Participant Name: _____ Date: _____

Title of Study: Insomnia Treatment and Health Following Exposure to Past Stressful Events

Principal Investigator: Monica Kelly, PhD VA Facility: VA Greater Los Angeles Healthcare System

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the National Institutes of Health's (NIH) National Heart, Lung and Blood Institute (NHLBI). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

This study provides a non-medication treatment for symptoms related to past stressful/traumatic event(s) followed by a non-medication sleep education and treatment program for sleep problems that remain after completing the trauma treatment. By doing this study, we hope to determine if a sleep education program is effective in improving sleep quality and how the program affects health. Your participation in this research will last about 11 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You will learn about posttraumatic stress disorder (PTSD) and common sleep conditions, like insomnia. You will learn about non-medication strategies to help you manage PTSD symptoms and to help you sleep better. It is possible that after this program your PTSD symptoms and sleep will improve. For a complete description of benefits, refer to the Detailed Information section of this informed consent form.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may not want to volunteer for this study, because you might feel uncomfortable answering some of the questions, or it might be inconvenient for you to attend the research sessions. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Monica Kelly, PhD at the VA Greater Los Angeles Healthcare System. If you have questions, suggestions, or concerns regarding this study, you have a study-related injury, or you want to withdraw from the study her contact information is: (818) 891-7711. Ext. 36066.

FOR IRB USE ONLY

PI/SC Approval Date:

VA GLA IRB
Effective Date: February 3, 2025

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to test the sleep, mental health and physical health outcomes of a sleep education program for sleep problems that remain after completing treatment for PTSD in Veterans over the age of 50.

PTSD and poor sleep are known to impact physical health. This study will look at whether treating PTSD and sleep problems has an impact on cardiovascular (heart) health (specifically blood pressure) and metabolic health (blood levels of glucose, insulin, hemoglobin A1C and lipids).

By conducting this research project, we hope to discover what treatments are the most effective for Veterans who have sleep problems and a mental health condition related to having experienced past stressful or traumatic events.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 5 years to complete. Your individual participation in the project will take 11 months, with most of the activities occurring in the first four months. A total of 167 Veterans will be enrolled into this study.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Due to the COVID-19 pandemic, some or all research visits may occur using VA approved video telehealth platforms, like VA Video Connect. Study staff will help you use this system on your personal computer or smartphone. If the visits are in-person, you may be required to answer COVID-19 screening questions prior to each visit, wear a mask throughout the visit, and maintain social distancing.

If you decide to take part in this study, this is what will happen.

Baseline Health and Sleep Evaluation (3 visits, 60 minutes each):

Visit 1 (approximately 60 minutes)

1. You will be asked to answer a questionnaire regarding your health history, medications and personal information, such as your marital status, number of children, and employment.

2. A sample of blood (20mL, a little more than 1 tablespoon) will be collected from your arm to measure markers of metabolic health (glucose, insulin, hemoglobin A1C and lipids). A certified phlebotomist will collect the samples at the West Los Angeles or the Sepulveda VA.

3. You will be asked to wear a blood pressure monitor at home for 24 hours as a measure of cardiovascular (heart) health. You will wear the blood pressure cuff around your upper arm. The cuff will inflate every 30 minutes.

4. You may be screened for sleep apnea. At the end of visit 1, you may be provided a portable sleep apnea monitoring device to wear for one night. This device is worn on your wrist and has two sensors: a plastic sensor worn on the index finger and a 2" sensor worn on the chest to detect snoring and body position. These sensors are painless. You will return the device and all devices either in-person or by mail to the Sleep Research office.

Visit 2 (approximately 60 minutes)

1. You will return any study equipment provided to you at Visit 1 (in person or by mail depending on COVID-related restrictions on in person visits).

2. You will be asked to answer questionnaires about your health, mood, and stressful experiences, including past trauma and symptoms of post-traumatic stress disorder.

3. You will be given a sleep watch and a continuous glucose monitor (CGM) sensor to wear for 7 consecutive days. The sleep watch looks like a wristwatch and will measure when you are asleep and when you are awake. The CGM sensor measures changes in your body's insulin levels during the day and night. The sensor includes a small filament (a tiny needle, about the size of a thread) that will be inserted into your upper arm or abdomen. You will be provided with a CGM reader device that will record the data from the sensor. You will be asked to keep the reader device near your body at all times over the 7-day period.

4. While you wear the sleep watch and the CGM sensor, you will be asked to keep a sleep diary each day. It will take about 1-2 minutes per day to complete the diary. You will return the sleep diary with the sleep watch.

Visit 3 (approximately 60 minutes)

1. You will return any study equipment provided to you at Visit 2 (in person or by mail depending on COVID-related restrictions on in person visits).

2. You will be asked to answer an additional questionnaire regarding your health, sleep patterns and habits, and your quality of life.

Medical Record Review

If you volunteer to participate in this study, you are also agreeing to let the research staff review your VA medical records to obtain information about your:

- use of VA services (including treatments for insomnia and trauma-related symptoms) over the past year
- diagnoses and treatment (including diagnoses and treatment related to mental health conditions and drug and alcohol abuse)
- current medications

Final eligibility determination for participation in PTSD treatment and sleep education programs

Information collected from the health and sleep evaluation, the medical record review, the post-traumatic stress disorder evaluation, and the results of your sleep apnea screening test will be reviewed by the research team to see if you are eligible for continuing in the study. If you suffer from any condition that would make it difficult for you to take part in study activities, you will be excluded from further participation. If this condition is a new finding, we will inform you and, with your permission, your doctor of these findings. Study staff will advise you of whether the study treatments may or may not be appropriate for you based on the information gathered from the baseline assessment, in other words, whether you are eligible or not eligible for the study. This eligibility meeting will be conducted either in person or via telephone/video telehealth based on your preference. If the study may not be appropriate for your needs (if you are not eligible), study staff will also advise you on how to receive clinical care if you desire, such as reaching out to your current medical or mental health care providers for referrals. If the study is not appropriate for your needs (if you are eligible), study staff will review the remaining study activities and will confirm your continued interest in participation in the clinical trial.

PTSD Treatment Program

If you are eligible to be in the study, you will receive a PTSD treatment program. You will meet with a PTSD and sleep specialist for 12 in-person (or video) sessions. These sessions will take place at the

VA West Los Angeles or Sepulveda campuses, or by computer using a VA approved video telehealth platform. The "Approximate Timeline of Study Activities" table (page 6) shows the schedule for the PTSD Treatment program.

The PTSD treatment program will focus on providing education about PTSD and will teach you non-medication strategies to improve your PTSD symptoms. The strategies include tracking, evaluating, and changing unhelpful thoughts that have developed after experiencing a traumatic or very stressful event or series of events. This PTSD treatment does not require you to describe the details of your past traumatic experiences, rather, it focuses on updating your current thinking to help improve how you feel.

Sleep Education Program

After completing the PTSD treatment program, you will receive asleep education program.

For the sleep education program, you will meet with a sleep specialist for 5 in-person (or video) sessions. The "Approximate Timeline of Study Activities" table (page 6) shows the schedule for the Sleep Education program.

These sessions will take place at the VA West Los Angeles or Sepulveda campuses, or by computer using a VA approved video telehealth platform.

The content of sessions in sleep education program will focus on providing education about common sleep disorders, like sleep apnea and insomnia, and will teach you non-medication strategies to improve your sleep. You will be asked to answer a questionnaire at the beginning of session 1 and at the end of session 5. These questionnaires ask for your opinions about the treatment program. You will not be given sleeping medications as part of either treatment program. If you are currently using a sleeping medication, you will continue to follow your doctor's recommendations.

The 12 PTSD treatment sessions and the 5 sleep education sessions will be audio-recorded for the purpose of making sure that study staff follow the protocol for each session and for staff training purposes. Selected questionnaires may also be audio-recorded for staff training purposes. These recordings will not be disclosed to anyone outside of the VA study team.

Yes, I give my permission to be audio-recorded.

_____(subject's initials)

No, I DO NOT consent to be audio-recorded.

_____(subject's initials)

Follow-up Evaluations

You will receive four follow-up evaluations:

- Post-PTSD treatment follow-up (in-person or by video): One week after the PTSD treatment program ends (2 visits)
- Post-sleep education program follow-up (in-person or by video): 5 weeks after the sleep education program ends (2 visits)
- 6-month follow-up (in-person or by video): 6-months after the sleep education program ends (2 visits)

Approximate Timeline of Study Activities

Week/Mo	Session	Program	Location	Amount of time
Baseline	Health and Sleep Evaluation		In-person or video	45-60 minutes x3 visits
1	1	PTSD Treatment	In-person or video	45-60 minutes
2	2	PTSD Treatment	In-person or video	45-60 minutes
3	3	PTSD Treatment	In-person or video	45-60 minutes
4	4	PTSD Treatment	In-person or video	45-60 minutes
5	5	PTSD Treatment	In-person or video	45-60 minutes
6	6	PTSD Treatment	In-person or video	45-60 minutes
7	7	PTSD Treatment	In-person or video	45-60 minutes
8	8	PTSD Treatment	In-person or video	45-60 minutes
9	9	PTSD Treatment	In-person or video	45-60 minutes
10	10	PTSD Treatment	In-person or video	45-60 minutes
11	11	PTSD Treatment	In-person or video	45-60 minutes
12	12	PTSD Treatment	In-person or video	45-60 minutes
13	Post- PTSD Treatment Follow-up		In-person or video	60-90 minutes
14	1	Sleep Education	In-person or video	45-60 minutes
15	2	Sleep Education	In-person or video	45-60 minutes
16	3	Sleep Education	In-person or video	45-60 minutes
17	4	Sleep Education	In-person or video	45-60 minutes
18	5	Sleep Education	In-person or video	45-60 minutes
19	Post-Sleep Education Program Follow-up		In-person or video	60-90 minutes
3-month	3-month Contact		Telephone	15 minutes
6-month	6-month Follow-up		In-person or video	60-90 minutes

The information collected at each follow-up evaluation will be the same as the information collected at the baseline evaluation and described previously (see pages 2-3). The measures that will be completed in each of the two visits at all three of the follow-up evaluations are as follows:

Visit 1 (approximately 60 minutes)

1. Blood sample (20mL, a little more than 1 tablespoon)

2. 24-hour blood pressure monitoring at home.

3. Wear a sleep watch and a continuous glucose monitor sensor while keeping a sleep diary at home for 7 consecutive days.

4. Answer questionnaires about your health, quality of life, sleep patterns and habits, your mood, and stressful experiences.

Visit 2 (approximately 30 minutes)

1. Return study equipment provided to you at Visit 1 (in person or by mail depending on COVID-related restrictions on in person visits).

2. Answer additional questions about your health, quality of life, sleep patterns and habits, your mood, and stressful experiences.

We will also reach out to you by telephone 3-months after the sleep education program ends to briefly assess your current status and update your contact information.

All activities are being undertaken for research purposes only.

Collection and Analysis of Blood Data

We will collect a total of 100 mL (about 7.5 tablespoons) of blood from you over the course of the four study assessments. Blood samples will be analyzed for glucose, insulin, hemoglobin A1C and lipids as measures of metabolic health. These blood samples will be collected and processed by the VA clinical laboratory. Results of blood sample analyses will be entered into your VA electronic medical record. If you have any concerns about your health, please contact your primary care provider for further evaluation.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Keep your study appointments. If you miss an appointment, please contact research staff to reschedule as soon as you know you will miss the appointment.
- Return the sleep diaries as well as the sleep watch, blood pressure, glucose monitoring and sleep apnea equipment.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?
You may experience the following risks and discomforts as a result of participating in this study:

24-hour ambulatory blood pressure monitor: The known risks associated with wearing the ambulatory blood pressure monitor are minimal. Wearing the blood pressure monitor for a 24-hour period may be annoying or uncomfortable for you. Rarely, they may cause skin irritation or an allergy. The skin around the cuff should be kept clean and dry to reduce the likelihood of skin irritation. To reduce discomfort, you should keep your arm extended in the same position and avoid movement when the cuff automatically inflates for all measurements. To minimize skin irritation, we have limited the monitoring to the shortest timeframe necessary to collect relevant blood pressure data.

Continuous glucose monitor (CGM): Wearing the CGM sensor 24 hours a day and collecting data via CGM reader for one week may be annoying or uncomfortable for you. Inserting the sensor can cause slight pain, and mild soreness at the site of the sensor may persist for a short period of time afterward. There is also a small risk of bruising at the site the sensor, which should resolve. Rarely, the sensor may cause skin irritation or an allergy. To avoid irritation, keep the skin around the sensor clean and dry. If any significant irritation or evidence of skin injury occurs, you should remove the sensor and alert study staff. To minimize skin irritation, we have limited the monitoring to the shortest timeframe necessary to collect relevant glucose data.

Sleep watch: The known risks associated with wearing the sleep watch are minimal. The watch may be annoying or uncomfortable for you. Rarely, the watch may cause skin irritation or an allergy. To avoid irritation, keep skin under the watch clean and dry. If any significant irritation or evidence of skin injury occurs, you should remove the device and alert study staff. To minimize skin irritation, we have limited the monitoring to the shortest timeframe necessary to collect relevant sleep data.

Blood sample: You may feel some physical discomfort from the blood sample. The needle can cause slight pain when the phlebotomist inserts it into the vein, and mild soreness at the site of the needle stick may persist for a short period of time afterward. There is also a small risk of bruising at the site of the blood draw, which should resolve. To minimize discomfort, we will draw only the minimum amount of blood necessary and will schedule your visit at a time of day that is the most convenient for you.

Questionnaires: You may feel uncomfortable answering questions about your health, mood, sleep habits, and past stressful events. You can choose to skip any questions that are sensitive or make you feel uncomfortable.

PTSD Intervention Program: You may find that coming to the 12-session PTSD treatment program is tiring or inconvenient. Participants will be advised that they may experience increased PTSD symptoms or discomfort (e.g., emotional distress) as a temporary result of their discussing unhelpful thoughts related to past trauma exposure (e.g., trauma-related memories, irritability) that will likely resolve within a few weeks.

Sleep Education Program: You may find that coming to the 5-session Sleep Education program is tiring or inconvenient. As you make adjustments to your sleep habits within the program, you may experience more daytime sleepiness at first. It will be important that you follow the instructions given by your program instructor if this occurs.

Home sleep apnea test (HSAT): Only participants who screen positive for sleep apnea and who have not previously had clinical testing for sleep apnea will complete the HSAT. There are no significant known risks associated with the HSAT. You may experience minor skin irritation related to the fingertip sensor and wrist-mounted device or may find the device slightly uncomfortable to wear. To minimize discomfort, we have limited the HSAT monitoring to the shortest timeframe necessary to collect relevant sleep data.

COVID-19: We will follow all guidance from VA Office of Research and Development (ORD) and our local VA facility regarding methods to reduce the risk of COVID-19 transmission during all in person visits. This may include use of masks, personal protective equipment and social distancing. This may also include conducting portions of the assessments and intervention sessions via telehealth.

It is possible that there are other unforeseeable risks.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include:

- You will learn about PTSD, healthy sleep and common sleep disorders, such as insomnia.
- You will learn about non-medication strategies to help you manage PTSD symptoms and to help you sleep better.
- It is possible that after this program your PTSD symptoms and sleep will improve.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. If this is your decision, you can choose to receive

treatment for PTSD or sleep problems from the VA or from a community provider. You can discuss these options with your primary care provider.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- We will ask you for your social security number to access your VA medical record. If you do not wish to provide your social security number, you can still participate.
- You will be assigned an identification (ID) number and this ID number will be used instead of your name (or other identifiers) on all study records.
- Research records and payment forms will be kept in locked file cabinets in locked offices and stored on password protected computers. Access will be limited to authorized Sleep Research staff.
- The audio-recordings of the questionnaires, PTSD treatment and sleep education sessions will not contain your name.
- We will not share your records or identify you unless we are legally required. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Greater Los Angeles IRB, our local Research and Development Committee may request to access research records.
- The results of this study may be published in the medical literature or presented at scientific medical or educational meetings, but your name or identity will not be revealed, and your records will remain confidential unless disclosure of your identity is required by law. Because of the need to release information to the parties listed above, absolute confidentiality cannot be guaranteed.
- In accordance with California law, confidentiality cannot be guaranteed if the investigator becomes aware that you may be a danger to yourself or to others or becomes aware that child abuse or elder abuse is occurring.
- Identifiers might be removed, and the coded information will be used for future research without seeking additional informed consent from you. Your coded information may be distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.
- Once you sign this informed consent, the study investigator and/or study staff will create a research record. If this is a study with a medical intervention, information about your enrollment in this study will be entered into the medical record at VA. While this study does not include any medical intervention, study data may be included in your medical record to help facilitate your

clinical care if medically relevant results are observed in your data (e.g., results of sleep apnea testing may be added to your chart to help connect you with care through the sleep clinic).

- A description of this clinical trial and the currently approved informed consent 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. ClinicalTrials.gov Identifier: NCT05516277

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL I RECEIVE COMPENSATION FOR PARTICIPATING?

You will be compensated up to $200 for your time while participating in this study. You will receive a $50 gift card after you complete the initial evaluation (baseline evaluation), the second evaluation

(post-PTSD treatment), the third evaluation (post-sleep education program) and the fourth evaluation (6-month follow-up).

You will receive these gift cards even if you do not complete all the parts of an evaluation. However, if you do not complete any of the evaluation, if you do not return the monitoring devices, or if you withdraw from the study before the assessment, you will not receive a gift card.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution. This care may be provided by the VA Greater Los Angeles Healthcare System or arrangements may be made for contracted care at another facility. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at (310) 478-3711. If you want to speak to someone who is not a member of the study to discuss problems, ask questions or voice concerns, you can call the Research Office and speak to the Office of the Associate Chief of Staff (310) 268-4437.

DO I HAVE TO TAKE PART IN THE STUDY?

Taking part in this study is completely voluntary. It is up to you to decide whether to take part in this study. If you decide to take part, you may still withdraw at any time. There is no penalty to you if you choose not to participate and there is no penalty if you decide to withdraw from this study. If you do not wish to be in this study or leave the study early, you will not lose any benefits or services to which you are otherwise entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff and it will not affect the usual care that you receive as a patient.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Dr. Kelly has the right to end your participation in this study for the following reasons:

- you do not meet all of the criteria for being in the study after we review your medical record and your responses to the questionnaires,
- we discover that you have a medical or psychiatric problem that prevents you from participating or requires referral for specialized treatment,
- you do not follow the study procedures.

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PI/SC Approval Date:

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study.

You may call the Research Office and speak to the Office of the Associate Chief of Staff (310) 268-4437 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FUTURE RE-CONTACT

With your permission, Dr. Kelly and her research team may contact you after this study is completed to invite you to participate in future studies.

Yes, I give my permission to be re-contacted for future research by Dr. Kelly or a member of her research team.

_____(subject's initials)

NO, I DO NOT give my permission to be re-contacted for future research by Dr. Kelly or a member of her research team.

_____(subject's initials)

FOR IRB USE ONLY

PI/SC Approval Date:

Participant Name: _____ Date: _____

Title of Study: Insomnia Treatment and Health Following Exposure to Past Stressful Events

Principal Investigator: Monica Kelly, PhD VA Facility: VA Greater Los Angeles Healthcare System

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms _____ _____ has explained the research study to you. You have been told of the risks or discomforts and possible

benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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PI/SC Approval Date:

CALIFORNIA BILL OF RIGHTS
RIGHTS OF HUMAN SUBJECTS IN MEDICAL EXPERIMENTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given an opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

FOR IRB USE ONLY

PI/SC Approval Date: