STUDY TITLE: Adjustment Disorders in the US Military: Disease Trajectories and ADNM-20-Mil Validation
NCT NUMBER: NCT06885554
IRB NUMBER: USUHS.2024-132
DOCUMENT: Adjustment Disorder Screening Tool Validation and Treatment Device Study Informed Consent Form
DOCUMENT DATE: 04/02/2025

Uniformed Services University of the Health Sciences
CONSENT TO PARTICIPATE IN RESEARCH
Title: *Adjustment Disorders in the US Military:*
Disease Trajectories and ADNM-20-Mil Validation
Adjustment Disorder Screening Tool Validation and Treatment Device Study
Principal Investigator: *Jouhayna Bajjani-Gebara, PhD, MHSC, MSN, PMHNP-BC*

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:

Faculty at the Uniformed Services University of the Health Sciences in conjunction with military healthcare providers at your local military treatment facility are conducting this study to learn about adjustment disorders in military populations. It is the most frequently diagnosed mental health problem in military populations, but little research has been conducted on it. There are also challenges associated with diagnosing and assessing adjustment disorders, and we aim to help provide insight on the diagnosis and assessment processes.

You are being asked to take part in this research study because you are an active duty service member who has been diagnosed with an adjustment disorder and are over the age of 18. About 60 service members will participate in this study over a 3-year period.

If you choose to participate in this research study, you may or may not be asked to use a device called Sana that is an electronic eye mask that might reduce symptoms commonly found in adjustment disorder. All participants in this research study will be asked to use a device called Empatica that is a wristband that monitors your heat rate, electrodermal activity, and sleep disturbance. You will be asked to wear Empatica or Empatica and Sana for a total of 28 days and use a smartphone application ("app") for Empatica on your own personal phone or tablet.

In addition to device use, this study involves completing four sets of online and three sets of audio (voice) recorded phone assessments about stressful events and/or mental health symptoms from now through 6 months from now. Each set of online assessments will take about 10-20 minutes to complete, total, and each set of audio (voice) recorded phone assessments will take

about one hour to complete, total. This research study will also use mental health diagnostic and treatment information from your electronic health record.

If you choose to participate in this study, your current treatment for adjustment disorder symptoms and/or other mental health conditions or symptoms should remain about the same throughout the study and, if you are a person who can get pregnant, you must not be pregnant at this time and not intend to become pregnant during participation in this study. If you do become pregnant, we will need to withdraw you from the study, and we may contact you to learn the pregnancy outcome after you have been withdrawn from the study.

The primary risk associated with participation in this study is the potential for you to be uncomfortable, embarrassed, or distressed while answering the assessments and/or using the device(s). You will have the option to skip any questions you are uncomfortable answering and stop use of the device(s) at any time. If you become distressed while completing the assessments or using the device, you can contact your local study team for help. If your need is more urgent, you can contact the Military Crisis Line or your location's appropriate emergency response number.

Your decision will not affect your future care at your local military treatment facility. 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 are a US active duty service member with an adjustment disorder. The purpose of this research study is to develop a screening tool for adjustment disorder in military personnel and test the effectiveness of the Sana light device at reducing symptoms commonly found in adjustment disorder in military personnel.

The length of participation is six months. Each set of online assessments is estimated to take about 10-20 minutes of your time. Each set of audio (voice) recorded phone assessments is estimated to take one hour of your time. Device use will last for 28 straight days.

Engaged use for the Sana device is expected to take up to one hour of your day each day of that 28-day period. You will be asked to complete a short online questionnaire to record use of the Sana device each time you use the Sana device.

There is no engaged use for the Empatica Embrace device, but it is expected to be worn 23 hours 7-days per week (all hours of the day but those for charging the device) during the 28-day period. The Empatica device has a smartphone app that must be used with it. You will be asked to download and use this app on your own personal smartphone or tablet."

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There will be about 60 people taking part in this study overall. Enrollment will be evenly divided between 3-4 MTFs, with between 15-20 participants enrolled at each site over a period of about three years.

This research study involves an investigational device called Sana. This means that this device has not yet been approved or cleared by the Food & Drug Administration (FDA) for treating adjustment disorder or symptoms commonly found in adjustment disorder. However, the FDA has not objected to its use in this research study to learn more about its safety and/or effectiveness. This device is for RESEARCH PURPOSES ONLY.

At the end of this research study, the clinical results, including research results about you will not be shared with you.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to have some tests and 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. If you have received this form, that means that you have already been screened and determined to be eligible to participate in this study.

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

If you decide to participate in this research study, 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 involves wearing a device called Sana. Sana is an electronic eye mask that delivers pulses of light and sound that help to relax the person using it. It is worn twice daily for 22-minutes each session every day of the week for four weeks (28 days). Participants assigned to this group will also be asked to use a device called Empatica. Empatica is an electronic wristband that monitors heart rate, electrodermal activity, and sleep disturbances. Empatica is worn 23 hours per day every day of the week for four weeks (28 days).

WARNING LABEL: Sana should NOT be used by anyone who has a history of epilepsy or seizure disorder. It especially should NOT be used by anyone who has photosensitive epilepsy or seizures.

Sana is not approved for use in pregnant people because it has not yet been studied for use by people who are pregnant. If you are a person who can get pregnant, you must not be pregnant at this time and not intend to become pregnant during participation in this study. If you become pregnant during this study, you will need to immediately stop using the Sana and/or Empatica device and contact your usual health care provider and the study team. You will also be

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withdrawn from the study if you become pregnant and we may contact you to learn the pregnancy outcome after you have been withdrawn.

The other group involves wearing just Empatica, which is still to be worn 23 hours per day every day of the week for four weeks (28 days).

The Empatica device require use of a smartphone app on your own personal smart phone or tablet.

Both groups will also be asked to complete assessments about stressful events and/or mental health symptoms. Over a period of *six months*, we will ask you to complete these *:*

- four sets of online assessments (about 10-to-20 minutes to complete) and
- three sets of voice (audio) recorded assessments over the phone with a specially trained member of the study team (about one hour to complete).

You will be asked to complete these once at the start of your participation, a second time three months later, and the final (third) time three months after that. There will be one set of online assessments at the 1-month mark from start of study. Your electronic health record will also be used by the research study team to collect diagnostic and treatment information about your mental health.

For us to be able to collect the best information, it is best if you keep your usual treatment for adjustment disorder and/or other mental health conditions, such as anxiety or depression, the same throughout the study. We will check in with you at each visit about any changes in status of your treatment, such as the type and frequency of therapy and/or type and doses of prescription medications for your adjustment disorder and/or other mental health disorder. Please note that we will discuss with you if you are still eligible to stay in the study or not based on those changes.

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 feelings of discomfort, psychological or social stress, coercion, physical harm, and breach of confidentiality.

You may experience discomfort or stress with some of the assessment questions, or you may find some of the assessments make you feel anxious or stressed. You may also feel mildly embarrassed if you reveal something thought to be socially undesirable. However, you will have the option to skip or choose not to respond to any question and to withdraw from the study without penalty or loss of military benefit to which you are entitled at any time.

The Sana device has been designed so that it is customizable such that the user can change the level of administered light so that it is comfortable. However, there is always some risk to using a new device. You may feel uncomfortable or distressed by having to wear a device. However, you can discontinue your participation at any time.

Please stop Empatica and/or Sana device use if you have concerns about the safety of the device, or you feel unwell during or after its use and contact your doctor as soon as possible. You do not need to wait for the therapy session to end to stop device use. Also, please reach out to the study team to report this incident once you are feeling better.

Stopping use of Sana at the end of the study period could be also distressing if you have found it works for you.

You may also feel like you have to participate in this research study because you might have heard about it from your healthcare provider or someone in your chain of command. This research study is entirely voluntary and you should only participate in it if you want to.

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.

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

If you experience distress, discomfort, or harm at any time during the study, contact the study team via telephone at 301-295-1951. Research staff will be available during regular business hours (Monday to Friday, 8am-5pm EST). Correspondence will typically be answered in the same day. After hours correspondence will be answered within the next business day, whenever possible.

If your need is more urgent, you can contact the Military Crisis Line or your location's appropriate emergency response number.

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

If you are assigned to use the Sana device, you may directly benefit from use of the Sana device as it could improve symptoms commonly found in adjustment disorder. Additionally, as this study aims to validate a standard assessment tool to diagnose adjustment disorders in the active duty military population, this population will benefit from having a tool to diagnose adjustment disorders and this research study will contribute to broader scientific knowledge.

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

There may be other options for treating adjustment disorder. Alternative treatments and/or procedures that may be available to you include: psychotherapy and pharmacological therapy. You should talk with your personal physician (if applicable) about these options.

Choosing not to take part in this research study is also an option.

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There may be other research studies involving experimental treatments that could be helpful to your condition.

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

Yes, for your participation, you will receive up to a total of $370. You will be eligible to receive a $60 ClinCard for completion of all of the first set of assessments off duty hours, up to a $35 ClinCard (or card reload) each week of the 28-days device period (earning $5/day for device use as specified each day, to be paid out weekly), a $50 ClinCard (or card reload) for completion of all of the second set of assessments off duty hours and return of Sana and/or Empatica devices at the end of the device period, a $60 ClinCard (or card reload) for completion of all of the third set of assessments off duty hours, and a $60 ClinCard (or card reload) for completion of all of the fourth set of assessments off duty hours.

Note that federal personnel participating as human participants in DoD-conducted research while on-duty may not be compensated for general research participation. Subjects must complete research tasks during off-duty time in order to collect compensation.

Completion of all initial assessments	**Device use completion**				**Completion of all assessments at 3 months**	**Completion of all assessments at 6 months**	**Maximum total compensation**
$60	Maximum at 7days	Maximum at 14days	Maximum at 21days	Maximum at 28days	$60	$60	**$370**
	$35	$35	$35	$85 ($35+$50)			

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

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

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

Principal Investigator: Jouhayna Bajjani-Gebara, PhD, MHSC, MSN, PMHNP-BC
Address: Uniformed Services University of the Health Sciences, 4301 Jones Bridge Rd, Bethesda, MD 21211
Phone: 301-295-1116
Email: jouhayna.bajjani-gebara@usuhs.edu

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

This research study is funded by Military Operational Medicine Research Program (MOMRP) and is run by Uniformed Services University (USU) in conjunction with the Henry Jackson Foundation for the Advancement of Military Medicine (HJF). The Uniformed Services University of the Health Sciences is the sponsor of this study.

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

12. SOURCE OF FUNDING:

This research study is funded by an award from the Military Operational Medicine Research Program.

13. LOCATION OF THE RESEARCH:

Uniformed Services University of the Health Sciences
4301 Jones Bridge Rd
Bethesda, MD 20814

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are not any financial interests and/or other personal arrangements to disclose.

15. 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 members of the research team at your local military treatment facility and the Uniformed Services University of the Health Sciences as well as applicable Institutional Review Boards (IRBs), 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 will be taken to protect the confidentiality of the data in this study. After ensuring you have read and understand the information in this informed consent form, you will document your consent on this form for the study files. You will be assigned a study ID by the local research team. The study ID will be used to mask your personal information such as name and other identifiable information in research data, so research data will be identified by this study ID instead of your name or something else that could identify you. A master list linking your identifiable information such as your name with your study ID will be kept in a locked office and file cabinet or in a password-protected electronic database on a secure network. Only approved study personnel will have access to information that could be used to distinguish or trace an individual's identity.

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

If applicable, 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 results. You can search this Web site at any time.

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. This may include information regarding your pregnancy status and any indication of suicidal ideation.

Only those with a need-to-know will have access to your data. The local research team at your military treatment facility will only have access to data they help to collect—that can include information from eligibility screenings, online assessments, and your electronic health records. The primary research team at the Uniformed Services University of the Health Sciences will have access to all of your data from the research study. There are also some specialty data analysts at institutions outside of those already listed that may have access to your data. Sana will not have access to any of your study data. Empatica will have information from the app but will not be allowed to retain or use any of your study data. All of your data collected from Empatica will be transferred to the Uniformed Services University of the Health Sciences study team via a secure online method. Your data will be stored at all times on password-protected, encrypted government computers and accessible only by permitted users on the study team.

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.

16. LONG TERM USE OF DATA

The investigator has requested to save data collected from your participation in this research study for possible use in future research. The data that will be saved for future use will not include identifying information such as your name, phone number, or address.

You may either choose to not allow any further use of your data or give consent now for the use of your data to be used in future studies. This future research may be in the same area as the original study or it may be for a different kind of study. You will be provided choices at the end of this consent form to allow or deny use in future research studies.

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.

17. USE OF INFORMATION AND SPECIMENS

Although research that uses your data may lead to the development of new inventions, products, or discoveries (some that might be patented and licensed), there are no plans to share any potential profits with you.

While this study is on-going, your data will be handled in accordance with this study's protocol and applicable regulations at the Uniformed Services University of the Health Sciences.

Data that we obtain from you for this study might be used for future studies. We will remove anything that might identify you from the data. However, we are unable to do that with the audio-recorded voice data as your voice is considered identifiable. Thus, you will be provided choices at the end of this consent form to allow or deny use of your voice data in additional and/or future research for this reason. Data may also be given to another investigator and/or research institution without getting additional permission from you.

18. INCIDENTAL FINDINGS

You will be asked to complete assessments that are used as part of the diagnostic process for various mental health disorders. Thus, there is a possibility that while reviewing assessment results we may find something that we did not expect to see in this study. Upon completion of all online assessments, you will receive a list of mental health resources and will not be notified of

any incidental or unexpected finding. If you have any concerns after taking part in the assessments please contact your local health provider.

19. 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.

20. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must notify the USU Principal Investigator or your local study team via phone or email. If you do not follow these procedures, you may not be withdrawn from the study. If you decide to no longer participate in this research study, data that was collected up until you withdraw from the study may still be used in the analysis. If you do not wish for your data to be used, you must say that when you request to withdraw.

If you are using a device to reduce symptoms as part of this research study, you will no longer be eligible to continue to use that or other devices. Contact your personal physician to discuss medical treatment and/or symptom reduction for your condition.

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 or email to the USU 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 she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria. If you become pregnant, we will need to withdraw you from the study; after you have been withdrawn, we may contact you to learn the pregnancy outcome. Additionally, if you show risk of suicidal ideation, you will be withdrawn from the study and local emergency mental health services may be called.

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

If you think that you have a research-related injury, notify the Principal Investigator immediately using the contact information in the section below.

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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.

22. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) AUTHORIZATION TO USE OR DISCLOSE (RELEASE) HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY:

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: Information from your medical record and other information we collect related to your mental health will be used in this research study to help develop a tool to screen and diagnose adjustment disorders in active duty service members and to assess the effectiveness of Sana at reducing symptoms commonly found in adjustment disorder in active duty service members. Information we collect from you will be used for this study in the ways described in this document and for future research that has yet to be planned.

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

Information from your medical record will be used for this research study. This information includes diagnostic codes, demographic information such as your gender and race, and specific mental health diagnostic assessments such as the Generalized Anxiety Disorder-7 items (GAD-7) and Insomnia Severity Index (ISI). We will use this information without your name or other identifying information like your address or medical record number on it so that others who receive your information cannot identify you.

In addition to collecting personal health information from your medical record, we are going to ask you to complete standard mental health assessments online and over the phone. While the information we will collect online and over the phone is not your personal health information, it is information that could be diagnostic if it were asked by your healthcare provider, so we are going to treat it the same way we treat your protected personal health information. We will also use this information from these assessments without your name or other identifying information like your address or medical record number on it. However, voice recordings from the phone assessments may be identifiable because your voice is unique to you.

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

Military treatment facilities that have treated you in the last year will help to provide your health information from your medical record to us for the purpose of this research study.

The other information collected will be used for the sole purpose of this research study.

C. Who may receive your health information?

In addition to the research study team at your local military treatment facility and any research team member who is directly collecting data from you, the research study team at the Uniformed Services University of the Health Sciences will have access to your health information as well as:

- Data coordinating or analysis centers that will receive and process data
- Sponsors who want access to research data or who will actually own the research data, and/or
- Institutional Review Boards (IRBs) or Data Safety and Monitoring Boards.

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 <u>future</u> research studies?

Yes, your health information *<u>is</u>* requested for future research studies as specified below:

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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:

  Principal Investigator: Jouhayna Bajjani-Gebara, PhD, MHSC, MSN, PMHNP-BC
  Address: Uniformed Services University of the Health Sciences, 4301 Jones Bridge Rd, Bethesda, MD 21211
  Phone: 301-295-1116
  Email: jouhayna.bajjani-gebara@usuhs.edu

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.

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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.

23. CONTACT INFORMATION:

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

Principal Investigator: Jouhayna Bajjani-Gebara, PhD, MHSC, MSN, PMHNP-BC
Address: Uniformed Services University of the Health Sciences, 4301 Jones Bridge Rd, Bethesda, MD 21211
Phone: 301-295-1116
Email: jouhayna.bajjani-gebara@usuhs.edu

Uniformed Services University of the Health Sciences Human Research Protection Program Office
The Human Research Protection Program (HRPP) 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.

HPA/HRPP POC: Petrice Longenecker, PhD, MA, CIP
Phone: (301) 295-3303

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at: (301) 295-3303 or 4301 Jones Bridge Road, Room A2051, Bethesda, MD 20814.

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.

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SIGNATURE OF PARTICIPANT

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

Long-Term Use of Data

Please indicate if you do or do not give permission to have your data from this study used for future research:

○ I give permission to have my data used in future research

○ I do not give permission to have my data used in future research

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

(USUHS) IRB 1
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