Department of Veterans Affairs

AUTHORIZATION FOR USE AND RELEASE OF VETERANS HEALTH ADMINISTRATION (VHA) INFORMATION FOR RESEARCH

PARTICIPANT/SUBJECT NAME *(Last, First, Middle Initial)*:	**DATE OF BIRTH** *(MM/DD/YYYY)*

VA FACILITY *(Name and Address)*:

VA PRINCIPAL INVESTIGATOR *(PI)* **NAME AND CONTACT INFORMATION** *(e.g., mailing address, VA email and phone number)*:

RESEARCH PROJECT TITLE:

RESEARCH PROJECT PURPOSE:

SUBJECT NAME *(Last, First, Middle Initial)*:	**DATE OF BIRTH** *(MM/DD/YYYY)*

VA USE OF YOUR INFORMATION:

VHA information that this authorization covers is personal information about you maintained by VHA, including your health records, C&P exams, research project related records, 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, use, and disclose to entities identified on this form your past or present health information in addition to new information collected for this research project. The VA PI/research team are committed to protecting your privacy and the confidentiality of information related to your health care and this research project. **NOTE:** Offices within VA/VHA for official purposes including oversight of VA research, such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), Cooperative Studies Program (CSP) (when applicable), the VA Office of Inspector General (OIG), the VA Office of General Counsel (OGC), the Institutional Review Board (IRB), the Research and Development Committee (R&DC), and the local Human Research Protection Program (HRPP) also may have access to your information in the performance of their VA/VHA job duties.

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

Your information used for this VA research project includes the information marked below:

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

☐ Demographic Information *(e.g., name, social security number, age, race, etc.)*

☐ Billing or Financial Records *(e.g., account numbers, banking information for direct deposit (when applicable), co-pays, etc.)*

☐ Photographs, digital images, video, or audio recordings of you

☐ Questionnaire, survey, participant/subject diary and/or other research project related form

☐ Provider(s)

☐ Non-VA Health Records

☐ Concerned Others

☐ Other: _____

☐ Specific information concerning sensitive diagnoses ***(VA Only Instructions:** Subject must check the applicable boxes below before signing this form - the research team may check the boxes on the subject's behalf if requested to do so by the subject during their discussion)*:

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

REQUIRED BANKING OR FURTHER ANALYSIS OF YOUR DATA OR SPECIMENS:

☐ Not Applicable - No Data or Specimen Banking

***(VA Only Instructions:** Use this section for **required** research project (conditional) banking. If banking is a required (conditional) part of this research project to store "Data" and/or "Specimen(s)" for future use, or if "Not Applicable" is selected, remove the pages for "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." (pages 5-6)*

When banking or further analysis is an optional (unconditional) research activity, select "Not Applicable" above and complete the "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" (pages 5-6).

If the research project has both required banking or further analysis (conditional) and optional (unconditional) research banking or further analysis, complete this section and the "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" (pages 5-6).

THIS RESEARCH PROJECT INCLUDES:

☐ **Required *(conditional)* banking of your data and/or specimen(s)** -- An important required part of this research project is to save the following in a secure repository/bank not only for this research project but for future research projects. This action *(saving/banking of your data and/or specimen(s))* is required for participation in this research project. If you do not agree to allow this use of your data and/or specimen for future research projects as approved by the required committees, such as the Institutional Review Board *(IRB)*, then you will not be able to participate in this research project.

☐ Data ☐ Specimen

☐ **Both Required *(conditional)* and Optional *(unconditional)* banking of your data and/or specimen(s) --** If you will allow the research team to bank or conduct further analysis of your data and/or specimen, then you must also complete the "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" page.

☐ Data ☐ Specimen

SUBJECT NAME *(Last, First, Middle Initial)*:	**DATE OF BIRTH** *(MM/DD/YYYY)*

DISCLOSURE OF YOUR INFORMATION:

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

By signing this authorization, you allow VA PI/research team to disclose your information to other people or institutions that are not part of VA/VHA as noted below. Once your information is disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the people or institutions receiving your information.

☐ A non-VA Institutional Review Board (IRB) who will oversee the research project:

_____

_____

☐ The research project Sponsor/Funding Source who is either a VA or non-VA person or entity who takes responsibility for, initiates, or funds this research project:

_____

_____

☐ The research project Sponsor/Funding Source will also bank *(select all that apply)*:
☐ Data ☐ Specimens including data attached to or provided with the specimens ☐ Specimens only

☐ The Compliance and Safety Monitors who advise(s) the Sponsor or PI regarding the continuing safety of this research project:

_____

_____

☐ Other Federal agencies required to monitor or oversee research:
- ☐ Department of Health and Human Services (DHHS) Food and Drug Administration (FDA)
- ☐ Governmental Accountability Office (GAO)
- ☐ DHHS Office of Human Research Protection (OHRP)
- ☐ Internal Revenue Service (IRS)
- ☐ Other:

_____

_____

☐ A Non-Profit Corporation (NPC):

_____

_____

Specific purpose(s) is/are:
- ☐ Payment/compensation
- ☐ Staffing
- ☐ Other: _____

☐ Other:
- ☐ VA Contracted Laboratory Services for the purpose of:

_____

_____

- ☐ VA Contracted Transcription Services for the purpose of:

_____

_____

- ☐ Other Services: _____
  for the purpose of: _____
- ☐ Other Services: _____
  for the purpose of: _____
- ☐ Other Services: _____
  for the purpose of: _____

SUBJECT NAME *(Last, First, Middle Initial)*:	**DATE OF BIRTH** *(MM/DD/YYYY)*

ACCESS TO YOUR INFORMATION CREATED OR OBTAINED IN THE COURSE OF THIS RESEARCH PROJECT:

While this research project is being conducted, you will:

☐ Be able to access and obtain a copy of your research related health records.

☐ Not be able to access and obtain a copy of 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 and obtain a copy of the research records after the research project is completed.

REVOCATION:

You can revoke *(take back)* your authorization *(permission)*, in writing, at any time. If you revoke your authorization *(permission)*, the VA PI/research team *(they)* can continue to use or disclose your information that they collected before they received your revocation. This includes your information that they relied upon for the research project up until the time that you revoke *(take back)* your authorization *(permission)*. The VA PI/research team will not collect more information about you after you revoke *(take back)* your authorization *(permission)*. If you revoke *(take back)* your permission, you will no longer be able to participate in this research project but the benefits to which you are entitled will NOT be affected. Your written revocation is effective as soon as it is received by the VA PI or any member of the research team. You must provide your revocation in writing and may use VA Form 10-10116 available at Find A VA Form | Veterans Affairs. You must send your written revocation request to the VA PI/research team at the following address:

EXPIRATION:

(VA Only Instructions: *A research project that has data or specimen banking must not select "Expire at the end of this research project.")*

Unless you revoke *(take back)* your permission to allow VA/VHA to access, use, and/or disclose your information, this authorization will:

☐ Expire at the end of this research project

☐ Expire at the end of this research project for all data use and collection related to the research project. Any research project information that has been placed into a repository to be used for future research project(s) will not expire.

☐ Expire on the following date or event: _____

☐ Not expire because the research project does not end.

SUBJECT NAME *(Last, First, Middle Initial)*:	**DATE OF BIRTH** *(MM/DD/YYYY)*

TO BE FILLED OUT BY THE RESEARCH SUBJECT

RESEARCH SUBJECT SIGNATURE:

This authorization was explained to me and I was given the opportunity to ask questions. If I believe that my privacy rights were compromised, I may contact the VHA medical facility Privacy Officer to file a verbal or written complaint.

I authorize and give my permission for the access, use and disclosure of my information as described in this form. I will be given a signed copy of this form for my records.

Signature of Research Participant/Subject — Date *(MM/DD/YYYY)*

For individuals who are unable to make their mark due to physical limitation:

Signature of Witness #1 *(if applicable)* — Date *(MM/DD/YYYY)*

Printed Name of Witness #1

Signature of Witness #2 *(if applicable)* — Date *(MM/DD/YYYY)*

Printed Name of Witness #2

Include/attach documentation of legal authority for the below named individual to act as the research subject's Personal Representative: Appropriate Power of Attorney *(POA)*, Legal Guardian appointment, or Next of Kin if authorized by Federal, State, local or tribal law that establishes such authority (*e.g., parent of a minor)* as noted in VHA Directive 1605.01.

Signature of Personal Representative *(if applicable)* — Date *(MM/DD/YYYY)*

Printed Name of Personal Representative

For Personal Representatives who are unable to make their mark due to physical limitation:

Signature of Witness #1 *(if applicable)* — Date *(MM/DD/YYYY)*

Printed Name of Witness #1

Signature of Witness #2 *(if applicable)* — Date *(MM/DD/YYYY)*

Printed Name of Witness #2

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

SUBJECT NAME *(Last, First, Middle Initial)*:	**DATE OF BIRTH** *(MM/DD/YYYY)*

VA FACILITY *(Name and Address)*:

VA PRINCIPAL INVESTIGATOR *(PI)* **NAME AND CONTACT INFORMATION** *(e.g., mailing address, VA email and phone number)*:

RESEARCH PROJECT TITLE:

PURPOSE:

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

This additional authorization was explained to me, and I was given the opportunity to ask questions about this activity. By signing below, I am authorizing for VA/VHA to:

☐ Store my health information in a research data repository at:

_____

_____

which is sponsored/run by:

_____

_____

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

_____

_____

and sponsored/run by:

_____

_____

☐ Share my health information and/or biological specimens with other people or institutions involved in this research project that are not part of VA/VHA for the purpose of storing my health information and/or biological specimen/tissue in a non-VA research repository.

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

_____

_____

_____

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Future research of data maintained within a VA research data repository will only occur after the new research project has been approved by all required committees to ensure the protection of your individual privacy.

Future use of biological specimens within a VA repository will only occur after the new research has been approved by all required committees.

Signature of Research Participant/Subject — Date *(MM/DD/YYYY)*

For individuals who are unable to make their mark due to physical limitation:

Signature of Witness #1 *(if applicable)* — Date *(MM/DD/YYYY)*

Printed Name of Witness #1

Signature of Witness #2 *(if applicable)* — Date *(MM/DD/YYYY)*

Printed Name of Witness #2

Include/attach documentation of legal authority for the below named individual to act as the research subject's Personal Representative: Appropriate Power of Attorney *(POA)*, Legal Guardian appointment, or Next of Kin if authorized by Federal, State, local or tribal law that establishes such authority *(e.g., parent of a minor)* as noted in VHA Directive 1605.01.

Signature of Personal Representative *(if applicable)* — Date *(MM/DD/YYYY)*

Printed Name of Personal Representative

For individuals who are unable to make their mark due to physical limitation:

Signature of Witness #1 *(if applicable)* — Date *(MM/DD/YYYY)*

Printed Name of Witness #1

Signature of Witness #2 *(if applicable)* — Date *(MM/DD/YYYY)*

Printed Name of Witness #2