Study Title**: Supplementation with Amino Acid Rehabilitative Therapy in TBI (SmART-TBI): A Randomized Placebo-Controlled Trial to Improve Sleep**

NCT number: **NCT04603443**

Document: **ICF, IRB Approval date 6/26/2025**

Subject Name: _____ Date: _____

Title of Study: Supplemental Amino Acid Rehabilitative Therapy in TBI (SmART-TBI)

IRB Number: 4413

Principal Investigator (Researcher): Miranda Lim, MD, PhD ICF Version Date: 11-22-2022

WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS OR WISH TO OFFER INPUT?

About the research, call the study coordinator at (503) 721-1044.

If you become sick or injured or if you feel your privacy or confidentiality may have been violated (e.g., someone without authorization has received personal information about you), call Dr. Miranda Lim at (503) 220-8262 extension 57404.

To speak with someone not connected with this research study about your rights, discuss problems, concerns and questions, obtain information and/or offer input, please call the VA Portland Health Care System Research Office at (503) 273-5125, or the VAPORHCS Privacy Officer at (503) 273-5037.

SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

WHAT AM I BEING ASKED TO DO?

We are asking you to take part in a research study that is being funded by the Department of Veterans Affairs. We conduct research studies to try and answer questions about how to prevent, diagnose, and treat diseases.

We are asking you to take part in this research study because you may have had a history of head injury or traumatic brain injury (TBI).

TAKING PART IN THIS STUDY IS YOUR CHOICE

You can choose to take part or not to take part in this study. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

The VA Authorization for Use and Release of Individually Identifiable Health Information (Collected) for VHA Research to use your protected health information is also your choice. You may refuse to sign this consent form and the authorization. However, to participate in this study, you must sign this consent form and the authorization.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to see how consumption of branched chain amino acid (BCAA) supplementation is tolerated and how it affects symptoms commonly associated with TBI, like sleep and memory.

WHAT IS THE USUAL APPROACH TO MY DIAGNOSIS?

The usual approach for patients who are not in a study is to get advice from their doctor.

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WHAT ARE MY CHOICES IF I DECIDE NOT TO TAKE PART IN THIS STUDY?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.

WHAT WILL HAPPEN IF I DECIDE TO TAKE PART IN THIS STUDY?

If you decide to participate, you will be asked to have a number of tests and procedures including:

- Drink extra water for 2 weeks.
- Ingest the study supplement twice daily for 12 weeks.
- Complete a daily study diary.
- Place a bedmat under your mattress to track your sleep and wear a wrist activity tracker for ~14 weeks.
- Complete 2 overnight sleep studies if a recent clinical one is not available to share with the study..
- Complete brain function testing at 2 time points.
- Complete an ice bath pain test at 2 time points.
- Complete questionnaires and biospecimen collection (may include genetic testing) at 6 time points. The biospecimens collected may include saliva, sweat, and blood.

Your participation in the study will consist of testing at 7 time points over 6 months. Testing may take up to 2 hours. The overnight sleep study will take up to 12 hours and may need to be repeated once per time point as needed to get good sleep data.

If you decide to take part in this study, you will get the study supplement for up to 12 weeks.

This study can be completed at the VA Portland Healthcare System, remotely in your home, or as a combination of in person and at home visits. If you would like to do the study remotely, you will need an internet connection, email address, and mailing address to receive study supplies.

As part of this study, your contact information, biospecimens, and study data will be placed into a repository for future research.

A detailed description of all study procedures is located below in the “What will happen during this study?” section.

WHAT ARE THE RISKS AND BENEFITS OF TAKING PART IN THIS STUDY?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

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RISKS

We want to make sure you know about a few key risks right now however we provide more below information in the "What are the risks and possible discomforts from participation?" section.

This study involves collecting information directly from your medical record. The research team will make every effort to protect your information. However, a loss of privacy could occur. If there is information in your medical record you do not want shared you should consider this risk before agreeing to take part in this study.

Some members of your family may not want research done on your tissues to understand the genetics or possible inherited disorders of you and your family. This may cause conflict with your family members and could affect your decision or the decisions of family members to have children. You may want to hold a discussion with your family members before agreeing to take part in this study.

Taking part in this study means you may need to make additional visits to the Portland VA. As a result, you may have more travel or personal costs and/or need to take time off from work.

BENEFITS

You may or may not personally benefit from being in this study. You may benefit from dietary BCAA supplementation by improved sleep and/or quality of life. By serving as a participant, you may help us learn how to benefit patients in the future.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?

Yes, you can decide to stop taking part in the study at any time. If you decide to withdraw, you will be asked to return all of the study equipment.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

ARE THERE OTHER REASONS WHY I MIGHT STOP BEING IN THE STUDY?

Yes. The study team may take you off the study if there is any reason to believe you cannot or will not comply with all study requirements.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

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WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. The primary purpose of this study is to learn more about traumatic brain injury and sleep problems.

DO THE RESEARCHERS HAVE A PERSONAL, FINANCIAL OR OTHER INTEREST IN THIS STUDY?

Dr. Miranda Lim is a researcher on this study and may also be your health care provider. Her research team is interested in both the clinical welfare of their patients who participate in this study and in the conduct of this study overall. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another provider who is in no way associated with this study. You are not under any obligation to participate in any research study offered by your health care provider.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 200 people will participate in this research study at the VA Portland Health Care System.

WHAT WILL HAPPEN DURING THIS STUDY?

The procedures described below will be done for research purposes and will not be completed if you decide not to take part in the study. None of the procedures will impact your usual care at the VAPORHCS.

Study personnel will discuss the study with you and, if agreeable, you will sign the associated consent and authorization forms. After providing verbal and written informed consent, you will participate in the testing time points below, termed “Visits,” which will either take place at VAPORHCS or in your home.

This is a randomized study. That means that neither you nor your doctor can choose whether you will receive BCAA or placebo. That will be decided by chance (like tossing a coin, heads could mean you get BCAA, and tails that you get the placebo). You have a 75% chance of getting BCAA in this study.

At each optional blood draw, 5 tubes would be drawn equaling 35ml of blood, or ~2.5 tablespoons.

This study can be completed at the VA Portland Healthcare System, remotely in your home, or as a combination of in person and at home visits. If you would like to do the study remotely, you will need an internet connection, email address, and mailing address to receive study supplies.

Visit 1:

- You will complete a series of questionnaires related to your sleep quality, cognition, pain, and physical and mental health. These questionnaires will also ask about your history of traumatic brain injury (TBI/concussion). This is to establish an accurate diagnosis and history of your brain injury (if applicable). You have the option to complete this at Visit 2 instead.

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- You will be given a special wristwatch called an actiwatch that tracks activity and light exposure, allowing us to better understand your natural sleep-wake cycle. This watch is fully waterproof and should be worn continuously for the full duration of the study.

- You will be given a study diary with instructions on how to complete it. You will make daily entries relating to when you go to bed and when you wake up. You may also complete the study diary electronically. In this case, a link will be emailed or texted using an automated service called Twilio to you daily and you will input when you were asleep the night before.
- You will be given a bedmat that we will ask you to place underneath your mattress. This will track the times when you are in and out of bed, restlessness, breathing rate, and heart rate.

- You will complete a blood draw. You have the option to complete this at Visit 2 instead. This will not occur if you opt to do the study completely remotely.
- You will be asked to provide a 2 ml saliva sample. This can be completed at Visit 2 instead.
- You will be asked to provide a sweat sample. A sweat sample will be given to you and you will be asked to wear it for 12-72 hours on your core. You can shower with this on, but we ask you to avoid bathing or swimming while wearing it. This may be completed at Visit 2 instead.
- You will complete a series of brain tests assessing thinking speed, memory, and reaction time. These may be audio recorded. You have the option to complete this at Visit 2 instead.
- You may undergo an ice bath pain test where you will be asked to submerge your non-dominant hand in a cold ice bath and we will time when you sense the cold as pain. You can complete this at Visit 2 instead.
- You will undergo an overnight sleep test. You will be given a home sleep testing device to use at home. If your home sleep study does not provide good sleep data, we may ask you to repeat this.
- If you'd prefer, many parts of this visit can be completed at your home over video conferencing. Equipment will be mailed to you and we will discuss over video chat all instructions on how to use them. You can complete the questionnaires electronically, and the TBI interview and cognitive testing can be completed over video conferencing.

Daily Participation Between Visit 1 and 2 (~2 weeks):

- You will be asked to fill out a study diary indicating when you are sleeping every day.
- You will be asked to drink 20 ounces of water twice a day; once in the morning and once in the afternoon.

Start of supplement Visit 2 (~2 weeks after Visit 1):

- You will be given a new actiwatch, returning the one you had been using to study staff.
- You will be randomized to receive a placebo or BCAA and instructed on when and how to consume it.
- You will be given access to study diaries to make daily entries reporting when you went to bed and when you woke up, and when you consumed the study drug.
- If you did not complete the testing described in Visit 1, you will be asked to complete them at Visit 2.

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Daily Participation Between Visit 2 and 5 (~12 weeks):

- You will be asked to consume your supplement twice daily in the morning and afternoon.
  - You will be asked to keep the empty packets for counting at the next study visit.
  - You will be asked to try different flavorings to adjust the supplement taste to your liking. (These flavorings will be made available at no cost to you)
- You will be asked to complete a study diary indicating when you are sleeping and when you consume your supplement.

Check-in Visit 3 (~4 weeks after Visit 2) ***-and-*** Check-in Visit 4 (~4 weeks after Visit 3):

- You will return the actiwatch.
- You will count all used supplement packets in person or via video chat with study staff.
- You will be given another 4 week supply of supplement and a new actiwatch.
- You will complete a series of questionnaires.
- You may complete a blood draw. (This will not be done if you are completing the study remotely)
- You will provide another sweat sample.

End of supplement Visit 5 (Ideally ~4 weeks after Visit 4)

Some visit 5 activities may also be requested at any time during the study if there are any substantial pauses in participation during supplementation (at the investigators discretion).

- You will return the bedmat and actiwatch.
- You will count all used study supplement packets in person or via video chat with study staff.
- You will complete a series of questionnaires.
- You will complete brain tests.
- You will complete the ice bath pain testing.
- You may complete a blood draw. (This will not be done if you are completing the study remotely)
- You will provide another sweat sample.
- You will complete another overnight sleep study.

Follow up Visit 6 (~4 weeks after Visit 5) ***-and-*** Follow up Visit 7 (~8 weeks after Visit 6)

- You will complete a series of questionnaires.
- You may complete a blood draw. (This will not be done if you are completing the study remotely)
- You will provide another sweat sample.

We will contact you by phone or encrypted email at multiple time points during the study to answer any questions you may have and to ask you a few questions about how things are going.

We may also mail, email, or text you questionnaires and the sleep diary to fill out throughout the study.

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Summary Table:

	Visit 1 / At home		Visit 2	At home	Visit 3	At home	Visit 4	At home	Visit 5	Visit 6	Visit 7
Time point:	**Day 0**	**Week 1-2**	**Week 2**	**Week 2-6**	**Week 6**	**Week 6-10**	**Week 10**	**Week 10-14**	**Week 14***	**Week 18****	**Week 26*****
Informed consent	X										
Receive actiwatch and/or bedmat	X		X		X		X				
Consume extra water		X									
Complete sleep diary		X		X		X		X			
Questionnaires		X			X		X		X	X	X
Blood draw		X			X		X		X	X	X
Saliva collection		X									
Sweat collection		X			X		X		X	X	X
Overnight sleep study		X							X		
Ice bath pain testing		X							X		
Brain testing		X							X		
Receive Supplement			X		X		X				
Consume supplement				X		X		X			
Total time	**~20 min**	**~16 hrs (12 sleep)**	**Any travel time**	**~28 hrs**	**~120 min**	**~28 hrs**	**~120 min**	**~28 hrs**	**~15 hrs (12 sleep)**	**~120 min**	**~120 min**

*Or at supplement end (and may be also requested if there is a pause in supplementation.)

**Or 4 weeks after Visit 5

***Or 8 weeks after Visit 6

Remote/at home visits: In an effort to reduce the burden of travel to the Portland VA, you have the option to complete these visits remotely through the phone and video conferencing. In these cases, we may mail questionnaires, saliva and sweat collection tubes, equipment, and the supplement and conduct the brain testing through teleconferencing. We will provide pre-addressed, pre-paid envelopes for anything that needs to be sent back to us. Alternatively, if both you and the study personnel are comfortable, a member of the study team may travel to your home and conduct the visit there. A link to the questionnaires may also be emailed to you, whereby you can then complete them electronically. Everything can be completed remotely with the exception of the blood draw.

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Supplement: In this study, some people will receive the real study supplement, and some will receive a fake supplement called a placebo. A placebo is a pill or solution that tastes, looks and smells like the study drug but has no real medicine in it. A placebo is sometimes called a “sugar pill.” The placebo being used is a powder containing rice protein and only a low dose of BCAA.

This is a randomized study. That means neither you nor your doctor can choose whether you will receive the study drug or the placebo. That will be decided by chance (like tossing a coin, heads could mean you get the study drug and tails that you get the placebo). You have a 75% chance of getting the study drug in this study.

You and the study team members will not know which supplement (or dose) you get. The study is done this way because sometimes knowing that you are getting the test drug can change the results of the study. Also, sometimes people get side effects from placebos. Even though no one will know which supplement (or dose) you receive in this study, if you start having serious side effects, for your safety, the study doctors can find out if you are getting the test drug or placebo. Please ask the study doctor for more information if you have any questions about this kind of study.

Data/Sample banking: As part of this study, we are obtaining biospecimens and research data from you. We intend to use this data and biospecimens for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding RBD or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration.

We are asking you to allow your contact information (including first and last names, telephone numbers, mailing addresses, and e-mail addresses), blood samples, saliva samples, and sweat samples (including any identifiers, such as date of study visit or specimen collection), and other study data to be stored (“banked”) in VA repository (MIRB 4086) that is stored in an Oregon Health and Science University (OHSU) REDCap database. The repository may then release your biological samples, and/or study data for use in future research, which may include research about various sleep or neurodegenerative disorders. If you agree, we may contact you for future research studies.

Your biological samples will be stored indefinitely for use in future research. Future research may include genetic research. Genes are the units of DNA--the chemical structure carrying your genetic information--that determine many human characteristics such as the color of your eyes, your height, and whether you are male or female. Future genetic research may also include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may be passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down.

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WHAT ARE THE RISKS and POSSIBLE DISCOMFORTS of PARTICIPATION?

In addition to the risks described above in the Summary of Key Information About This Study, "What are the risks and benefits of taking part in this study?" section, the following risks could occur if you choose to take part in this study.

Information that identifies you will be collected in this study and shared with our university affiliate, Oregon Health & Science University (OHSU) by means of entering data into a secure electronic database. All hard copies of your questionnaires and consent forms will be in a locked drawer of a filing cabinet in a locked room, inside of a secured access area at VAPORHCS. The research team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft. It also could carry other risks, such as social embarrassment.

Study product: There are no reported major risks with consuming either BCAA or the placebo in the quantities proposed in this study. BCAAs have been studied extensively across multiple diseases. However, you may experience stomach issues such as indigestion, either from the study product consumed or the liquid consumed. Symptoms related to BCAA or the volume of liquid ingested are mild and quickly go away.

BCAAs do not interact or cause problems when taken with other medications, however, Dr. Lim will review all medications you are taking before giving you study product. If other health care providers prescribe new drug(s) for you while you are in this study, please tell Dr. Lim before you take the new drug. You could also have your provider talk to Dr. Lim before prescribing the new drug. **Do not take any new over-the-counter drugs or herbal or dietary supplements** while you are in this study unless you first check with Dr. Lim.

(For Women):
You should not become pregnant while participating. BCAA are not known to affect a fetus but could affect a fetus in ways that we do not yet know about. If you are sexually active and at risk of getting pregnant, you and your male partner(s) must use one or two methods of birth control that work well, like birth control pills, a patch, long-acting progestins, an IUD, a diaphragm or condom with spermicide, or abstinence. You will have to do this the whole time you are in this study. If you become pregnant during the study, tell Dr. Lim immediately.

If you are a man with a female partner, it is not necessary to avoid pregnancy, as your female partner is not consuming the extra supplement that could affect the developing fetus.

Questionnaires: Some of the questions may seem personal, embarrassing, or they may upset you. You may refuse to answer any of the questions. If your survey answers indicate that you are reporting depressing or have depressive symptoms during the course of the research study, we may notify your primary mental health provider or primary care physician who may then make a referral. If you should ever express thoughts of wishing to harm yourself or considering suicide, you may call the National Suicide Hotline at 585-393-7938 or we may facilitate a transfer to that call for you.

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Overnight sleep study: You may be more tired than normal the morning of following this sleep study, given that you may be sleeping in a different environment than you are used to. Surface electrodes may cause minor skin irritation, and may leave a minor residue that will need to be washed off with soap and water.

Blood draw: You may feel some pain or discomfort from the needle when your blood is drawn. There is a small chance the needle will cause bleeding, a bruise, an infection, or fainting.

Sweat Patch: The adhesive used on the sweat patch may irritate your skin. If this occurs you will not be required to participate in the sweat collection for the remainder of the study.

Head injury discussion anxiety: We will ask you about head injuries that you have had over the course of your life. This can be traumatic to talk about and can cause anxiety. If this causes you anxiety and distress the study doctor can refer you to a mental health care provider.

Ice bath pain testing: You may feel momentary discomfort or pain during the cold sensitivity testing. This test may cause a small area of redness, tenderness, or bruising.

Brain tests: The brain tests consist of brief pencil and paper, question and answer tests designed to evaluate your thinking abilities (e.g., attention, language, memory, etc.). Some of the testing may be mentally challenging and/or fatiguing to you. We may audio record parts of these tests for later assessments. The audio recording will be produced while performing certain brain tests for the purpose(s) of confirming our records and additional assessments. By signing this consent form, you authorize the use of the audio recording(s) for research purposes. All research-related audio tapes will be held in accordance with the VA records control schedule.

Genetic Information: Your genetic information may be shared in a public online database for future research. The database will not contain any information that directly identifies you, such as your name, address, or birth date, so it is unlikely that someone would know the genetic information came from you. In the future, people may develop ways to identify you or your blood relatives from this information, but currently, there is not a way to identify you without having additional information to compare to it, such as information from your DNA sample.

The Genetic Information Nondiscrimination Act (GINA), a federal law, generally makes it illegal for health insurance companies, group health plans, and employers of 15 or more employees to discriminate against you based on your genetic information.

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote or fire you or when setting the terms of your employment.
- However, there is a serious risk, if there is a loss of confidentiality and certain genetic information reaches your current or future life, disability, or long-term care insurance carrier, your employer (if s/he employs fewer than 15 employees), or others, that you or members of your family may experience some type of discrimination resulting in (1) **loss of life insurance, disability insurance, or long-term care insurance coverage and/or** (2) **loss of job**. All researchers associated with this study will make every reasonable effort not to disclose any of this information, but it is important for you to understand that the possibility of this information being disclosed exists, despite every reasonable effort. If you have any questions, please ask Dr. Miranda Lim, who can be reached at 503-220-8262 ext 57404. The VAPORHCS also abides by the Oregon Genetic Privacy law (ORS 192.531 through ORS 192.549) and its requirements concerning confidentiality and the legal remedies provided by that law for breach of its requirements. You have not waived your legal rights by signing this form. For clarification on this subject, or if you have further questions, please call the VA Regional Counsel office at (503) 412-4580.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Your identity will not be disclosed unless you give specific, separate consent or if required by law. All VA research records will be held in accordance with the VA records control schedule.

Identifiers related to you (i.e. information that can identify you) will be used in this research study and will include: First and last name, last four digits of SSN, address, phone number, email, date of birth, date of VAPORHCS visits, and medical history relating to sleep disorders, head injury and other history relating mental health. These identifiers may be used to obtain information about you and/or your health from VA records and from the health information sources listed on the HIPAA authorization.

In the future, identifiers may be removed, and de-identified information and/or biospecimens about you used for future research studies (not part of this study) without additional informed consent obtained from you. This means the people working on future research studies will not be able to identify who you are.

Your study data and biological samples will be shared with other researchers as part of this study. A code number will be assigned to your data and blood samples. Only personnel for this study will be authorized to link the code number to you. Other researchers who may receive your data and blood will be given only the code number and will not be given any other information to link the code back to you.

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All other parties, including employers, insurance companies, personal physicians and relatives, will be refused access to the data and blood samples, unless you provide written permission or unless otherwise required by law.

Information related to you will be shared with other researchers as part of this study and will include the following identifiers that may identify you or your family members: your name, address, phone number, and email. These identifiers may be used to contact you about participation in future research studies.

The study tests are completed in a database called REDCap. The REDCap database is password protected and maintained by the Oregon Clinical & Translational Research Institute (OCTRI) at Oregon Health & Science University (OHSU). A user profile based on your study ID number will be created for you, which will not contain your name or other identifying information. Your email address will be stored in this database, in order that you may be sent the links to the study tests. The database will collect your responses to questions, but will not contain any identifying information about you. By signing this informed consent, you give permission for this data to be maintained by OCTRI, which will be responsible for maintaining the security and confidentiality of the transferred data.

When the study team sends you a survey invitation or reminder by text message or automated voice call, your phone number will be shared with Twilio, Inc. No other data will be shared.

Text messages are not fully secure and, while efforts will be made to limit content that could identify you, text messaging increases the risk, however slight, that your health information could be compromised. By agreeing to receive these texts you are assuming liability of that risk. You may also choose to not receive texts or Opt-out of receiving texts.
The audio recording will be produced during cognitive testing for the purpose(s) of ensuring accurate results. By signing this consent form, you authorize the use of the *audio recordings* for research purposes. All research-related audio tapes will be held in accordance with the VA records control schedule.

We will create a note in your VHA medical record that stating that you participated in this study and completed follow up visits, if applicable. We will not upload any of the study data and results to your medical record.

Mandatory reporting of suspected child, elder, or vulnerable adult abuse. Under Oregon Law, suspected child, elder or vulnerable adult abuse must be reported to appropriate authorities.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

This study involves a drug regulated by the US Food and Drug Administration (FDA), the FDA may choose to inspect research records that include identifiable medical records, identifying you as a subject of this study.

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Possibility of Disclosure and Notice of Privacy Practices.
The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it may no longer be protected. Our Notice of Privacy Practices provides more information on how we protect your information. If you do not have a copy of the notice, the research team will provide one to you. (Notice of Privacy Practices available online at http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3048).

HOW LONG WILL YOU KEEP MY INFORMATION?

Your blood, saliva, sweat, study data, and contact information will be stored in the repository indefinitely.

WILL I BE TOLD ABOUT ANY STUDY RESULTS?

The results of research tests will not be made available to you because the results will be general and not relate directly to you and/or your medical care. You may request a copy of the publication of this study when available.

Individual home sleep study: We do not plan to share your research home sleep test data with you. However, if we discover information that may be important to your health we will contact you to recommend a repeat sleep study in a non-research laboratory. A clinical study may reveal information about your health that is upsetting –or– you may be caused unnecessary stress if no issue is found. You or your insurance would be responsible for all costs associated with any follow-up testing and medical care.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
Non-Veterans receiving sleep studies ***at*** *the VAPORHCS sleep clinic* will need to either pay for the cost of the study or their insurance will need to be billed. To avoid these potential costs, all subjects will be asked to have their sleep study at home by default.

All of the other activities in this study are for research purposes only and you will not be required to pay for care and services received as a subject in a VA research project. None of the participants will pay for the supplement and equipment because they are only for research study purposes.

Some Veterans are also required to pay co-payments for medical care and services provided by VA ***that are not part of this study*** (e.g., normal hospital and prescription expenses that are not part of the research study, any treatment that is standard clinical treatment for your condition).

Subject Name: _____ Date: _____

Title of Study: Supplemental Amino Acid Rehabilitative Therapy in TBI (SmART-TBI)

IRB Number: 4413

Principal Investigator (Researcher): Miranda Lim, MD, PhD ICF Version Date: 11-22-2022

WILL I BE PAID FOR PARTICIPATING? You will be paid the following amounts in gift cards, check, or other cash equivalent for compliance in our study. To reduce account tracking burden we may pay you for all of your study activities at the very end of your participation unless you request otherwise. You will be paid partial amounts depending on what aspects of the study you complete:

- Visit 1: Up to $180 for completing all scheduled testing and procedures. As needed, partial payments may be given instead as follows:
  - $20 for completing questionnaires
  - $20 for completing brain (cognitive) testing
  - $20 for providing biological samples
  - $120 for completing overnight sleep testing
- Visit 2: $20 for completing study diary, other testing/procedures, receiving study drug and instructions
- Visit 3: Up to $40 for completing all testing and procedures including actigraphy and bedmat. As needed, partial payments may be given instead as follows:
  - $20 for completing the questionnaires and sleep diary
  - $20 for biological samples
- Visit 4: Up to $40 for completing visit and all procedures including actigraphy and bedmat. As needed, partial payments may be given instead as follows:
  - $20 for completing the questionnaires and sleep diary
  - $20 for biological samples
- Visit 5: Up to $180 for completing all testing and all scheduled procedures including completion of any drug consumption. As needed, partial payments may be given instead as follows:
  - $20 for questionnaires and sleep diary
  - $20 for brain (cognitive) testing
  - $20 for biological samples
  - $120 for overnight sleep testing
- Visit 6: Up to $40 for completing testing and all procedures. As needed, partial payments may be given instead as follows:
  - $20 for completing the questionnaires
  - $20 for biological samples
- Visit 7: Up to $40 for completing testing and all procedures. As needed, partial payments may be given instead as follows:
  - $20 for completing the questionnaires
  - $20 for biological samples

Total payment for completing all the activities shown above: $540

Subject Name: _____ Date: _____

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Studies that include subject reimbursement using electronic funds transfer (EFT) will use your Social Security Number. An Internal Revenue Service (IRS) Form 1099 may be generated, which will use your Social Security Number. This payment is considered taxable income. If you owe money to the government, this payment may be garnished to satisfy the debt.

WILL ANYONE PROFIT FINANCIALLY FROM THIS STUDY?

Samples obtained from you in this research may be used to make a discovery that could be patented or licensed to an individual, the federal government or a private entity. There are no plans to provide financial compensation to you should this occur. However, should the VA ever provide your samples for research or commercial use, it will do so in such a way as to protect your privacy and confidentiality as stated in the CONFIDENTIALITY section of this document.

WHAT WILL HAPPEN IF I AM HURT?

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 your non-compliance with study procedures. Additional compensation, beyond paying for treatment, has not been set aside.

The VA will also provide all necessary assistance in the event of any violation of confidentiality or privacy (for example, identity theft resulting from the loss of a social security number by anyone associated with this study). For eligible Veterans, compensation damages may be payable under 38 United States Code 1151. For all study participants, compensation damages resulting from the negligence of federal government employees may be available in accordance with the provisions of the Federal Tort Claims Act. For additional information concerning claims for damages, you may contact VA Regional Counsel at (503) 412-4580. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

WHAT DO I NEED TO DO TO DROP OUT (WITHDRAW) AFTER I SIGN THIS CONSENT FORM?

You may withdraw from this study at any time. This will not affect your rights as a VHA patient or your eligibility for medical care and benefits for which you are otherwise eligible with this institution or with the VHA. To withdraw, you must provide verbal (in-person or call 503-220-8262 x57404) or written intent to Dr. Lim or a member of the research team.

Write to: VA Portland Health Care System
3710 SW US Veterans Rd
Mailcode: P3-RD42, Attn: Miranda Lim

Subject Name: _____ Date: _____

Title of Study: Supplemental Amino Acid Rehabilitative Therapy in TBI (SmART-TBI)

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If you do withdraw, all data collection will stop but the data already collected will remain in use. If you do withdraw, we will not look at your medical record for purposes of the research anymore and will not collect any more information about you. However, we will keep and use the data that we already collected before you withdrew your consent.

Can someone else stop me from being in the study?
Your participation may be terminated by the investigator if there is any reason to believe you cannot or will not comply with all study requirements or have adverse reactions to the study product.

Signature

A study member has explained the study to me and answered all of my questions. I have been told of the risks and/or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I have been told I do not have to take part in this study and refusal will involve no penalty or loss of VHA or other benefits to which I am entitled.

In case there are medical problems or questions, I have been told I can call Dr. Lim at 503-220-8262 x57404 from 08:00 to 17:00, Monday through Friday. If any medical problems occur in connection with this study, the VA will provide emergency care.

By consenting to participate, I authorize the use of my blood samples.

If you agree, your contact information, blood samples, sweat samples, saliva samples, and other study data may be stored and used in future research. Only a restricted number of approved study personnel, repository personnel, and other researchers will have the ability to link the blood samples or study data back to you.
I voluntarily consent to allow my contact information, blood samples and/or data from this study be stored in a repository and, as described in this form, used for future research.

I agree to the following future uses of my contact information, study data, and blood samples:

- Contacting me in person when I come to the VA, by letter, and/or by phone
- Research about any type of health care issue, disease or disorder
- Any VA or non-VA researchers

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My signature below indicates that I have read, or had read to me, all of the above information about the study, and that my rights as a research subject have been explained to me. I authorize the use of my information and blood samples as described in this form. In the future, if I decide that I no longer wish to participate in this research study, I agree that my information and blood samples which were already collected, may continue to be used only for this research by removing all identifying information. However, identifiers may be stored separately and held in accordance with the VA records control schedule.

I voluntarily consent to participate in this study. I have been told that I will receive a copy of this consent form.

_____
Printed Name of Subject

_____ _____ _____
Signature of Subject Date Time

_____
Printed Name of Person Obtaining Consent

_____ _____ _____
Signature of Person Obtaining Consent Date Time

Subject Name: _____ Date: _____

Title of Study: Supplemental Amino Acid Rehabilitative Therapy in TBI (SmART-TBI)

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Addendum: Banking your Contact Information for Future Research

Center for Neuroscience and Regenerative Medicine (CNRM) TBI Research Opportunities and Outreach for Participation in Studies **(TROOPS) referral program –**

WHAT IS THE PURPOSE AND WHAT WILL HAPPEN?

You may be eligible for other CNRM-funded or CNRM-collaborative studies. We are asking you to allow your contact information (including name, email, phone number, enrollment status, and enrollment date) to be stored ("banked") in a repository located at the CNRM. Your participation in this program is voluntary. If you decide to take part, you will be asked to provide some information about yourself and your health, which will be used to determine your eligibility for CNRM-funded and collaborative studies. By signing this form below, you agree to allow study staff to provide your contact and enrollment information listed above to the TROOPS staff. Your information will be sent securely and will not be shared with anyone else.

Please contact CNRMstudies@usuhs.edu with any questions that you may have about participating in this referral program.

WHAT ARE THE RISKS?

Information that identifies you will be banked. The repository team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft. It could also carry other risks, such as the stresses that can come with a loss of privacy.

HOW LONG WILL YOU KEEP MY INFORMATION?

Your research data will be stored indefinitely, but will be deleted if:

- You request to be removed from the TROOPS referral program
- You say you are not interested when contacted by the TROOPS staff
- You are unreachable by TROOPS staff after three contact attempts\

Subject Name: _____ Date: _____

Title of Study: Supplemental Amino Acid Rehabilitative Therapy in TBI (SmART-TBI)

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CAN I WITHDRAW MY PERMISSION TO USE MY CONTACT AND ENROLLMENT INFORMATION?

To withdraw your consent for future use of your contact and enrollment information, contact TROOPS staff by phone at 240-234-0502 or via email at cnrmstudies@usuhs.edu

You will still receive all the medical care and benefits for which you are otherwise eligible. This will not affect your rights as a VHA patient.

HOW WILL MY CONTACT AND ENROLLMENT INFORMATION BE USED FOR FUTURE RESEARCH?

If you agree, your name, email, and phone number may be used by CNRM associated project researchers to contact you regarding future research studies. Enrollment date and status will be used by the TROOPS staff to estimate when you may have completed our study and be available to be contacted about other studies.

If you would like to be referred to these research studies through the CNRM participant referral program (TROOPS), please visit https://troops.cnrm.nih.gov
Allowing study staff to provide your name and contact information (email, phone number) to the TROOPS staff is voluntary. Please indicate your choice below.

With regard to sharing my contact information with TROOPS CNRM investigators and approved study staff:

☐ YES, I authorize the sharing of my contact and enrollment information with TROOPS staff.

I agree to the following future uses of my contact and enrollment information:

- Contacting me with study opportunities by phone or by email
- Only research about TBI
- Only CNRM funded or CNRM collaborating project researchers

☐ NO, I do not authorize sharing of my contact information with TROOPS staff.

Subject Name: _____ Date: _____

Title of Study: Supplemental Amino Acid Rehabilitative Therapy in TBI (SmART-TBI)

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Principal Investigator (Researcher): Miranda Lim, MD, PhD ICF Version Date: 11-22-2022

Signature

A study team member has explained the banking of my contact and enrollment information for future research to me and answered all of my questions. I have been told of the risks and/or discomforts and possible benefits of the banking.
I have been told that I may refuse permission for banking of my contact and enrollment information for future research and that refusal will involve no penalty or loss of VHA or other benefits to which I am entitled.

In case there are problems or questions, I have been told I can call Dr. Miranda Lim at 503-220-8262 x57404

My signature below indicates that I have read, or had read to me, all of the above information about the banking of contact and enrollment information, and my rights as a research subject have been explained to me.

By indicating YES above, I voluntarily authorize my contact and enrollment information to be stored in a repository and used for future research, as described in this form. I have been told that I will receive a copy of this consent form.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____
Printed Name of Person Obtaining Consent

_____ _____ _____
Signature of Person Obtaining Consent Date Time