

COVER PAGE: Study Informed consent and HIPPA Informed Consent

IRB Study Informed Consent APPROVAL: 06 February 2025 (most recent amendment);
original document approval 06 March 2024.

IRB HIPPA APPROVAL: 06 March 2024

Study Title: Characterizing the effects of Leukocyte-platelet-rich fibrin on sleep and
perceived quality of life on mucogingival periodontal surgery healing.

NCT #: NA

Meets 2018 Common Rule Requirements

59th Medical Wing

CONSENT TO PARTICIPATE IN RESEARCH

Title: Characterizing the effects of leukocyte-platelet-rich fibrin on sleep and perceived quality of life on mucogingival periodontal surgery healing

Principal Investigator: David L Seiler, DDS/ Capt USAF

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

Please take time to carefully review this information. 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 potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

Participation in this study is entirely voluntary, and you have the right to withdraw your consent at any time without providing a reason. Withdrawal from the study will not affect your relationship with the investigators or any medical care you may receive.

The purpose of this research study is to investigate the potential influence of leukocyte-platelet rich fibrin (L-PRF) applied at the palatal harvest site on sleep patterns, perceived quality of life, and the healing process following mucogingival periodontal surgery. By exploring these factors, the study seeks to advance our understanding of tissue healing mechanisms and potentially improve surgical outcomes for subjects undergoing mucogingival surgery. Mucogingival surgery involves taking your own tissue from the roof of your mouth and placing it in another location to enhance esthetics, tissue thickness, or root coverage. It will require sutures to hold the graft harvest in place during the healing phase.

There will be two groups in this study. One group will receive the application of L-PRF at the palatal harvest site, while the other group will receive a substance to help prevent/stop bleeding from the bleeding site (hemostatic agent). L-PRF is made from your own blood and provides beneficial growth factors to aid in tissue healing.

This study will last a maximum of 3 weeks (3-7 days of sleep monitoring prior to surgery, and two weeks of sleep monitoring post-surgery). This study will require the use of a sleep monitoring device for a three-week timeframe as well as the completion of quality of life questionnaires.

By participating in this study, you may not directly benefit from the procedures being investigated. However, the findings from this research may contribute to a better understanding

of the factors influencing tissue healing after mucogingival surgery. Additionally, the use of L-PRF may potentially enhance the healing process and improve surgical outcomes for future subjects.

Risks May include:

- Discomfort and Pain: Mucogingival surgery and blood draws may cause some temporary discomfort and pain.
- Bruising or Swelling: There is a possibility of experiencing bruising or swelling at the surgical site and/or blood draw site.
- Infection: Although all efforts will be made to maintain a sterile environment, there is a slight risk of infection associated with any surgical procedure.
- Graft Failure: In the context of mucogingival surgery, the use of grafts, including L-PRF, and autogenous tissue from the palate carries a risk of graft failure. Despite careful planning and technique, there is a possibility that the graft may not integrate successfully or provide the desired outcome. If graft failure occurs, additional treatment or procedures may be necessary to address the issue.
- Data Breach: While measures will be taken to protect your personal information, there is a minimal risk of a data breach that could lead to the unauthorized access of your data.

Alternative procedures or courses of treatment include no treatment, use of suture at palatal harvest site, or the use of cyanoacrylate at the palatal harvest site.

This study requires use of a mobile application on your phone that is managed by a vendor not associated with the DoD. Before you download the app, please review the vendor terms of agreement and privacy policy. Information about the sleep monitoring device can be found at these links, <https://sleepimage.com/about-sleepimage/> <https://sleepimage.com/wp-content/uploads/Introduction-to-SleepImage.pdf>. The data you provide may be collected and used by the SleepImage App (<https://sleepimage.com>) according to its terms of agreement and/or user privacy agreement.

<https://sleepimage.com/wp-content/uploads/Terms-of-Use.pdf>
<https://sleepimage.com/wp-content/uploads/Privacy-Policy.pdf>

Your decision will not affect your future care at the Air Force Postgraduate Dental School (AFPS). 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 in all sections of the consent form, including the risks and possible benefits to you.

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

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 been diagnosed with a mucogingival defect (gum deficiency) which may benefit from a tissue graft procedure. The purpose of this research study is to learn about the effects of leukocyte-platelet-rich fibrin on

sleep and perceived quality of life on mucogingival periodontal surgery healing. The duration of participation per visit is approximately two hours for initial eval, three hours for surgical procedure, five minutes at 24 hour and 72 hr for questionnaire completion, 30 minutes for post-operative appointments (1-week and 2-week) and 1 minute sleep device activation nightly.

There will be about 80 people taking part in the study at AFPDS, over a period of 1.5 years

During the study, you will have about four visits with a periodontics resident at the Air Force Postgraduate Dental School (AFPDS). You may need to return to AFPDS in case of complications.

This study is looking at leukocyte and platelet rich fibrin (L-PRF) which is a growth factor rich fibrin clot that is extracted from subjects of bloods that may aid in tissue healing. L-PRF has been well-studied but further investigation is required before determining its specific clinical effect. This means that L-PRF is considered experimental for the treatment of the palatal harvest site for a mucogingival surgery.

At the end of this research study the clinical results, including research results will not be shared with you without request. You will be eligible to receive your own medical records and sleep data as well as a copy of the final report of the complete study.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, an initial exam will be required and the subject must provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process". These tests may have been done or this information collected as a part of your regular medical care.

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

After you sign informed consent, you will complete a pre-surgical quality of life (QoL) survey, and download the SleepImage smartphone app. You will be briefed on how to use the sleep monitoring device and will record at least 3 nights of sleep prior to surgery. On the day of surgery, you will be randomly assigned to one of two groups. Randomization is a process like flipping a coin and means you will have a chance of being assigned to either of the groups.

One group will receive the application of L-PRF at the palatal harvest site, while the other group will receive a hemostatic agent. Subjects receiving L-PRF will have a needle placed in a vein in their arm to extract 40 mL of blood prior to the start of the procedure. Vials of blood will be centrifuged and the L-PRF membrane will be applied at the harvest site. The catheter will be removed after the procedure.

At 24 and 72 hours after surgery, you will complete the same QoL survey through a Qualtrics survey. You will continue to monitor your sleep with the SleepImage ring for two weeks after the surgery. It is very important that you activate the sleep monitoring device via your smartphone each night prior to going to bed and deactivate the monitoring system when you

wake up. At the one-week and two-week follow up visit, you will complete the same QoL surveys. At the two-week follow up appointment, you will return the SleepImage ring to your provider. If the device is misplaced or damaged during the trial, the study will cover the cost of replacement. At the final post-operative appointment, PIs will assist you in removing the application from their smart phone.

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:

Venipuncture Complications: 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.

Graft failure: The mucogingival graft may fail to incorporate and provide the desired outcome of the procedure, such as root coverage or thickening of the tissue.

Infection: Every time a subject undergoes surgery there is a small likelihood of post-operative infection. It is very important to follow all of the provider's post-operative instructions.

Palatal tissue necrosis: The tissue on the roof of your mouth may die and slough off due to lack of oxygen and blood supply.

L-PRF failure: the L-PRF may not provide pain relief during healing phase.

Confidentiality Complications: 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. Subjects will create a SleepImage account with their personal email, date of birth, and first/last name which will generate an unidentifiable subject number, which will be tracked in a secured file (Master Key of identifiable PII) accessible only by the PIs.

SleepImage Ring may cause irritation or disruption of normal sleeping patterns.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?:

By participating in this study, you may not directly benefit from the procedures being investigated. However, the findings from this research may contribute to a better understanding of the factors influencing tissue healing after mucogingival surgery. Additionally, the use of L-PRF may potentially enhance the healing process and improve surgical outcomes for future subjects.

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

There may be other options for pain reduction and healing at the palatal harvest site. Alternative treatments and/or procedures that may be available to you include: the use of sutures or

cyanoacrylate at the palatal harvest site. You should talk with your personal dentist (if applicable) about these options. Choosing not to take part in this research study is also an option.

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

Capt David L. Seiler DDS

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

As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

10. SOURCE OF FUNDING:

Funding for this research project is provided by Clinical Investigations and Research Support at 59th Medical Wing, JBSA-Lackland, TX.

11. LOCATION OF THE RESEARCH:

Air Force Postgraduate Dental School at JBSA Lackland, TX

12. 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/Portals/54/Documents/DD/forms/dd/dd2005.pdf>

The research team will keep your research records. These records may be looked at by staff from the AFPDS, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: a master key of subject information only accessed by primary investigators. Unidentifiable study number given to each subject at the start of the study.

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

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.

Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

13. 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. Identifiers may be removed, and de-identified information may or may not be used or shared for future research. You have a number of options with regard to this request. You may choose either to not allow any further use of your data, or allow use of only de-identified data.

☐ I give permission to use my only de-identified data for future research studies

☐ I do not give permission to use my data for future research studies

This future research may be in the same area as the original study or it may be for a different kind of study.

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.

14. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see 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.

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.

- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

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.

15. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means 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 or loss of benefits to which you are otherwise entitled.

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.

16. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must notify the Principal Investigator and return the sleep monitoring device. If you do not follow these procedures, you may be contacted for retrieval of government property.

If you are receiving treatment as part of this research study, treatment may still be rendered as needed.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the Principal Investigator as discussed in the HIPAA Authorization Form.

The Principal Investigator of this research study may terminate your participation in this research study at any time if it is determined to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

At the final post-operative appointment, PIs will assist each subject in removing the application from their smart phone.

17. 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 immediately using the contact information in the section below.

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.

18. 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.

Principal Investigator: David L. Seiler

Phone: 636-236-7036

Mailing Address:

2133 Pepperrell St.

San Antonio, TX 78236

59th Medical Wing Human Research Protection Program (HRPP) Office

The Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Administrator/HRPP POC: Ms. Jessica Mercado

Phone: 210-292-2977

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:

SA IRB Office: Brooke Army Medical Center
ATTN: MCHE-ZQ, Department of Quality and Safety
3551 Roger Brooke Drive
Fort Sam Houston, Texas 78234-6315
Phone: 210-916-2598

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.

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

Printed Name of Participant

Signature of Participant

Date

Printed Name of Administering Individual

Signature of Administering Individual

Date

**AUTHORIZATION TO USE OR DISCLOSE
HEALTH INFORMATION THAT IDENTIFIES
YOU FOR A RESEARCH STUDY**

C.2024.040

Principal Investigator (PI) Name and Rank: David L. Seller, Capt

Corps and Service/Organization: Air Force 59th Medical Wing

Title of Research Study: Characterizing the effects of leukocyte-platelet-rich fibrin on sleep & perceived quality of life on mucogingival periodontal surgery healing

I. Purpose of this Document

An Authorization is your signed permission to use or disclose your health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by the Department of Defense (DoD), permits the Military Health System (MHS) to use or disclose your health information with a valid Authorization. The MHS is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force. A valid Authorization must include the core elements and required statements as contained in this document.

Please read the information below and ask questions about anything you do not understand before deciding to give permission for the use and disclosure of your health information.

II. Authorization

The following describes the purposes of the requested use and disclosure of your health information:

In order to analyze the healing process at the palatal harvest site following mucogingival surgery, all pertinent medical history will be obtained for patient safety and surgical considerations. Additionally, sleep patterns and sleep quality will be recorded to determine any effect of the use of L-PRF.

A. What health information will be used or disclosed about you?

If you agree to participate in this study, the members of the study will access your medical record for information that will ensure you meet the criteria of the study. This is to ensure that you do not have any medical conditions that may impact the results of the study. Additional health information will include names, telephone numbers, email addresses, medical record numbers, device identifiers, DoD ID, and medical history associated with your condition.

B. Who will be authorized to use or disclose (release) your health information?

The Military Treatment Facilities (MTFs) where you have received care will use and disclose your health information for the purposes of this study.

**AUTHORIZATION TO USE OR DISCLOSE
HEALTH INFORMATION THAT IDENTIFIES
YOU FOR A RESEARCH STUDY**

C.2024.040

C. Who may receive your health information?

- The Principal Investigator and research study team
- The San Antonio Institutional Review Board
- The Brooke Army Medical Center Human Research Protections Office representatives
- Military Health System (MHS) representatives
- State and Federal Government representatives, when required by law

D. What if you decide not to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you will not receive research-related treatment.

The MHS **will not** condition (withhold or refuse) treatment that is not part of this study, payment, enrollment, or eligibility for benefits on whether you sign this Authorization.

E. Is your health information requested for future research studies?

Yes, your health information is requested for future research studies as specified below:

Future studies relating to sleep, L-PRF, or QoL may be continued by other residents of the AFPDS.

Your health information will not be used for future research studies unless you give your permission by initialing your choice below:

_____ I give permission to use my health information for future research studies

_____ I do not give permission to use my health information for future research studies

F. Can you access your health information during the study?

You may have access to your health information at any time, unless your identifiers are permanently removed from the data.

G. Can you revoke this Authorization?

- You may change your mind and revoke (take back) your Authorization at any time. However, if you revoke this Authorization, any person listed above may still use or disclose any already obtained health information as necessary to maintain the integrity or reliability of this research.
- If you revoke this Authorization, you may no longer be allowed to participate in this research study.
- If you want to revoke your Authorization, you must write to:

Capt David Seller
2133 Pepperrell St
San Antonio, TX 78236

**AUTHORIZATION TO USE OR DISCLOSE
HEALTH INFORMATION THAT IDENTIFIES
YOU FOR A RESEARCH STUDY**

C.2024.040

H. Does this Authorization expire?

No, it does not expire

I. What else may you want to consider?

- No publication or public presentation about the research described above will reveal your identity without another signed Authorization from you.
- If all information that does or can identify you is removed from your health information, the remaining de-identified information will no longer be subject to this Authorization and may be used or disclosed for other purposes.
- In the event your health information is disclosed to an organization that is not covered by HIPAA, the privacy of your health information cannot be guaranteed.

**AUTHORIZATION TO USE OR DISCLOSE
HEALTH INFORMATION THAT IDENTIFIES
YOU FOR A RESEARCH STUDY**

C.2024.040

Signature of Research Participant or Personal Representative:

Your signature acknowledges that:

- You authorize the MHS to use and disclose your health information for the research purposes stated above.
- You have read (or someone has read to you) the information in this Authorization.
- You have been given a chance to ask questions, and all of your questions have been answered to your satisfaction.

Participant Signature

Date

Participant Printed Name

**AUTHORIZATION TO USE OR DISCLOSE
HEALTH INFORMATION THAT IDENTIFIES
YOU FOR A RESEARCH STUDY**

C.2024.040

Principal Investigator (PI) Name and Rank: David L. Seiler, Capt

Corps and Service/Organization: Air Force 59th Medical Wing

Title of Research Study: Characterizing the effects of leukocyte-platelet-rich fibrin on sleep & perceived quality of life on mucogingival periodontal surgery healing

I. Purpose of this Document

An Authorization is your signed permission to use or disclose your health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by the Department of Defense (DoD), permits the Military Health System (MHS) to use or disclose your health information with a valid Authorization. The MHS is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force. A valid Authorization must include the core elements and required statements as contained in this document.

Please read the information below and ask questions about anything you do not understand before deciding to give permission for the use and disclosure of your health information.

II. Authorization

The following describes the purposes of the requested use and disclosure of your health information:

In order to analyze the healing process at the palatal harvest site following mucogingival surgery, all pertinent medical history will be obtained for patient safety and surgical considerations. Additionally, sleep patterns and sleep quality will be recorded to determine any effect of the use of L-PRF.

A. What health information will be used or disclosed about you?

If you agree to participate in this study, the members of the study will access your medical record for information that will ensure you meet the criteria of the study. This is to ensure that you do not have any medical conditions that may impact the results of the study. Additional health information will include names, telephone numbers, email addresses, medical record numbers, device identifiers, DoD ID, and medical history associated with your condition.

B. Who will be authorized to use or disclose (release) your health information?

The Military Treatment Facilities (MTFs) where you have received care will use and disclose your health information for the purposes of this study.

**AUTHORIZATION TO USE OR DISCLOSE
HEALTH INFORMATION THAT IDENTIFIES
YOU FOR A RESEARCH STUDY**

C.2024.040

C. Who may receive your health information?

- The Principal Investigator and research study team
- The San Antonio Institutional Review Board
- The Brooke Army Medical Center Human Research Protections Office representatives
- Military Health System (MHS) representatives
- State and Federal Government representatives, when required by law

D. What if you decide not to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you will not receive research-related treatment.

The MHS **will not** condition (withhold or refuse) treatment that is not part of this study, payment, enrollment, or eligibility for benefits on whether you sign this Authorization.

E. Is your health information requested for future research studies?

Yes, your health information is requested for future research studies as specified below:

Future studies relating to sleep, L-PRF, or QoL may be continued by other residents of the AFPDS.

Your health information will not be used for future research studies unless you give your permission by initialing your choice below:

_____ I give permission to use my health information for future research studies

_____ I do not give permission to use my health information for future research studies

F. Can you access your health information during the study?

You may have access to your health information at any time, unless your identifiers are permanently removed from the data.

G. Can you revoke this Authorization?

- You may change your mind and revoke (take back) your Authorization at any time. However, if you revoke this Authorization, any person listed above may still use or disclose any already obtained health information as necessary to maintain the integrity or reliability of this research.
- If you revoke this Authorization, you may no longer be allowed to participate in this research study.
- If you want to revoke your Authorization, you must write to:

Capt David Seiler
2133 Pepperrell St
San Antonio, TX 78236

**AUTHORIZATION TO USE OR DISCLOSE
HEALTH INFORMATION THAT IDENTIFIES
YOU FOR A RESEARCH STUDY**

C.2024.040

H. Does this Authorization expire?

No, it does not expire

I. What else may you want to consider?

- No publication or public presentation about the research described above will reveal your identity without another signed Authorization from you.
- If all information that does or can identify you is removed from your health information, the remaining de-identified information will no longer be subject to this Authorization and may be used or disclosed for other purposes.
- In the event your health information is disclosed to an organization that is not covered by HIPAA, the privacy of your health information cannot be guaranteed.

**AUTHORIZATION TO USE OR DISCLOSE
HEALTH INFORMATION THAT IDENTIFIES
YOU FOR A RESEARCH STUDY**

C.2024.040

Signature of Research Participant or Personal Representative:

Your signature acknowledges that:

- You authorize the MHS to use and disclose your health information for the research purposes stated above.
- You have read (or someone has read to you) the information in this Authorization.
- You have been given a chance to ask questions, and all of your questions have been answered to your satisfaction.

Participant Signature

Date

Participant Printed Name