VA Portland Health Care System (VAPORHCS)

Institutional Review Board

Request for Waiver or ALTERATION of Informed Consent PROCESS

And

WAIVER OF authorization to release medical records or health information

*Complete this questionnaire if the request is to waive or alter the elements of the informed consent requirements or the informed consent process, and for permission to use identifiable information in the conduct of this research study under a waiver of authorization.*

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| **Principal Investigator (PI):**        |
| **Contact Person:**       | **Extension:**       | **E-mail:**       |
| **Project Title and (if ongoing study):****VA MIRB and/or eIRB Number:**       |

1. Describe what subject group(s) this waiver of informed consent process and waiver of authorization covers *(e.g. all subjects of the study, or a specific subject group(s) within the study that includes multiple subject groups).*
2. Justify why the research **and privacy risks** of the research are no more than minimal[[1]](#footnote-1), [[2]](#footnote-2)

***NOTE:*** *The research must be no more than minimal risk in order to meet waiver criteria for approval.*

**3.**  Does this research project involve an investigational new drug, an investigational device, or is the research governed by the Food and Drug Administration? YES [ ]  NO [ ]

***NOTE:*** *If* ***YES****, the process of informed consent may not be waived or altered, except as per the requirements outlined in 21 CFR 50.23-24.*

**4.** Is the research to be conducted by, or subject to, the approval of state or local government officials and is designed to study, evaluate, or otherwise examine one or more of the following? YES [ ]  NO [ ]

If **YES**, check as applicable:

[ ]  public benefit or service programs;

[ ]  procedures for obtaining benefits or services under those programs;

[ ]  possible changes in or alternatives to those programs or procedures; or

 [ ]  possible changes in methods or levels of payment for benefits or services under those programs

**3**. Is the research to be conducted under a Department of Defense Addendum? YES [ ]  NO [ ]

 If **YES,** is the primary purpose of the study to obtain data regarding the effect of either a research intervention or research interaction with subjects? YES [ ]  NO [ ]  *If* ***NO****, skip to A.*

 If **YES,** do you have a waiver from the Secretary of Defense? YES [ ]  NO [ ]

 ***NOTE:*** *If* ***NO****, the informed consent process cannot be waived.*

**SECTION A: Please identify with specificity any identifiers to be used and their sources**

 ***NOTE:*** *Protected Health Information (PHI) = health information + identifiers*

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|  | **Identifier** | **Source(s) of Information** |
| [ ]  | Names |       |
| [ ]  | All geographical subdivisions smaller than a State (including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of the zip code if according to the current publicly available data from the Bureau of the census: a) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and b) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000). |       ***(specify both type of subdivision and source)*** |
| [ ]  | All elements of dates (except year) for dates directly related to an individual (including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older).  |       **(*specify both type of date and source)*** |
| [ ]  | Telephone numbers |       |
| [ ]  | Fax numbers |       |
| [ ]  | Electronic mail addresses |       |
| [ ]  | Social security numbers |       |
| [ ]  | Medical record numbers |       |
| [ ]  | Health plan beneficiary numbers |       |
| [ ]  | Account numbers |       |
| [ ]  | Certificate/license numbers |       |
| [ ]  | Vehicle identifiers and serial numbers, including license plate numbers |       |
| [ ]  | Device identifiers and serial numbers |       |
| [ ]  | Web Universal Resource Locators (URLs) |       |
| [ ]  | Internet Protocol (IP) address numbers |       |
| [ ]  | Biometric identifiers, including finger and voice prints |       |
| [ ]  | Full face photographic images and any comparable images |       |
| [ ]  | Any other unique identifying number, characteristic, or code |       |

**SECTION B: Describe all additional study information and their source(s).**

**B.1.** ***If not fully covered above***, please describe all of the information and/or biospecimens **and their source(s),**obtained under this waiver, (e.g. age from VINCI, employment status such as VAPORHCS PAC Nurse from VA publicly available directory, types of ICD-10 codes and/or disease(s)/condition(s) from VAPORHCS electronic health record, tumor tissue from VAPORHCS pathology lab, types of information from repository, specific health information from screening questionnaire, etc.,). ***NOTE:*** *If* ***fully*** *covered above, please state “N/A.”*

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| **General Criteria for Waiver of Consent and Authorization** |
| 1. Discuss reasons why it would not be possible to obtain informed consent/authorization from individual subjects:
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| **2.** Justify why it would not be practicable to conduct this research without access to and use of the identifiers, specified in Sections A and/or B above, and without this waiver of HIPAA authorization. ***NOTE:*** *inconvenience in obtaining authorization is an insufficient reason; provide sufficient reasons - e.g., workload, manpower, timeline, etc.* [ ]  N/A: NO identifiable private information or identifiable biospecimens will be used under this waiver  |
| **3.** Describe why the waiver (i.e. not obtaining informed consent and authorization for subjects) will not adversely affect the rights and welfare of the subjects. *(e.g. research does not include sensitive information, study will yield only generalizable results and will not impact individual welfare, etc.)*:  |
| **4.** Explain how you will, if applicable and appropriate, provide the subjects with additional pertinent information after they have participated in the study, **or indicate “Not applicable” and explain** *(e.g. retrospective records review study that will yield only generalizable results and will not impact individual clinical care and/or health care decisions)*:  |
| **Additional Criteria for Waiver of Authorization & Required Information Security Officer and Privacy Officer Review (per, VHA Directive 1605.01)** |
| **5.** Justify why the PHIto be used or disclosed is the minimum necessary to accomplish the research objectives *(e.g. if the research is about tinnitus justify why the study accesses and/or uses substance abuse information; if research is retrospective chart review of referral practices and average age of first colonoscopy, justify why the study collects all diagnosis from subjects, etc.):* |
| **6.** Describe your plan to protect PHI from improper use and disclosure *(e.g. a detailed explanation about how this will be accomplished including limitations of physical or electronic access to the information and other protections)*: ***NOTE:*** *A plan to destroy research-related data, including identifiers, must comply with the VA VHA records control schedule (RCS) 10-1 located at:*[*https://www.va.gov/vhapublications/rcs10/rcs10-1.pdf*](https://www.va.gov/vhapublications/rcs10/rcs10-1.pdf)1. Where will the PHI be stored that was obtained under this waiver?
2. Who will have access to the PHI that was obtained under this waiver?
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| **7.** Will this research use information and/or biospecimens about drug abuse, alcohol abuse, HIV infection and/or sickle cell anemia? [ ]  YES [ ]  NO**If YES, to 7:**1. Will the information and/or biospecimens include identifiers?

[ ]  YES [ ]  NO1. Do you assure that the purpose of the information and/or biospecimens, obtained under this waiver, is to conduct scientific research and that personnel involved in the study will not identify, directly or indirectly, any individual subject in any report of the research, or otherwise disclose subject identities to anyone outside the IRB-approved VA personnel **(*for this study*)** in any manner?

[ ]  YES [ ]  NO |
| **8.** Will de-identified (i.e. not linkable by the recipient) information and/or biospecimens be disclosed outside of the IRB-approved VA personnel for this study? [ ]  YES [ ]  NO***NOTE:*** *A Data Use Agreement will be needed for this disclosure*.   |
| ***Disclosure of identifiable information and/or biospecimens outside of the IRB-approved VA personnel for this study is not allowed, except as required by law, for authorized oversight of the study, or for uses or disclosures otherwise permitted under applicable regulations and approved by the facility Privacy Officer and permitted by the HIPAA Privacy Rule.******NOTE:*** *If PHI is to be disclosed, study teams* ***must*** *consult the VAPORHCS Privacy Officers, prior to submission, as they will need to approve such disclosures. A waiver of HIPAA authorization is* ***NOT*** *sufficient to fulfill the requirements of other applicable privacy regulations such as the Privacy Act of 1974 (5 U.S.C.552a).* **9.** Will identifiable information and/or biospecimens be disclosed outside of the IRB-approved VA personnel for this study? YES [ ]  NO [ ]  *(If* ***NO****, skip to Investigator’s Assurances and Signature)***If YES to 9,** *please attach documentation of approval (e.g. email) from the VAPORHCS Privacy Officers and answer items a thru f below****:***1. Specify the individual(s) and/or entity(ies) who will receive the information:
2. Justify the need for the use by or disclosure to the individual(s) and/or entity(ies):
3. Explain whether the information will be directly identifiable, or coded and linkable by the study team and/or recipient(s) when it is disclosed:
4. List the data points (e.g. ICD-10 codes, types of health information, survey questions related to a particular condition or personal information, etc., and any identifiers specified in Sections A and/or B that will be shared:
5. Explain how the identifiable information will be transmitted/delivered to the entit(ies) specified in item a above.
6. Explain how the transmitted data will be stored, retained, destroyed, and/or further disclosed to the entit(ies):
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INVESTIGATOR'S ASSURANCES:

1. I will maintain subject confidentiality as approved by the VAPORHCS IRB or the combined VAPORHCS-OHSU IRB.
2. I will provide, whenever appropriate, research subject participants with additional pertinent information after participation, if designated by the IRB.
3. I verify that the requested information will be protected from improper use and disclosure. I will not re-use or disclose PHI to any other person or entity, except as required by law, for authorized research oversight, or as otherwise permitted under applicable regulations and approved by the facility Privacy Officer.
4. I certify that I will make every effort possible to protect the PHI accessed, used and disclosed in this research project.
5. *I certify my plan to destroy research-related data, including identifiers* ***(see Q.6)****, will comply with the VA VHA records control schedule (RCS) 10-1.*

**Signature of PRINCIPAL INVESTIGATOR Date**

**Signature of IRB Co-Chair / Voting Member Date**

1. *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. 45 CFR 46.102(i) [↑](#footnote-ref-1)
2. For HIPAA only, the requirement is: Explain why the use or disclosure of the PHI involves no more than minimal risk to the privacy of the individuals. [↑](#footnote-ref-2)