WALTER REED NATIONAL MILITARY MEDICAL CENTER
CONSENT TO PARTICIPATE IN RESEARCH

1. PROTOCOL TITLE: "RECONsolidation of Traumatic memories to ResOLve Posttraumatic Stress Disorder (RECONTROL)"

KEY INFORMATION:

You are being asked to consent to participate in a voluntary research study. The purpose of the study is to see if a new approach for posttraumatic stress disorder (PTSD) works better than current treatments. After an initial assessment to make sure you have PTSD, you will take part in 10 intervention sessions about once per week for 10 weeks. This will be followed by assessments after the 10th intervention to see if your symptoms have improved, and again several times over the next 12 months to see if the improvements are lasting. You will also be asked to give a blood sample, and complete some tests of memory and thinking on an I-Pad, before and after the intervention. Foreseeable risks/discomforts include anxiety and other similar emotions during the intervention sessions, and bruising, soreness or infection at the site of the blood draw. Reasonably expected benefits of participation to you or others include improvement in your PTSD symptoms. Alternatives to participation include getting care for your PTSD from a primary care or behavioral health provider.

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your participation in this study. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about, including the risks and possible benefits to you.

Please tell these researchers if you are taking part in another research study.

You do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty.

Your decision will not affect your future care at Walter Reed National Military Medical Center (WRNMMC).

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you have a diagnosis of PTSD or think you may have symptoms of posttraumatic stress. This study is for active or retired service members who have symptoms of posttraumatic stress. The purpose of this study is to compare the response rates and symptoms between those who complete a course of Prolonged Exposure (PE) therapy with those who receive Reconsolidation of Traumatic Memories (RTM) therapy for PTSD. Currently, there is more evidence to support PE than any other PTSD treatment. However, there are some individuals whose symptoms do not get much better or may need a longer course of treatment. A central aspect of PE is to ask you to close your eyes and recall your traumatic experience, and to describe it in as much detail as you can, over and over again, until it no longer bothers you so much. RTM does not ask you to recall your trauma in great detail, but instead asks you to imagine you are in the projection booth of a movie theater, showing a brief (40 seconds or so) black and white movie of your traumatic experience, and to watch yourself seated in the theater watching the movie. RTM is a newer approach that may result in a quicker or better response, but a fair, head to head comparison of these two approaches is needed, in which all who take part receive one or the other approach on a random basis, to see which works best and quickest. RTM has been studied in some veterans before, but it is important to see if it can do better than PE when compared directly and fairly in U.S. military service members, so we know whether it should be recommended to others in the future.

The total time that you may take part in this study up to 15 months. This includes 10 intervention sessions, each lasting approximately 90 minutes, and 5 assessments extending out to 12 months after the intervention sessions are completed, each lasting about 90 minutes as well. If your schedule allows and if you prefer, you may be able to do the 10 sessions in as little as 2 weeks. You also may be able to stop earlier if your symptoms get much better and you and your therapist agree that you have recovered from your PTSD.

There will be 108 people taking part in this study at WRNMMC.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to provide some information and answer some questions so that the Investigator can confirm that you qualify for the study. This is called the “Screening Process”. You will be asked questions about your medical history, PTSD symptoms, and medications to confirm that you are eligible.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You will be asked to:

1. Answer some questions about you and your health history. This will include your age, branch of service, rank, years in service, number of deployments, PTSD symptoms, previous traumatic experiences, history of traumatic brain injury and a list of current medications. This information will be used to describe the overall population of service members who choose to participate in this study.

2. Allow us to contact your health care provider, so we can explain the study to them, and to make recommendations regarding your care, if indicated.
3. Agree to be assigned to one of two groups, on a random basis (like a coin toss). One group will receive the RTM therapy and the other will receive the PE therapy.
4. Discuss previous traumatic experiences with the study therapist repeatedly throughout each session, if in the PE arm.
5. Follow the directions of the therapist in picturing yourself in a movie theater and imagining a movie up on the screen, if in the RTM arm.
6. Come in for up to 10 intervention sessions, each lasting up to 90 minutes, over a period of 10 weeks. If your symptoms go away more quickly, you may be able to stop before 10 sessions.
7. Complete neurocognitive assessments, or tests of your memory and thinking, at your first visit and again after your treatment is done.
8. Complete questionnaires about your symptoms at the beginning, during the course of, and at the end of the treatment period.
9. Complete three follow-up assessments in person at 2, 6 and 12 months after you finish the treatment, so we can tell how long improvements in symptoms last with both PE and RTM.
10. Agree to get your blood drawn, specifically one tube of plasma, one tube of serum, and two pax-gene tubes, no more than 2 tablespoons total, at your first visit and again after your treatment is done. The blood samples will help us to look for changes in your DNA, or genetic code, that can provide evidence of your response to treatment. Your sample will not be labeled with your name or any of your personal identifying information, only with a unique code. (See the end of the form to specifically address this—you can still be in the study without doing the blood draw if you prefer).

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there is a risk of:

- Some people may be uncomfortable answering questions about their traumatic experiences or injuries or feel stressed about doing questionnaires. You do not have to answer any question that makes you uncomfortable.
- Discussing your feelings and reactions to your trauma may make you feel upset. The therapist will help you to work through your feelings and try to ensure that you feel better by the end of each session.
- Suicidal ideation is sometimes comorbid with PTSD, and may be expected to occur in some participants in this study. If you have such thoughts, please let the study staff know so that they can help you to address these thoughts.
- You may have a bruise or be sore at the site where blood is drawn. There is also a slight possibility of infection at the site where the blood is drawn, though we do clean the area well to try to prevent this. You may also experience dizziness due to the blood draw.
- Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you. We do not put your name or other personal identifiable information on your blood samples, only a study code, so that it cannot be traced to you, and we keep the codes as well as the samples in secure locations.

- While every effort will be made to protect the confidentiality of your responses to questionnaires regarding your symptoms, we cannot absolutely guarantee that breaches of the confidentiality of your information will not occur, and release of personal health information could cause stress, anxiety, or embarrassment.

There may also be other risks of taking part in this study that we do not yet know about.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

The possible benefits to you as a research participant in this research study are that your symptoms may improve. However, there is no guarantee that you will benefit from being in this research; it is possible that your symptoms might remain the same or even worsen. The study results may also help us to learn more about the benefits of RTM and how it compares to that of PE that will help us to learn more about how best to help future service members who have PTSD.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

There may be other options for treating your symptoms. Alternative treatments that may be available to you include medications and/or other various types of psychotherapy or "talk" therapy. You should talk with your personal physician (if applicable) about these options. Choosing not to take part in this research study is also an option. There may be other research studies involving experimental treatments that could be helpful to your condition.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

Yes. You will receive $50 for each of 2 blood draws performed as part of this study: at the baseline, and after completing the intervention. In addition, if you are not a federal government employee (e.g. you are a military retiree, a reservist not in active duty status, or a military dependent), you will be compensated $50 for each of 5 assessments, or up to $250 in total for these assessments, and $350 overall when including the compensation for the blood draws. If you are an active-duty service member, a reservist in active duty status, or a civilian federal employee, and are determined to be in a non-duty status at the time that the assessment is conducted, you will be also eligible for this compensation. However, if you are determined to be in a duty status at the time, you will not be eligible for compensation for an assessment, only for a blood draw.
You will receive a debit card for any compensation to which you are entitled, with each $50 increment added to the balance on the card at the time that the corresponding blood draw or assessment is completed.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. WHO IS CONDUCTING THIS RESEARCH?

This research is being conducted by a team of clinical researchers who are based at Walter Reed National Military Medical Center and Uniformed Services University. The study is led by Dr. Michael J. Roy, MD, MPH, whose positions and contact information are provided in section 13 below.

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

This is an investigator-initiated research study and there is no sponsor.

12. SOURCE OF FUNDING:

This study is funded by the Center for Neuroscience and Regenerative Medicine (CNRM),

13. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Michael J. Roy, MD MPH, Fellow of the American College of Physicians
Director, Division of Military Internal Medicine
Professor of Medicine
Principal Investigator, Recruitment Core, Center for Neuroscience and Regenerative Medicine
Uniformed Services University
Staff, Internal Medicine, Walter Reed National Military Medical Center
Bethesda, MD
Phone: (301) 295-9601
e-mail: michael.roy@usuhs.edu

14. LOCATION OF THE RESEARCH:

All study procedures will take place at:
Walter Reed National Military Medical Center
8901 Wisconsin Ave,
Bethesda, MD 20889

Data Analysis will be conducted at:
Department of Medicine
Uniformed Services University
4301 Jones Bridge Rd
Bethesda, MD 20814

15. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are no financial interests or other personal arrangements that WRNMMC, the research team members, or their immediate family members, might have in this study.

16. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at:
https://www.esd.whs.mil/Directives/forms/dd2000_2499/

Procedures to protect the confidentiality of the data in this study include but are not limited to: These records may be looked at by staff from the WRNMMC Institutional Review Board (IRB), the Uniformed Services (USU) IRB, the Center for Neuroscience and Regenerative Medicine (CNRM), and other government agencies as part of their normal duties. These duties include making sure that research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed. Complete confidentiality cannot be promised, particularly for military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities. In addition, the research team may be required to report illegal activities, such as drug use, to your Commanding Officer, which could affect your military career.

Your research records may be disclosed outside of WRNMMC or USU, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to authorized research study personnel.

You will not be personally identified; all information will be presented as coded data. Your name or other ways to identify you personally will not appear in any published paper or presentation related to this study. Your research records may be shared with research collaborators at other sites, but in this case will only be identified by a unique code number, not with any personal identifying information. Information about the code will be kept in a secure location and access limited to authorized research study personnel. This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA).

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command

authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

The designated research team members will have access to your records and agree to safeguard your research related health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

17. LONG TERM USE OF DATA

The investigator has requested to save selected data collected from your participation in this research study for possible use in future research. You have a number of options with regard to this request. The Center for Neuroscience and Regenerative Medicine (CNRM) will initially store all study data in an electronic data capture and storage system in a coded manner, so that no personal information, such as your name, is stored with the data, but a list will be securely maintained separate from the data by the research team that links the codes with your personal information. After analyses are finished, the codes will be destroyed, and the data will then be de-identified. If the stored data still has a code or identifying link, you can request to be contacted and sign a separate consent form to allow the use or available of this data in another study. You may also choose either to not allow any further use of your data or give consent now for the use your data to be used in future studies. This future research may be in the same area as the original study or it may be for a different kind of study. After the completion of the analyses planned as a part of this study, the codes to your personal information, also known as identifiers, may be removed from collected information or biospecimens and may be used for future research studies without collection of additional consent from the subject or legally authorized representative.

Any future research using your retained data will require a research protocol for the proposed study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

18. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify your Principal Investigator, Dr. Michael Roy, immediately at (301) 295-9601.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military, dependent of active duty military, retiree), you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are authorized space-available medical care for your injury at a DoD hospital or

an DoD clinic; medical care charges for care at a DoD hospital or a DoD clinic will be waived for your research-related injury. If you obtain care for research-related injuries outside of a DoD or DoD hospital or clinic, you will not be reimbursed for those medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

19. WHAT WILL HAPPEN TO YOUR SAMPLES AFTER THE RESEARCH HAS ENDED?

During this research study, you could be asked to provide the following types of samples (biological specimens): blood samples.

Although research that uses your samples may lead to the development of new inventions, products, or discoveries (some that might be patented and licensed), there are no plans to pay you for them.

While this study is on-going, your samples will be handled in accordance with this study's protocol and applicable regulations at the following laboratory:
Center for Neuroscience and Regenerative Medicine (CNRM) Biospecimen Repository
12725 Twinbrook Pkwy
Rockville, Maryland 20852

The samples will be stored in secured freezers at CNRM for up to 20 years, if you give your consent to this in section 22, below. If funding for the storage of samples is lost and alternative arrangement cannot be made, any remaining unused samples may be destroyed before 20 years. If there are remaining samples after 20 years, and continued funding for their storage is available, IRB approval of continued storage will be requested, and if provided, the samples may be stored longer than 20 years. If IRB approval is not granted for continued storage, remaining unused samples would be destroyed at that point.

Future Use of Biologic Specimens: The investigators in this study are asking for your permission to store your samples described above for future use in other research studies. The specifics of these future research studies are unknown at this time, but these studies will frequently be in the area of post-traumatic stress disorder and traumatic brain injury research.

Your samples would be stored with the following information: a coded Global Unique Identifier (GUID) and a Study identification number. These codes are not provided to investigators receiving samples from the Repository for analysis.

The storage (bank) area is maintained at the:
Center for Neuroscience and Regenerative Medicine (CNRM) Biospecimen Repository

12725 Twinbrook Parkway
Rockville, Maryland 20852

The Director of the CNRM Biospecimen Repository is responsible for the storage bank. The Repository Director's phone number is: 301-295-4612. Future research investigators requesting portions of your samples from the bank must have the approval of the CNRM Biorepository Steering Committee and must also have a research protocol for their newly proposed research study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants). It is possible these other researchers will request approval from an IRB to contact you in the future.

Some future research studies may include genetic testing of your samples stored at the bank. Since storage (banking) of biologic specimens for future genetic testing is still undergoing development, the benefits and risks of genetic testing are not fully known at this time. It is believed that the risks are very low. Using new technology, information about your DNA structure (genetic information) gained from your banked samples can be used to indicate risk for developing certain diseases. This genetic information is unique to you and may indicate changes in your future health status or life expectancy, or that of your children and other relatives. These discoveries could be stressful and cause psychological difficulties or family problems. It is also possible that during future research, people of your ethnic background may be found to be at more risk for certain diseases. This could stigmatize your ethnic or cultural group.

Release of personally identifiable genetic information may pose a possible risk of discrimination or increased difficulty in obtaining certain types of insurance for you and your family members. If study results were accidentally disclosed and if you require psychosocial and/or genetic counseling and this counseling was not available at WRNMMC, you might have to pay part or all of these costs. The Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110-233) also known as "GINA" is a federal law that prohibits discrimination in health insurance coverage and employment based on genetic information. However, GINA does not apply to employers with fewer than 15 employees. GINA's protections in employment do not extend to the US military. Nor does it apply to health insurance through the TRICARE military health system, the Indian Health Service, the Veterans Health Administration, or the Federal Employees Health Benefits Program. The law also does not cover long term care insurance, life insurance or disability insurance. While GINA's employment protections do not apply to military members and Federal employees, there is an Executive Order that protects federal employees from genetic discrimination in employment and the military has its own policies in place that may protect genetic discrimination. GINA's protection should apply for a military member once he or she leaves the service and enters the private sector. For active duty service members, if we learn of something that puts your well-being or that of members of your unit at risk, or of illegal activities, we may be required to inform your command, which could adversely impact your career.

Potential risk would occur if the confidentiality of your data is breached. Because of the consequences of a breach of confidentiality, every effort will be made by the bank to protect your privacy. The storage bank's procedures to protect the confidentiality of your data include:

Use of coded identifiers which provide the only link to you or your data; removal of all personal identifying information from the information provided to persons obtaining portions of your sample for analysis for research purposes; password and firewall protection of all computers on which information related to the samples you provide is stored. All computers housing information relating to your samples and the freezers containing the samples that you provide are located in locked rooms within the locked, keycard-requiring CNRM Twinbrook facility. Your samples could be stored indefinitely at the bank, or until none is left to use. Generally, you will not be provided with the results of the future studies using your samples from this bank. This is typically the case because the research results at that early point will not have a clear meaning for or direct clinical benefit to you. However, you may choose to be informed of results in some cases, in section 22, below.

You may request that your specimen be withdrawn from the bank at any time if you decide you no longer want to participate. This can be done by notifying the Principal Investigator, Dr. Roy.

20. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled. You may also withdraw your blood samples from the biospecimen repository either with or without withdrawing from the study yourself. In either case, please contact the Principal Investigator, Dr. Roy.

If you are a part of this research study and choose to withdraw, you will no longer be eligible for the research. Contact your personal physician to discuss medical treatment for your condition.

Your taking part in this study may also be stopped without your consent if the military mission requires it, or if you lose your right to receive medical care at a military hospital. The principal investigator of this research study may terminate your participation in this research study at any time if he determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

21. VOLUNTARY PARTICIPATION:

The decision to take part in this research study is completely voluntary on your part. You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

22. INCIDENTAL FINDINGS

There is a possibility that during your participation we may identify an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

You do not have an option to decline receiving information about an incidental finding. An incidental finding may cause you to feel anxious, but the PI or another member of the research team will talk to you if there is an incidental finding and explain it to you.

We will also give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

23. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Michael J. Roy, MD MPH, Fellow of the American College of Physicians
Staff, Internal Medicine, Walter Reed National Military Medical Center
Director, Division of Military Internal Medicine
Professor of Medicine
Principal Investigator, Recruitment Core, Center for Neuroscience and Regenerative Medicine
Department of Medicine
Uniformed Services University
4301 Jones Bridge Road
Bethesda, MD 20814
Phone: (301) 295-9601
e-mail: michael.roy@usuhs.edu

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at: (301-295-8273) or 8901 Wisconsin Ave, Bethesda, MD 20889

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

Please initial the sentences that reflect your choices, and then sign below:

With regard to storage of data:

_____ I do not authorize the storage of data collected as a part of this study for future use in research studies.

_____ I authorize the storage of data collected as a part of this study for future use in research studies.

With regard to future research studies done on stored data that has a link to my personal identity:

_____ I do not wish to be notified by investigators in the event of research findings of potential impact to my family members or myself.

_____ I wish to be notified by investigators in the event of research findings of potential impact to my family members or myself. I agree that my current principal investigator may use any appropriate identifier to locate me in the future.

With regard to storage of biological specimens (blood samples), please initial by the line indicating your wishes:

____ **YES**, I give permission to have my blood drawn and to use my blood samples for future research studies. I understand that the samples will not have any personal identifiers with them, but they are coded, so they may be able to be traced back to my personally identifiable information.
____ **NO**, I decline the blood draw procedure.

Donated samples may also be used for genetic testing. Please initial by the line indicating your wishes:
____ **YES**, I give permission to use my blood samples for future studies involving DNA testing. I understand that the samples will not have any personal identifiers with them, but they are coded, so they may be able to be traced back to my other research records.
____ **NO**, I decline to have my blood samples used for research studies involving genetic testing.

With regard to future research studies done on my biological specimens kept at the storage bank:
____ **YES**, I wish to be notified by investigators in the event of research findings of potential impact to my family members or myself.

_____ **NO**, I do not wish to be notified by investigators in the event of research findings of potential impact to my family members or myself.

With regard to sharing my contact information with other CNRM investigators:
_____ **YES,** I authorize the sharing of my contact information with other researchers conducting future studies, if I might be eligible for them.

_____ **NO,** I do not authorize sharing of my contact information with other researchers in the future, even if I might be eligible for other research studies.

SIGNATURE OF PARTICIPANT

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF WITNESS TO CONSENT/CONSENT PROCESS
(This individual can be a relative of the participant, but cannot be an individual involved with the research study.)

_____
Printed Name of Witness

_____ _____
Signature of Witness Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date