Subject Name: _____Last 4 SSN:_____ Date: _____

Title of Study: Electrophysiological Predictors and Indicators of Contingency Management Treatment Response

Principal Investigator: Sarah Forster, PhD VAMC: Pittsburgh (646)

LAY TITLE: Neurocognitive Factors in Substance Use Treatment Response: The Ways of Rewarding Abstinence Project (WRAP)

KEY ELEMENTS: This is a research study to find out if different approaches to rewarding abstinence are more effective in people with specific traits. Your participation in this study is voluntary.

If you choose to participate, you will be assigned to 1 of 2 possible treatment groups. All participants will be assigned to receive a treatment for stimulant use disorders called Contingency Management (CM). This treatment provides opportunities to win prizes for cocaine-negative ("clean") urine specimens over a 12-week period. Half of participants assigned to this treatment will receive Canteen Vouchers as prizes and the other half will receive specific prize items they have selected in advance. Before you know what group you have been assigned to, you will also be asked to complete a series of assessments – including an electroencephalography (EEG) procedure – to measure aspects of your personality and brain function that might impact your response to treatment. Many of these assessments will also be repeated after you have completed the 12-week treatment interval.

There are risks associated with study participation that are described in this document. Some risks include: mild skin irritation during or following the EEG and discomfort or distress during interview or self-report assessments. You may also directly benefit from participation in the study if you are assigned to receive Contingency Management and may have access to a version of the Contingency Management through this study that is not typically offered at VA Pittsburgh Healthcare System (VAPHS). You will also receive the indirect benefit of contributing to medical science and helping to advance future understanding of Contingency Management and recovery from substance use disorders.

If you do not participate in this study you may still be able to receive Contingency Management (with Canteen Voucher prizes) through the Center for Treatment of Addictive Disorders at VAPHS.
If you are interested in learning more about this study, please continue reading below.

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STUDY CONTACT INFORMATION:
If you have a general question about this research study, or if you have any concerns or complaints related to this research study, you may call Dr. Sarah Forster at 412-360-2365 or any of the investigators listed below.

If you experience any illness, injury or other medical problem that you feel may be related to this study, please call Dr. Steven Forman, Medical Director of Center for Treatment of Addictive Disorders at (412) 360-2295. In the case of a medical emergency contact your local emergency medical service or go to your local emergency room.

Sarah Forster, PhD
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STUDY SPONSOR: VA Clinical Science Research & Development

Additional information regarding the study sponsor can be provided upon request.

PURPOSE OF THE RESEARCH STUDY: The purpose of this research study is to investigate individual differences that may affect how Veterans respond to Prize-Based Contingency Management (CM), an intervention for stimulant use disorders offered through the VAPHS Center for the Treatment of

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Addictive Disorders. By understanding individual differences that affect treatment response, we can better personalize care to improve outcomes for Veterans in the future.

You are being asked to participate in this research study because you are a Veteran who may benefit from CM, are between the ages of 18 and 75, and have normal or corrected-to-normal vision and hearing. In order to participate in the study, you must also have no history of severe traumatic brain injury or neurological disease, no major cognitive impairment, and no severe or unstable medical or psychiatric condition. We are also excluding Veterans who are currently involved in a residential treatment program; however, these individuals might become eligible after they complete residential treatment. Female Veterans who are currently pregnant or breastfeeding will also be excluded from the current study.

Our goal is that approximately 180 Veterans will enroll in this study.

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 Website will include a summary of the results. You can search this Web site at any time.

DESCRIPTION OF THE RESEARCH STUDY:

In this study, you will be asked to (1) participate in a series of assessments prior to starting a 12 week treatment interval, (2) complete several brief check-in visits during treatment, (3) repeat several assessments from pre-treatment at the end of treatment, and (4) complete several additional monthly check-ins for 6 months after treatment. It is important for you to know that you will be randomly assigned to receive either one of two different types of CM treatment. Random assignment means that your treatment condition will be determined at random (like the flip of a coin). You will have a 100% chance of being assigned to Contingency Management treatment.

1. **Study Procedures**: Experimental procedures to be followed are outlined below. All study activities will occur at the Research Office Building (Building 30) or Consolidation Building (Building 29) at the University Drive Division of the VA Pittsburgh Healthcare System. Some research activities may also be conducted remotely (e.g., by telephone or video call).

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a. Screening Visit: The Screening Visit will take 2½ -3 hours to complete and will include the following components:
    1. Informed Consent: While we believe you meet our general eligibility requirements based on information collected during your initial contact with the study, we need a little further information from you to see if you meet criteria to participate in the full study protocol. Before we can proceed with any additional procedures, including determining eligibility, we must tell you more about the study and you will be given the opportunity to voluntarily consent to participate by signing this consent form. Even after signing the consent form, you are free to stop participating in the research at any time. Please note that, if you completed your Screening Visit by phone or video call, you will be asked to sign this form at the time of your Baseline assessment.
    2. Cognitive Screening and Interviews: If you consent to participating, we will subsequently ask you to complete a brief cognitive screening test and several interviews. Specifically, we plan to complete two interviews with you during the Screening Visit to assess your substance use patterns and history, as well as your history of mental health symptoms: the Addiction Severity Index-Lite and MINI; we may also ask you additional questions about substance use patterns using a technique called the Timeline Follow-Back Procedure. These interviews will take 60-120 minutes to complete. These procedures are necessary to determine eligibility and collect additional relevant information about you. We may also ask you to tell us about positive and neutral events you expect to come up in your life during the next year or so. Upcoming positive and neutral event information will also be used to create a personalized decision-making task that you will be asked to complete at the Baseline Assessment. This information may also be collected or updated at the Baseline visit.
    3. Questionnaires: We will ask you to fill out a demographic information form and may also ask you to begin several questionnaires with questions about your personality, preferences, and experiences. You will have the opportunity to

complete these questionnaires at home, if preferred, and may bring them in at the time of your Baseline Assessment. These questionnaires will take 20-50 minutes to complete.

b. Baseline Assessment: The Baseline Assessment will be conducted after the Screening Visit and will take 3-4 hours to complete. The Baseline Assessment includes the following components:

1. Breathalyzer, Urine and/or Oral Saliva Drug Screens: You will be given a breath (or saliva-based) alcohol test to make sure that you have not had any alcoholic beverages prior to testing. You will also be asked to provide urine and/or oral saliva specimens for drug screening. Urine and/or saliva screens will test for evidence of illicit substances such as THC (the active drug in marijuana and hashish), cocaine, methamphetamine, amphetamine, opiates, benzodiazepines (mild tranquilizers, such as Xanax and Valium), barbiturates, Phencyclidine (PCP), and MDMA (Ecstasy/Molly). If you test positive for any drug except THC, we will reschedule your test session to take place anywhere from 1 to 7 days later. You may also decline to undergo breathalyzer, urine and/or oral saliva drug testing but then you will not be able to participate any further in this project.
2. Cognitive-Behavioral Tasks: You will also be asked to perform tasks involving memory and decision-making. Tasks may be administered by a computer or directly by the experimenter and you will be asked to make verbal or button press responses. One of these tasks will be a personalized decision-making task, which will incorporate information you provided about upcoming events in your life.
3. EEG Procedure: During the visit, you will also be asked to perform computerized tests while undergoing an EEG to record your brain waves. Sensors will be placed next to and below your eyes, as well as on your head and forehead. The majority of sensors will be embedded in a fabric cap that will be

placed on your head. In order to pick up electrical signals from the surface of your skin, either tiny sponges (soaked in an electrolyte solution) or a conductive gel will be used to bridge the gap between sensors and the surface of your skin. Caps and sensors are thoroughly cleaned and disinfected after each use and new sponges are used for each recording session (if applicable). During the EEG procedure, the cap will be placed on your head and additional sensors will be positioned on your face and head. A pipette will then be used to administer a small amount of conductive gel or electrolyte solution at each site. After checking the quality of signal picked up by each sensor, we will ask you to perform two computer tasks involving button responses to stimuli on a computer screen while brain waves are recorded from the sensors.

c. Randomization and Treatment: After the Baseline Assessment, you will be randomly assigned to one of two different treatment conditions: (1) Voucher Prize-Based Contingency Management + Treatment-As-Usual or (2) Tangible Prize-Based Contingency Management + Treatment-As-Usual All participants will be assigned to one of the two Contingency Management (CM) conditions.

• *What do the two CM treatment conditions look like?* In both CM conditions, participants will be asked to attend brief (~10-15 minute) sessions with one of the researchers, twice weekly for 12 weeks. Before each session, we will ask you to provide a urine specimen. During each session, we will test your urine specimen with a point-of-care diptest and, if your urine is negative for cocaine, you will be eligible for prize draws from a fishbowl. The number of prize draws you get will increase with longer periods of abstinence (e.g., 2 draws for 2 consecutive negative results, 4 draws for 4 consecutive negative results, etc.) until you reach the maximum number of draws. Each draw from the fishbowl will return either a "word of encouragement" (e.g., letting you know you are doing "*Great Work!*") or a prize valued at approximately $1, $20, or $100. Specific prize probabilities and details will be discussed during your first CM session. However, you should know that average winnings amount to approximately $200 over the 12-week

period for both Voucher Prize-Based CM and Tangible Prize-Based CM. That is the say, the likelihood of winning prizes and prize amounts/values are the same in the two versions of CM under study. The only difference between the two CM conditions under study is the way in which prizes will be paid out. If you are assigned to **Voucher Prize-Based CM**, your prize winnings will be paid out in the form of Patriot Bucks (vouchers redeemable through VA Canteen Services including the Patriot Store, Patriot Café (cafeteria) and Patriot Brew (coffee shop)) at the end of each session. If you are assigned to the **Tangible Prize-Based CM**, you will have the option to either choose a prize from a prize cabinet or save toward a more expensive prize. In order to ensure that prizes are to your liking we will work with you to identify specific items you might want to purchase and will acquire these items for our prize cabinet.

- *What is Treatment-As-Usual?* Contingency Management is a treatment that works best when added on to a standard outpatient treatment plan. Such a plan might involve a combination of medications, group therapy, and individual counseling. We ask that all participants continue with their "Treatment-As-Usual" plan, as recommended by VAPHS providers. If you have not yet worked with a VAPHS provider to develop an individualized substance use treatment plan, we can place a consult for an Initial Evaluation or treatment planning session through the Center for Treatment of Addictive Disorders for you. **At a minimum we ask that all Veterans in the current study plan to participate in substance use treatment on at least two days per week**. For example, this could mean attending two groups per week, a group and a medication management visit, a group and an individual therapy visit, or any other combination.

d. Weekly Check-ins (During Treatment): You will be asked to participate in weekly Check-ins during the 12 week treatment interval (~12 weeks). Each check-in will generally take less than 5 minutes and will involve recording any substance use that has occurred. You may also be asked to complete a brief survey regarding recent use of CM vouchers, if applicable. If you are assigned to one of the two CM conditions, check-ins will generally occur during your CM visits and are not expected to significantly change the typical

appointment duration (~10-15 minutes). If you are not regularly attending CM visits (e.g., you were assigned to Treatment-As-Usual or you decided to stop attending CM) we can arrange to conduct check-in appointments by phone or in person, depending on your preference. If you are not regularly providing urine specimens during the 12 week treatment interval, we may also ask to do a urine drug screen and/or breath alcohol test with you as part of your check-in if the appointment takes place in person. However, results of any drug/alcohol screening conducted will be for research purposes only and will not be entered in your medical record. If a urine specimen is collected during a check-in, it will be immediately tested and disposed of and will not be retained for future use. You will also have the option to decline such testing at any time. We will ask you to participate in check-ins even if you choose not to complete the CM program. If you miss one or more check-ins, we will ask to conduct missed check-in assessments retroactively at the next study contact.

e. Follow-Up Visit: At the conclusion of the 12-week treatment interval (~12 weeks after Baseline Assessment), you will be asked to complete regular check-in activities and may also be invited to repeat some procedures from the Baseline Assessment. For example, you may be asked to have another EEG and repeat some of the cognitive testing, questionnaires, and interviews completed at the beginning of the study. We will notify you in advance if we wish to complete procedures from the Baseline Assessment with you and will schedule an office visit. This visit will take between 1-3 hours. Alternatively, a standard check-in appointment may be conducted if you are unable, ineligible, or unwilling to complete additional study activities at that time.

f. Monthly Check-in (After Treatment): You may also be asked to participate in monthly check-ins for approximately 6 months after you have completed the 12-week treatment interval (and, if applicable, your Follow-Up Visit). Monthly check-ins will generally be conducted by phone and will take 10-20 minutes to complete. During monthly check-in appointments, we will ask about any substance use that might have occurred during the past month and will record these data for research purposes. You will also have the option

to participate in monthly check-ins in person, if you prefer. If you attend monthly check-ins in person we may also ask to do a urine drug screen and/or alcohol breath test for research purposes. However, you will always have the option to decline such testing. If you miss one or more check-ins, we will ask to conduct missed check-in assessments retroactively at the next study contact.

2. **Study Duration**: The total duration of participation is estimated to be between 15 and 17 hours for most participants; however, this time commitment will generally occur over a period of nine months. The Screening Visit is expected to take 2.5-3 hours, the Baseline Assessment is expected to take 3-4 hours, treatment visits and check-ins will generally involve a commitment of 2 hours per month for 3 months, the Follow-Up Visit is expected to take 1-3 hours, and monthly check-ins will involve a time commitment of 1-2 hours over a six-month period. If you receive Contingency Management treatment outside the context of this study (e.g., through a standard clinical program), we may also utilize data from your electronic health record regarding your course of treatment, if available.

3. **Unexpected Findings**: During the EEG procedure we may see something that should be checked by your primary care doctor. If that happens, we will call you within a week of the test to let you know. We will then send the test results to your primary care doctor. If you do not have a primary care doctor, we will refer you to one within the VA system. Please note that we are not specifically looking for any medical problems so it is very unlikely that we will find any underlying issues. This test is not the same as regular medical care and the study personnel are not clinically trained to read EEG data. It is also possible that we might identify new information about your mental health that should be shared with your mental health treatment coordinator. For example, this might be the case if we find that you meet criteria for PTSD or depression and this has not previously been noted in your medical record. If there is information we believe should be shared with your mental health treatment coordinator, we will inform you of this prior to contacting your provider. Finally, if you have driven to a study appointment and your alcohol test result places you above the legal limit to operate a motor vehicle (BAC $\geq$ 0.08) we will repeat your test to confirm

the result. If the second test result confirms that you are above the legal limit, we will be obligated to contact VA police with your name and location. The VA police will then respond according to their procedure for handling intoxicated patients who are at risk of driving.

4. **Additional Follow-Up**: After you have completed this study, there is no further follow-up.

RISKS AND BENEFITS:

Potential risks and benefits of participation in the current research study are outlined below. You may also experience some side effects related to the procedures/medications/treatments you receive that are not part of the research, but are considered standard of care for your condition. A description of these side effects should have been provided to you by your physician.
Because there may be other risks associated with participating in multiple research studies, you must tell the research staff about any other studies you are currently participating in, both within and outside of the VA.

Contingency Management Treatment. If you are assigned to one of the two Contingency Management treatment conditions, you will receive Contingency Management as an adjunct to usual care. Importantly, both versions of Contingency Management studied herein (Voucher Prize-Based CM and Tangible Prize-Based CM) have been extensively studied and both are also regularly used within the VA, outside of the context of research. Importantly, for patients with problematic cocaine use, CM is considered the "standard of care," there are no specific risks associated with CM treatment, and there are no additional risks associated with CM as it will be delivered in this research study.

Electroencephalography (EEG) Procedure. The risks involved in the EEG portion of this study are similar to the risks present during routine clinical EEG assessments. It has been determined that the risks associated with an EEG are no greater than the risks associated with a routine physical examination. There are no established or consistently reported risks associated with the EEG procedure. However, the following side effects have been reported to occur in rare cases:

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1. On rare occasions, participants experience slight itchiness around electrode sites due to salt in electrolyte solutions and conductive gels used to improve EEG signal quality. This reaction occurs in approximately 1% of people. Please let study personnel know if you experience discomfort during the EEG procedure. You may choose to stop the EEG procedure at any time.
2. On rare occasions (~5% of the time), temporary redness of skin is noted following an EEG in locations where sensors were placed. Redness of skin will generally resolve within a few minutes without discomfort.
3. On rare occasions (~5% of the time), the placement of the sensors on the skin will cause a very small portion of the skin, less than 1 centimeter, to swell slightly; this might appear like a very small welt. This is caused by the retention of moisture under sensors and goes away soon after the sensors are removed.

Psychological Discomfort: There is a possibility that some of the questions you will be asked to answer during the screening, interview, or questionnaires may make you feel uncomfortable. You do not have to answer a question if you do not want to.

Unknown risks: In this research study (as with any human endeavor) there may be risks that we currently do not anticipate. As a research participant you must understand and agree to assume this unknown risk.

Benefits: You will not directly benefit from participating in this study. However, it is noted that participants assigned to the Tangible Prize-Based CM condition will have access to a version of CM that (while already used within the VA) is not currently offered at VA Pittsburgh and may have unique benefits. It is also possible that you will learn new information about yourself through participation in study interviews, self-report questionnaires, or other procedures. For example, you may encounter questions during interviews and/or questionnaires that you have not previously considered. You may also receive an indirect benefit in that you are contributing to medical science and helping to advance future understanding of treatment options for addiction. Specifically, your participation may help us understand individual differences that affect how people respond to CM. It is possible that findings from the current study will lead to improvements in the way CM is used to treat substance use disorders. This research may help us identify Veterans who are most likely to benefit from CM.

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ALTERNATIVES TO PARTICIPATION: You have the alternative not to participate in this research study. There may be other studies that you qualify for. Talk to your provider about such options.

NEW FINDINGS: You will be informed of any significant new findings during the course of the study, which may affect your willingness to continue to participate.

INVESTIGATOR INITIATED WITHDRAWAL: The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related injury. You will also be withdrawn if you are incarcerated due to legal proceedings during the study. This is necessary to protect your right to freely choose whether you wish to continue participating in research. However, you would have the option to re-consent to the study and resume participation upon release from incarceration. In such circumstances, you would be asked to review and sign a new copy of this informed consent document prior to resuming participation.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW: Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

Your doctor may also be involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. You are under no obligation to participate in this or any other research study offered by your doctor. Before you agree to participate in this research study, or at any time during your participation in this study, you may discuss your care with another doctor who is not associated with this research study.

MEDICAL TREATMENT: In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA. Except in limited circumstances, the necessary medical care must be provided in VA medical facilities. However, if such injury or illness occurred as a result of your failure to follow the

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instructions for this study, you may not be eligible for free care unless you have independent eligibility for such care under Federal Law.

FINANCIAL COMPENSATION: If you sustain an injury or illness as a result of participating in this research study, you may be eligible to receive monetary compensation for your damages pursuant to applicable federal law. If you believe that you are injured as a result of participation in this study, please contact the Principal Investigator. If compensation is available the Principal Investigator will provide you with an explanation as to what that compensation consists of, or where you can obtain further information regarding it.

COST AND PAYMENTS: You or your insurance will not be charged for any costs related to the research. However if you are receiving medical care and services from the VA that are not part of this study, and you are a veteran described in federal regulations as a "category 7" veteran, you may be required to make co-payments for the care and services that are not required as part of this research study.

The payment schedule is outline for each of the three study conditions in a table below (as a reminder, you will not know what condition you have been assigned to until after the Baseline Assessment:

Study Visit	Voucher Prize-Based CM	Tangible Prize-Based CM
Screening	$20	$20
Baseline Assessment*	**$35**	**$35**
Weekly Check-ins	12 x $5 = $60	12 x $5 = $60
Follow-Up Assessment*	$35	$35
Monthly Check-ins	6 x $10 = $60	6 x $10 = $60
Completion Bonus	$10	$10
TOTAL	**$220**	**$220**
***A performance-based bonus of $15-25 will be added at Baseline AND Follow-Up Assessment Visits**		
Total Compensation + Performance-based Bonuses: $220 + $30-$50 = $250-$270		

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For participating in the study explanation/consent review and pre-baseline screening and assessment procedures (Screening Visit), you will be authorized for $20 to compensate you for your time. We will additionally compensate you $35 for completion of the Baseline Assessment. For each weekly check-in during the 12-week treatment interval you will be authorized for $5; taken together, check-in payments will therefore amount to an additional $60 over that 12-week period. It is noted that these payments will be authorized at the time of check-in completion and will be issued even if the check-in is completed retroactively (e.g., you missed your check-in during Week 5 so we assessed Week 5 and Week 6 during your next check-in). If you complete the post-treatment Follow-Up, you will also receive $35 for time spent in these assessment procedures. For participants assigned to one of the two CM conditions, we will also ask to check-in with you on a monthly basis for 6 months after treatment has ended and you will be paid $10 for each of these assessments, amounting to an additional $60 over 6 months. As before, you will receive payments for monthly check-ins, even if they are conducted retroactively. Finally, after you have completed your last study visit and/or check-in assessment, you will be compensated an additional $10 for completing the study

In addition, to regular study payments, you will also receive a performance-based bonus from tasks you will be asked to complete at Baseline and Follow-Up assessments. The amount (and possibly, the timing) of this bonus payment will be determined by task performance. The average performance-based bonus payment will be $20. Taken together, full participation in the study will result in an average total payment of $260 over ~9 months for participants assigned to CM.

Except in limited circumstances, payments issued through VA are generated by Electronic Funds Transfer (EFT). Therefore, in order to receive payment associated with your participation in this study, you must be willing to receive EFT and to provide banking information to VA, if that information has not already been provided. In addition, due to limitations in the Financial Management System, payments made to you will generate Internal Revenue Service (IRS) Form 1099 regardless of amount. Payments will be reported to the IRS as income and your social security number will be used for this purpose. If you are a

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Veteran eligible for Beneficiary Travel, please speak with the research team to understand how research visits may impact your ability to receive Beneficiary Travel.

In addition to compensation described above, you may be provided with a same-day meal voucher for VA Canteen Services, to be used in the context of study visits exceeding a certain duration. It is additionally noted that, under specific, limited circumstances, a single use bus ticket may be made available to you if emergent transportation issues would otherwise preclude participation in specific study activities.

RECORD RETENTION: Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule, or longer, if required by other Federal regulations.

CONFIDENTIALITY AND USE AND DISCLOSURE OF DATA: There are rules to protect your private health information. Federal and State laws and the Federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization', for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including:

- Information from your Health Records such as diagnoses, progress notes, medications, lab or radiology findings (this may include progress notes from previous courses of Contingency Management, if applicable)
- Specific information concerning: Alcohol Abuse, Drug Abuse, HIV
- Demographic Information such as name, age, race, date of birth
- Questionnaire, Survey, and/or Subject Diary

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The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the:

Study Sponsor and Authorized Agents/Funding Source (e.g. a VA or non-VA person or entity who takes responsibility for; initiates, or funds this study): VA Clinical Science Research & Development; VA ORD (ORO/OIG)

Compliance and Safety Monitors (e.g. advises the Sponsor or PI regarding the continuing safety of this study): VA Clinical Science Research & Development Central Data Monitoring Committee (DMC)

In addition, Institutional Review Board, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO) may have access to your research records. Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient. Additionally, any medical information may be shared with your healthcare provider(s) with your consent, and possibly without your consent if permissible under Federal laws and regulations.

Finally, you consent to the publication of the study results or release of the data when published, so long as the information about you is anonymous and/or disguised so that your identity will not be disclosed

Confidentiality risks and precautions to decrease risk:
Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. As private information is collected about you as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you.

Any electronic or hard/paper copies of the information collected about you will be stored in a secured location. Only those individuals who are authorized to review your information will have access to it.

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Data sent to or reviewed by outside institutions, such as the study sponsor, central laboratories, or other collaborators will be de-identified and transmitted in aggregate form whenever possible and will be securely transmitted via approved means only. Data will only be transmitted to outside institutions when specifically required.

Future Use: Personal identifiers may be removed from identifiable private information in order to create a "de-identified" dataset for future use. De-identified data that can no longer be traced back to you may be used in future research studies or distributed to another investigator for future research studies without the need for you to provide additional informed consent. While there is currently no plan for future use of your data, it is possible that the de-identified dataset will be made available to the public through an online data archive in the future. However, this would only occur after VA Information Security and Privacy officers have confirmed that any and all information linking data to your identity have been fully removed from the dataset.

Revocation: You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Principal Investigator at the address below. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

Sarah Forster, PhD
Research Office Building (Bldg 30)
VA Pittsburgh Healthcare System
University Drive C, Pittsburgh, PA 15240

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

Subject Name: _____Last 4 SSN:_____ Date: _____

Title of Study: Electrophysiological Predictors and Indicators of Contingency Management Treatment Response

Principal Investigator: Sarah Forster, PhD VAMC: Pittsburgh (646)

RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above and any applicable consent addenda. Dr. Forster or his/her authorized representative has explained the study and any optional study components to you and answered all of your questions. The risks, discomforts, and possible benefits of this research study, as well as alternative treatment choices, have been explained to you.

A description of the study has been provided to you, including an explanation of what this study is about, why it is being done, and the procedures involved. You have the right to ask questions related to this study or your participation in this study at any time. You should be giving your consent only under conditions in which you (or the person representing you) have sufficient opportunity to carefully consider whether or not to participate in this study. Your consent should not be given under conditions that pressure you or try to influence your decision in any way.

Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. You understand that these Research Subjects' Rights also apply to any optional study components to which you have agreed to participate. You will receive a copy of this signed consent form.

If you have any questions about your rights as a participant in this study, or wish to speak more about the study with someone not associated with the research study, you can call the Associate Chief of Staff for Research and Development at (412) 360-2394

As long as the study is renewed as required by the IRB, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

By signing this form, you agree to participate in this research study.

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM PATIENT (Page 19 of 19)

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_____	_____	_____
Subject's Signature	Date	Time
_____	_____	_____
Investigator/Person Obtaining Consent	Researcher (Print)	Date

Version Date ***May 2, 2022 Version P1.8***