Department of Veterans Affairs

Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research

Subject Name (Last, First, Middle Initial)**:**	**Subject SSN** (last 4 only)**:**	**Date of Birth:**

VA Facility (Name and Address)**:**

VA Principal Investigator (PI)**:**	**PI Contact Information:**

Study Title:

Purpose of Study:

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI):

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.

Signing this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization.

Your individually identifiable health information used for this VA study includes the information marked below:

☐ Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings

☐ Specific information concerning:

☐ alcohol abuse ☐ drug abuse ☐ sickle cell anemia ☐ HIV

☐ Demographic Information such as name, age, race

☐ Billing or Financial Records

☐ Photographs, Digital Images, Video, or Audio Recordings

☐ Questionnaire, Survey, and/or Subject Diary

☐ Other as described:

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USE OF YOUR DATA OR SPECIMENS FOR OTHER RESEARCH: (Instruction: When banking or further analysis is an **optional** research activity, complete page 5 and leave this section blank. If banking is a required research activity to store "Data" and/or "Specimen" for future use or if "Not Applicable" is selected, remove page 5 in its entirety.)

☐ Not Applicable - No Data or Specimen Banking for Other Research

An important part of this research is to save your

☐ Data

☐ Specimen

in a secure repository/bank for other research studies in the future. If you do not agree to allow this use of your data and/or specimen for future studies approved by the required committees, such as the Institutional Review Board, you will not be able to participate in this study.

DISCLOSURE: The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

☐ Non-VA Institutional Review Board (IRB) at _____
who will monitor the study

☐ Study Sponsor/Funding Source: _____
VA or non-VA person or entity who takes responsibility for; initiates, or funds this study

☐ Academic Affiliate (institution/name/employee/department):
A relationship with VA in the performance of this study

☐ Compliance and Safety Monitors: _____
Advises the Sponsor or PI regarding the continuing safety of this study

☐ Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO):

☐ A Non-Profit Corporation (name and specific purpose):

☐ Other (e.g. name of contractor and specific purpose):

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Note: *Offices within VA/VHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may also have access to your information in the performance of their VA/VHA job duties.*

Access to your Individually Identifiable Health Information created or obtained in the course of this research: While this study is being conducted, you

☐ will have access to your research related health records

☐ will not have access to your research related health records

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

REVOCATION: If you sign this authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address:

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.

EXPIRATION: Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will:

☐ Expire at the end of this research study

☐ Data use and collection will expire at the end of this research study. Any study information that has been placed into a repository to be used for future research will not expire.

☐ Expire on the following date or event:

☐ Not expire

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TO BE FILLED OUT BY THE SUBJECT

Research Subject Signature. This permission (authorization) has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint.

I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this form. I will be given a signed copy of this form for my records.

_____ _____

Signature of Research Subject Date

_____ _____

Signature of Legal Representative (if applicable) Date

To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State Law)

_____

Name of Legal Representative (please print)

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VA Principal Investigator (PI)**:**	**PI Contact Information:**

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Optional Authorization Supplement for Placing My Data or My Biological Specimens in a Repository or for Conducting Optional Analysis of My Specimens for Future Use in Research

Purpose. This supplement to the authorization is for either banking of data and/or biological specimens (for example blood, urine, tissue) collected during the study for future research or for conducting optional analysis for this study . You are not required to provide this permission and not providing this permission will have no impact on your participation in this study, i.e., granting this permission is not a condition of participating in this study.

Research Subject Signature. This additional permission (authorization) has been explained to me and I have been given the opportunity to ask questions about this activity. By signing below, I am giving my permission for VHA to:

☐ Store my health information in a research data repository at

_____

and sponsored/run by _____

☐ Store my biological specimens (blood, tissue, urine, etc.) in a research biological specimen/tissue repository at _____

and sponsored/run by _____

☐ Further optional analysis of my specimens for the current study occurring below:

Future research of data maintained within a research data repository will only occur after further Institutional Review Board and/or other applicable approvals of the new research to ensure the protection of your individual privacy. Future use of my biological specimens will only occur after the new research has been approved by all required committees.

Signature of Research Subject _____ Date _____

Signature of Legal Representative (if applicable) _____ Date _____

To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State law)

Name of Legal Representative (please print)

_____