Defense and Veterans Center for Integrative Pain Management (DVCIPM) Pain Registry Biobank

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WALTER REED NATIONAL MILITARY MEDICAL CENTER (WRNMMC)
BETHESDA, MARYLAND

This consent form is valid only if it contains the IRB stamped date

Consent for Voluntary Participation in a Research Study Entitled:

Pain Registry Biobank

Principal Investigator:

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Attending Anesthesiologist, WRNMMC
Program Director, Defense and Veterans Center for Integrative Pain Management (DVCIPM)
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Current Duty Station: USUHS/WRNMMC

Study site: __WRNMMC, __ FBCH, __USUHS, ___WRAIR, ___NMRC, ___JPC, OTHER:

List OTHER study sites:

_____

1. INTRODUCTION OF THE STUDY

Researchers at Walter Reed National Military Medical Center (WRNMMC) are creating a new research resource called a Pain Registry Biobank. People who take part in this Pain Registry Biobank study will give samples of blood and/or spit, also known as saliva. They will fill out surveys that ask questions about their health, and allow the Pain Registry Biobank researchers to see their medical records now and in the future. This Pain Registry Biobank will be a warehouse of data that many researchers will use to study pain.

You are being asked to be in this study because you are receiving care at WRNMMC. Being in this study is voluntary. You may choose to be in or not be in the study. If you decide to be in this study, you may leave the study at any time. No matter what you decide, there will be no penalty to you and you will not lose any of the benefits you already have. Leaving the study will not affect your medical care. Please read the information below, and ask questions.

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.

The Pain Registry Biobank study is taking place at the WRNMMC, Madigan Army Medical Center (MAMC), Naval Medical Center San Diego (NMCSD) and Uniformed Services University. It is funded by the Uniformed Services University of the Health Sciences (USUHS) under the Henry M. Jackson Foundation's (HJF) Defense & Veterans Center for Integrative Pain Management (DVCIPM) program. DVCIPM is a HJF Program.

2. PURPOSE OF THE STUDY

This study will create and build the Pain Registry Biobank, which will be used to do research in the future. A Pain Registry Biobank will allow many researchers to do studies using the data and blood/saliva samples, while lowering the number of participants needed to complete all of these studies. If you agree to be in this study, you will be giving us permission to use the data and blood/saliva samples that we collect from you and use it for future research studies. Your blood samples may be used for genetic testing, including whole genome sequencing to study the composition and functioning of genes and their correlation with medically relevant conditions and characteristics. Before any researchers use your data and samples for future studies, the information that can identify you (like your namé) is removed. We do not know what these research studies will be right now, they will be decided in the future.

3. PROCEDURES TO BE FOLLOWED

If you agree to be in this study you will be asked to do the tasks listed below on.

- Day 1
- Sometime between Month 1 and 3
- Sometime between Month 6 and 9
- Sometime between Month 12 and 15
- Yearly as long as you are eligible for military health care

On Day 1, we will ask you to **allow the Pain Registry Biobank to review your medical records.** In your medical records, we will look at email, telephone number, age, height, weight, body mass index (BMI), (a measure of body fat based on your height and weight), active duty status, veteran status, most recent rank, branch of service, length of service, combat deployment history, sex, American Society of Anesthesiologists, (ASA) status, (ASA status is a classification system used to describe a patient's condition before surgery), dependent, service-connected/disability rating, brain injury history, past medical and mental health history, current medical conditions, past social history, past surgical history, to include anesthesia medications, prescription medication history to include opioids and pain treatments, current surgery, future visit dates Some of this information you might report to us. Some of the information we might get through a data transfer. A data transfer from the electronic health record system to DVCIPM's database. We will review your medical records for this information at each of the time points listed above.

On Day 1 and all other times we contact you, we will ask you do these three tasks:

1. Fill out health surveys

These surveys will ask you questions about you and your pain, sleep, mood, depression, anxiety, health, physical activity, and well-being. The surveys can be done using a computer tablet. A research staff member will help set you up. Answering all questions can take up to 20

minutes. If you are currently completing these surveys for standard of care, we may pull the data from the completed assessments.

2. Give a blood sample (approximately 3 tablespoons)
Your blood contains biomarkers and hormones. Researchers are very interested in studying these biomarkers. A research nurse, or other person trained in drawing blood, will draw your blood in a private space, or, if you are having a clinical blood draw, we will provide the research blood tubes, and your blood will be drawn at the same time. The initial blood draw is required and all subsequent blood draws are optional.

3. Give a saliva sample
The sample will be collected by trained research staff. You will be asked to guide your saliva into a saliva collection container aid, up to 10 ml. A saliva sample is optional. You can take part in this study without providing a saliva sample. You will be asked at the end of this consent form whether or not you agree to provide saliva samples.

The DVCIPM research team will monitor your appointment schedule and meet you at a follow up clinic appointment at the time points listed above. The DVCIPM research team will note your preferred method of contact, either e-mail, text or phone. We will contact you two weeks prior to your scheduled follow up time point.

If you are not coming back to a study site, a site where the study is being done, you will be asked to do the health surveys online. The Pain Registry Biobank team will email or text you instructions on how to do the online surveys. A study staff member will follow up with you to see if you need any help to fill out the surveys. If you choose to receive survey reminders using text messages, depending on your mobile device provider, data and messaging rates may apply. If you cannot do the surveys online, a research staff member can call you to ask you the survey questions on the phone. If you are not returning toa study site, we will not collect blood or saliva samples.

All procedures in this study are being done for research purposes only.

Blood/Saliva Sample Storage:

a. You will be assigned a code number, also known as the "study ID number." It will not be your name or DoD ID number. The study ID number will be used to label your blood and saliva samples, and also your survey answers and any clinical information we get from your medical record. The only connection between your study ID number and your name will be kept in double-locked secure files, and on a password-protected secure database. Only DVCIPM study staff will have access to the master link.
b. Your blood and saliva samples will be stored at the Center for Neuroscience and Regenerative Medicine (CNRM) Biorepository, and could be inspected by CNRM, USUHS, or HJF oversight compliance committee. CNRM is a USUHS/HJF program. WRNMMC regulatory personnel could also inspect the biobank. All samples will be kept in a secured (locked) freezer and identified only by codes. Only researchers within DVCIPM/CNRM or associated with DVCIPM may have access to the samples and related

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

c. DVCIPM has created an Oversight Committee to decide the best, ethical use of these data and samples. Meaning, if any researchers want to use the data and samples from the Pain Registry Biobank, they first have to get approval by the Oversight Committee.
d. If you are taking part in the DVCIPM CHIRP protocol, and you agree, we will transfer your data and left over blood to this Biobank. At the end of this consent, we will ask you to indicate whether or not you agree to this transfer of data and samples.

4. ALTERNATIVE TO PARTICIPATION

Choosing to not be in this study is your alternative to be in this study. No matter what you decide, you will get the same medical treatment.

5. AMOUNT OF TIME FOR YOU TO COMPLETE THE STUDY

The Pain Registry Biobank is a resource meant to help advance pain research and treatment for many years. There is no plan to end the Pain Registry Biobank. By being in this study, you are agreeing to be a part of the ongoing Pain Registry Biobank research indefinitely, or as long as you are eligible for military health care. Your data and sample donation will let researchers answer important questions on pain. For your part, answering surveys will take about 20 minutes each time they are completed. Each blood and saliva collection draw will take about 5 minutes.

6. NUMBER OF PEOPLE THAT WILL TAKE PART IN THIS STUDY

We expect to enroll 300 participants in this study per year for each study site (WRNMMC, MAMC, NMCSD, and USUHS) for a total of 1200 participants each year.

7. POSSIBLE RISKS AND DISCOMFORTS FROM BEING IN THIS STUDY

We do not believe you will have any health risks by being in this study. But, outlined below are some discomforts or risks that could occur.

- There may be some discomfort from having your blood drawn, and you may feel some pain, swelling, and bruising at the site of the needle stick. Some people feel dizzy or light-headed for a few minutes after blood is drawn.
- There is a possible risk that your personal information could be exposed. To minimize this risk, data records will be coded and stored on a secure and password-protected computer database and in locked file cabinets in a locked file room. Access to these records will be limited to the Pain Registry Biobank study staff.
    - As part of the analysis on your samples, the investigators will do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, and reactions to medication and responses to treatment. Genetic research raises certain questions about informing you of

any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is treatment or cure for a particular disease.

- A new Federal law, called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:
- Health insurance companies and group health plans may not request your genetic information that we get from this study.
- Health insurance companies and group health plans may not use your genetic information when making decisions about 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.
- All health insurance companies and group health plans and all employers with 15 or more employees must follow this law, dated 21 May 2010.
- GINA's health insurance protections do not apply to members of the military who receive their healthcare through TRICARE and for veterans who receive their healthcare through the Veterans' Administration. While GINA's employment protections do not apply to military members and Federal employees, presently an Executive Order protects federal employees from genetic discrimination in employment, and the military has its own policies in place that may protect against genetic discrimination. GINA's protections should apply to a military member once he or she leaves the service.
- Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance or higher rates for these kinds of insurance.

8. POSSIBLE BENEFITS FROM BEING IN THIS STUDY

You will not benefit from being in this study, but the information we learn from your data and samples may help us better understand pain and the best treatments for pain in the future.

9. CONFIDENTIALITY/PRIVACY OF YOUR IDENTITY AND YOUR RESEARCH RECORDS

The Principal Investigator will keep your study data. Staff from the WRNMMC Department of Research Programs, the WRNMMC Institutional Review Board, the DoD Higher Level Review, USUHS and HJF regulatory personnel, and other government agencies, such as US Army Medical Research and Materiel Command, may look at your study data as part of their duties.

These duties include making sure the study participants are protected. Confidentiality of your information will be protected to the extent possible under current regulations and laws but cannot be guaranteed. Complete confidentiality cannot be promised, including for military personnel, because important information about your health may need to be reported to appropriate medical or command authorities. Your study records may be disclosed outside of WRNMMC, but in this case, only a unique code number will identify you. Information about the code will be kept in a secure location and access limited to approved study team members. By

signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational reasons, and used generally to advance medical science. You will not be personally identified; all information will be presented as de-identified data. Also, you give your permission to use your de-identified study data to be compared to de-identified data obtained in other future studies. So, your individual name or any other identifying information will not appear in any published paper or presentation related to this study in a way that could directly identify you.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA).

Procedures to protect the confidentiality of the data in this study include but are not limited to: all data collected from you will be associated with a study ID #, which is assigned to you upon entrance into the study. The list matching study participant ID numbers with the names of the participants, known as the master list, is kept separately from the main research database. This master list is kept locally on the WRNMMC hospital network. The master list is password protected, and access is only given to credentialed WRNMMC staff who are specifically trained and assigned to working on this protocol.

All data stored in the main research database is coded. Access to the database is restricted to authorized personnel only, who have completed the requisite training and are assigned to work on this research study. Study staff access the database using unique usernames and passwords; passwords must be changed every 3 months. Actions by study staff or study participants that modify study data, or actions to download data by study staff from the research database are automatically logged. Any paper forms containing Protected Health Information (PHI) or Personally Identifiable Information (PII) used in the study are kept in the DVCIPM offices, in a locked file cabinet within a locked file room.

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.

10. CONDITIONS UNDER WHICH YOUR PARTICIPATION IN THIS STUDY MAY BE STOPPED WITHOUT YOUR CONSENT

Your taking part in this study may be stopped without your consent if being in the study might be dangerous or harmful to you. Your taking part in this study may also be stopped without your consent if a military mission requires it, or if you lose your right to receive medical care at a military hospital.

The study investigator may also withdraw you from the study without your consent for one or more of the following reasons:

- The study is cancelled
- Other administrative reasons
- Unanticipated circumstances

11. ELIGIBILITY AND PAYMENT FOR BEING IN THIS STUDY

You are eligible if you:

- Are 18 years old or older
- Able to understand English

Eligible for healthcare within Military Health Systems

You will not receive any payment for being in this study.

12. COMPENSATION IF INJURED AND LIMITS TO MEDICAL CARE

You will not receive any compensation (payment) if you are injured as a direct result of being in this study. This is not a waiver or release of your legal rights. You should discuss this issue with the study investigator before you enroll in this study.

If you are injured as a result of being in this study, you will be given medical care for that injury at no cost to you.

Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for care at military hospitals and clinics). Necessary medical care does not include in home care or nursing home care. If you need to be hospitalized, you may have to pay the normal fees for subsistence (hospital meals), as per standard regulations.

If at any time you believe you have suffered an injury or illness as a result of being in this research study, you should contact the Human Protections Administrator, Department of Research Programs, at Walter Reed National Military Medical Center at 301-295-8239.

13. COSTS THAT MAY RESULT FROM TAKING PART IN THIS STUDY

Depending on your mobile device provider, data and messaging rates may apply if you choose to have a reminder text (with the survey link) sent. At the end of this consent, you will be asked to indicate whether or not you wish to receive text messages about this study.

14. IF YOU DECIDE TO STOP TAKING PART IN THIS STUDY AND THE INSTRUCTIONS FOR STOPPING EARLY

You have the right to leave the project at any time by contacting the Principal Investigator, Dr. Chester Buckenmaier, or one of his designees at:

Chester C. Buckenmaier III, MD,
Attending Anesthesiologist, WRNMMC
Program Director, Defense and Veterans Center for Integrative Pain Management (DVCIPM)
Professor, Military Emergency Medicine, USUHS
Professor Anesthesiology, USUHS
cbuckenmaier@dvcipm.org
301-400-4228
11300 Rockville Pike, Suite 709 Rockville MD 20852

If you withdraw from this study, the research team will continue to use any data and samples that have already been collected. However, if you choose to withdraw, no new information will be collected from you or your medical records. You may also request to have any unused

samples or data destroyed. By leaving the study at any time, you in no way risk losing your right to medical care.

15. AUTHORIZATION FOR RESEARCH USE OF PROTECTED HEALTH INFORMATION
The Federal Health Insurance Portability and Accountability Act (HIPAA) includes a Privacy Rule that gives special safeguards to Protected Health Information (PHI) that is identifiable, in other words, can be directly linked to you (for example, by your name, Social Security Number, birth date, etc.). We must tell you how your PHI will be used.

(1) What information will be collected?
For this research study, we will be collecting information about your medical history, pain history, pain medication, inpatient and outpatient clinical notes, pain scores, medications, procedures, diagnosis codes and any other patient/provider contacts, along with your name, age, dates connected to your medical care, telephone number, email and postal address, DoD ID number, rank, and date of birth, electronic health record number.

(2) Who may use your PHI within the Military Healthcare System?
Pain Registry Biobank study staff members will have access to your health information to determine if you qualify to be in this study. If you decide to be in this study, they will also have access to your PHI in order to update your research information. Additionally, your PHI may be made available to other health oversight groups such as the WRNMMC Department of Research Programs and WRNMMC Institutional Review Board.

(3) What persons outside of the Military Healthcare System who are under the HIPAA requirements will receive your PHI?
Your PHI may be made available to USUHS and HJF regulatory oversight personnel.

(4) What is the purpose for using or disclosing your PHI?
The members of the research team need to use your PHI in order to track your research study participation and medical history.

(5) How long will the researchers keep your PHI?
There is no end date for this study to maintain your PHI. Since this study collects blood and saliva samples for storage in the Pain Registry Biobank, your samples and PHI will be maintained indefinitely. When the study does end the master list linking your personal identifying information with your study number will be destroyed three years after the end of the study and your study data will be destroyed five years after the end of the study.

(6) Can you review your own research information?
You will not be able to look at your research information.

(7) Can you cancel this Authorization?
Yes. If you cancel this authorization, however, you will no longer be included in the research study. The research data and samples collected prior to your request will not be able to be destroyed or withdrawn because they will already be among the statistics of the study. If you

want to cancel your HIPAA Authorization, please contact the Principal Investigator or Research Protocol Coordinator, in writing at:

Chester C. Buckenmaier III, MD, COL Retired
11300 Rockville Pike, Suite 709 Rockville MD 20852

(8) What will happen if you decide not to grant this Authorization?
If you decide not to grant this Authorization, you will not be able to be in this study. Refusal to sign this Authorization will not result in any loss of medical benefits to which you would otherwise receive.

(9) Can your PHI be disclosed to parties not included in this Authorization who are not under the HIPAA requirements?
There is a potential that your research information will be shared with another party not listed in this Authorization in order to meet legal or regulatory requirements. Examples of persons who may access your PHI include representatives of the DoD Higher Level Review, the Food and Drug Administration, the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP), and the DHHS Office for Civil Rights. This disclosure is unlikely to occur, but in that case, your health information would no longer be protected by the HIPAA Privacy Rule.

(10) Who should you contact if you have any complaints?
If you believe your privacy rights have been violated, you may file a written complaint with the WRNMMC Privacy Officer, located at 8901 Wisconsin Ave, Bethesda, MD 20889, Telephone: 301-319-4775.

(11) This authorization expires at the end of this research study.

(12) Your health information *is* requested for use or disclosure (release) in future research studies.

(13) 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 (released) for other purposes.
- Once your health information is shared or disclosed (released) outside of the MHS, the privacy of your health information cannot be guaranteed and it may no longer be protected by the Federal privacy laws (such as the HIPAA Privacy Rule).

Your signature at the end of this document acknowledges that you authorize DVCIPM personnel to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above. You will be given a signed copy

16. INCIDENTAL FINDINGS
There is a very rare possibility that while reviewing your test results a researcher may see an abnormality that they did not expect to see in this study. This is what we call an "incidental finding." We will not be reporting any incidental findings back to you .It is also rare that we would find evidence of overuse of medications. Should this occur, we will not report those findings back to you, or to your command.

17. CONTACTS FOR QUESTIONS ABOUT THE STUDY If you have questions about the study, or if you think you have a study-related injury you should contact the Principal investigator, Dr. Chester Buckenmaier, at 301-400-4228. For questions about your rights as a research subject, contact the Human Protections Administrator, WRNMMC Department of Research Programs in Building 17 at 301-295-8239 or WRNMMC Staff Judge Advocate Office at 301-295-2215.

By signing this consent form, you agree to participate in this research study, you understand that DVCIPM research staff will approach you at future time points for follow up; you understand that your coded data and biological specimens will be used in future research.

A signed copy of this consent form with HIPAA Authorization will be given to you.

Please initial your choice for each of the options below:

If you are also enrolling in the DVCIPM research project: 'Biomarker signatures of the sleep pain enigma; a CHIRP funded project', you agree to allow the remainder of your coded blood samples and your data from that study to be transferred, stored, and used, in this Biobank study. After you are done participating in that study, a Pain Registry Biobank staff member will follow-up with you.

_____yes _____no

I consent to receive text messages about this study:

_____yes _____no

I consent to provide saliva samples:

_____yes _____no

I consent to provide subsequent blood draws:

_____yes _____no

SIGNATURE OF SUBJECT
You have read (or someone has read to you) the information in this consent form. You have been given a chance to ask questions and all of your questions have been answered to your satisfaction.

BY SIGNING THIS CONSENT FORM, YOU FREELY AGREE TO TAKE PART IN THE RESEARCH IT DESCRIBES.

_____
Printed Name of Participant

_____ _____ _____
Signature of Participant Date Time

SIGNATURE OF RESEARCH TEAM MEMBER OBTAINING CONSENT
My signature is intended to attest that the information in the consent document and any other information was explained to and apparently understood by the subject that questions and concerns were addressed and that informed consent was freely given.

Printed Name of Person Obtaining Consent_____

_____ _____ _____
Signature of Person Obtaining Consent Date Time
(must be same as subject)