be given brief rest periods if you so desire. Should you feel anxious or unduly uncomfortable at any time during the session, you may ask that the session be stopped. At the end of the laboratory session, the IV and the sensors will be removed and we will give you relaxation instructions to help you reduce your craving and bring yourself into a relaxed mood. Once you are returned to your original mood state, the session will be over. You will be given a snack and will be able to leave the Yale Stress Center. The same procedures will be done each day for the three laboratory imagery sessions.

At the end of all three laboratory sessions, a member of the research team will meet with you to discuss the harmful effects of alcohol on the body and the option to transition into a treatment phase of the study.

Treatment and Recovery Assistance:

Upon completion of the laboratory sessions, you will continue to take the same dose of pregnenolone or placebo for another 6 weeks, for a total of 8 weeks. We will prompt you on your smartphone daily to remind you to take your study medication, and make ratings on your mood, craving, and tell us about your alcohol use using the smartphone platform as described above.

To check that you are taking your study medication, we will be collecting urines, and doing a blood draw at week 2,5, and 7. The study medication will have riboflavin added as a marker. Riboflavin produces a bright yellow discoloration of the urine when the medication is taken 2 to 8 hours prior, so study staff will be able to visually inspect whether you have taken the medication.

You will be seen at the at the Yale Stress Center (YSC), on 2 Church Street South (YSC) twice a week with 1x per week individual alcohol counseling with a YSC staff psychologist or qualified counselor. The purpose of this is to assist you in reducing your alcohol use and support your recovery from alcohol use. Throughout the study, we will ask you about your alcohol and drug use and other psychological and physical problems that you may have now or in the past. Study staff will provide you with weekly medication packs. We will also ask you to complete several paper and pencil tests about your alcohol use and problems you have. You will also take some mental tests. We will draw 15mL of blood once during the treatment phase to measure levels of naturally occurring hormones in your body.

Blood Sampling for Genetic Studies:

During the screening portion of the study, the YSC study nurse will take a sample of your blood for purposes of understanding genetic factors that may influence the way you behave / feel in response to stress. An additional

blood sample will also be drawn after five days of treatment with either the study medication or placebo to find out if new genes have turned on (activated) during that time.

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.

You will be told of any significant new findings that are developed during the course of your participation in this study that may affect your willingness to continue to participate.

Optional Specimens for Future Storage/Genetic Testing

You are invited to allow some of your samples (called specimens) and related information to be stored (banked) for future research for purposes of understanding genetic factors that may influence the way you behave / feel in response to stress. This may help researchers in the future learn more about how to prevent, find and treat addiction and stress related health outcomes.

Your specimens will be stored for an unlimited time, and may be used to make a cell line that will live indefinitely. Future research may look at your genes, which are the units of inheritance that are passed down from generation to generation. Genes are responsible for many things about you such as eye color, hair color, blood type and hundreds of other traits. Future genetic analysis may possibly include finding out the details of how your DNA is put together, such as whole exome or genome sequencing, or genome wide association studies (that is, looking at genes other than those associated with a specific disease).

When your specimens and information are stored, we are careful to try to protect your identity from discovery by others. Your samples and information will receive a unique code. Other researchers will only receive coded samples and information, and will not be able to link the code to you. Strict security safeguards are in place to reduce the chance of misuse or unplanned release of information.

Using your specimens for research will probably not help you. We do hope the research results will help people in the future.

There is a risk that your information could be misused, for example by associating your personal information with genetic testing results. The chance of this happening is very small. We have protections in place to lower this risk, such as assigning a unique code to you, and keeping your personal information separate from this code in locked cabinets and also protecting all electronic data with a password. There can also be a risk in uncovering genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a research study. Very rarely, health or genetic information could be misused by employers, health insurance companies, and others. There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans, and most employers (except those with fewer than 15 employees) to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Your specimens and information will only be used for research and will not be sold. There is a possibility that this research may lead to development of products that will be commercialized. If this happens, there is no plan to share any financial gain with you.

Research results will not be returned to you or your doctor. If research results are published, your name and other personal information will not be given.

The choice to take part is up to you. You may choose not to let us store and use your samples, and your care will not be affected by this decision. If you decide that your samples can be kept, you may change your mind at any time. Contact the study staff by phone or mail at (203) 737-3398, 2 Church Street South, New Haven CT 06519 to let them know you do not want your samples used any longer. Your samples will be made anonymous by destroying the code that's linking them to you).

I agree to allow my samples and information to be stored and used for future research as described above: (initial your choice)

_____YES _____No

Risks and Inconveniences

The main risks that might occur if you decide to participate in this study have to do with taking pregnenolone, the laboratory procedures, and the collection of genetic information. These are explained below:

i. Pregnenolone: Pregnenolone is a naturally occurring hormone and is well tolerated. It is sold over the counter as a dietary supplement. While controlled studies report minimal to no side effects, rare possible side effects of mild restlessness, acne, hair loss, hair growth on the face (in women), aggressiveness, irritability, and increased levels of estrogen have been reported anecdotally, but clinical research studies have used pregnenolone in psychiatric patients and healthy individuals without any side effects.

ii. Intravenous (IV): When an intravenous catheter is started, there is some risk that you may develop a bruise or bleeding where the IV enters the vein. Usually these go away in several days without any treatment. On rare occasions, dizziness, fainting, blood clot or infection may occur.

iii. Drawing of Blood:
A total amount of 432 mL of whole blood will be drawn throughout the entire study (4 ounces at each laboratory session plus blood for genetic studies and the initial physical exam, and single 5 ml tubes at weeks 2, 5 and 7 during the study period). This is less than a regular blood donation. People who are in good health are not usually affected by this kind of blood loss. However, to be safe, you should not donate blood for at least 8 weeks after the three laboratory sessions.

iv. The imagery procedures: The imagery task involves reliving a personal stressful event, a neutral event and a personal event associated with alcohol use. These can be anxiety provoking at the time of the task and may also lead to alcohol craving. Our previous experience has shown that once the task is over, there is very little anxiety that carries over, and the craving also decreases, so there is only minimal risk. During these imagery periods you may experience strong feelings and we will provide you with relaxation instructions to help you return to a relaxed state.

v. Placement of a sterilized cotton ball in your mouth may be an inconvenience. Our previous experience with this method is that once you become familiar with the cotton ball in your mouth you will become accustomed to it and will feel minimal discomfort.

vi. Genetic Information: Under some circumstances, it can be a risk for genetic information about you to be known. Variation in some genes is known to be directly related to risk for certain illnesses. Other genes we will be studying in your DNA may be shown at some point in the future to be related to illness. Since the results of

these genetic tests may be construed as prediction of risk of illness in some cases, we will keep the results confidential. We will not make any of our laboratory results available to you, nor will we add them to your medical record. Importantly, none of the information that might identify you as a participant in this study will be disclosed. (If you want to know your risk for genetic diseases, we will refer you to a genetic counselor.) We hope that this will prevent any information that could cause you trouble in the future (for example, by making it difficult for you to obtain health or life insurance, or employment or educational opportunities) from becoming known to anyone other than the scientists working on this study. We believe that the chance of this information becoming known to others in such a way that it would be harmful to you is very, very low. As identified above, there is a federal law called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans, and most employers, except those with fewer than 15 employees, to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Even if the genetic information we collected about you did become known to a third party such as an insurer, it is unlikely that, in most cases, this particular information could be used to harm you economically.

Benefits

There are no known benefits to you at this time. There are benefits to society, which would result from increased knowledge about new treatments for alcohol addiction.

Economic Considerations

We will pay you $20 for a remote intake interview session or $25 for an in-person intake interview session, $25 for the imagery and relaxation training session, and $100 for each of the 3 laboratory sessions. You will also be paid a $50 bonus for completing the laboratory sessions. Therefore, for completion of the laboratory phase, you will receive up to a total of $400.

To assist you in recovery, you will earn chances to win a prize ranging from 0 to $100 for each scheduled appointment that you keep. You will earn a chance to draw a prize, regardless of whether the urine sample you provide is clean or not. For every twice-weekly appointment you attend, the chance to draw a prize from a fish bowl increases by one. The fish bowl prizes are valued at 0, $1, $5, $20, or $100. Failure to keep your scheduled appointment, or failure to take your study medication will reset the number of draws to one. A flat $20 payment per week of treatment for completion of weekly appointments may also be used instead of the fish bowl.

In addition, for your participation in smartphone reminders you will be reimbursed at $2 a day, with a $6 bonus for completing all 7 days for smartphone survey completion, hence a possible total of $20 a week, or $160 for all 8 weeks of the study. You will also receive $25 per week for using the eMocha smartphone App for taking study medication. In addition, you will receive $25 for week 3, $25 for week 5, $25 for week 6, and a $25 bonus for completing the entire 8 weeks of study. Therefore, the total that you may be reimbursed if you complete all aspects of the study and the smartphone monitoring will be $860 plus the various amounts won for keeping appointments throughout the study.

If you decide to not continue with the treatment phase, twice-weekly follow-up appointments for one week will be scheduled after the laboratory sessions are complete. You will receive $25 for each visit. Therefore, if you only complete the laboratory phase ($400) with the follow up visits ($50) and smartphone monitoring ($40), the maximum total payment will be $490.

We will use a Bank of America pre-paid debit card to provide the payment for taking part in the study. We will have to share your name, address, and telephone number with Bank of America for ePayments. You will receive a card in the mail with the first payment. You will need to activate the card over the phone. Each additional payment will be automatically added to your card.

According to the requirements of the Internal Revenue Service (IRS), payments that are made to you as a result of your participation in this study may be considered taxable income. We will need your social security number for reporting of the study payments made to you. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

Treatment Alternatives/Alternatives

You should be aware that participating in this research study will delay your obtaining other medication or behavioral counseling treatment for your alcohol use disorder. If this is unacceptable to you, you should not participate in this study. You also do not need to participate in this study in order to receive treatment for alcohol dependence such as counseling, group therapy, and psychotherapy.

Confidentiality and Privacy

Any identifiable information that is obtained in connection with this study will remain confidential. We will make every effort to ensure your confidentiality. In all records of the study you will be identified only by a number. All research materials with personal information will be stored in locked cabinets. All data that is stored on a computer will be password protected. 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 at information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name, birthdate, and address. This information 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 and will not be disclosed or added to your medical record. All research materials with personal information will be stored in locked cabinets. All data that is stored on a computer will be password protected. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept until the study is closed, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form.

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

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- Records about phone calls made as part of this research
- Records about your study visits
- Medical information obtained during this research regarding sexually transmitted and other reportable infectious diseases, physical exam results, laboratory, and other test results
- Questionnaires, the use of illegal drugs and 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:

- National Institute of Health (NIH)
- 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.
- The Principal Investigator, Rajita Sinha, PhD
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Health care providers who provide services to you in connection with this study.
- Study Coordinator and Members of the Research Team
- Data Safety Monitor
- Food and Drug Administration (FDA)

To further protect your privacy, we have obtained a Certificate of Confidentiality (CoC) from the National Institute of Health (NIH). With this Certificate, the study investigators and anyone else involved in the project cannot be forced to disclose any information about you, such as your name, information regarding your participation in this research, urinalysis results, or other information that you provide to us as part of this research, to anyone, including the courts.

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. We may release identifying information in some circumstances, however. 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. We may also disclose medical information in cases of medical necessity, or take steps (including notifying authorities) to protect you from serious harm, including child abuse. 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.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). Also, because this research may be sponsored by NIH, staff from that and other Department of Health and Human Services agencies may review records that identify you for audit or program evaluation. They, too, will protect your privacy.

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, Yale-New Haven Hospital and the Connecticut Mental Health Center 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.

In Case of Injury

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

The Yale School of Medicine does not provide funds for the treatment of research-related injury. 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. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

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. 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. The researchers may withdraw you from participating in the research if necessary, for example you develop serious side effects or for non-compliance. 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 the Yale Stress 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 Dr. Rajita Sinha, 2 Church Street South, Suite 209 at the Yale Stress Center, 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 insure the integrity of the study and/or study oversight.

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 make a decision.

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 after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203/432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Rajita Sinha at (203) 737-5805. 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.