**For VA Exempt Studies ONLY**

**HIPAA Covered Component/Covered Entity Determination**

**(Checklist for Waiver of HIPAA Authorization follows)**

Description of the Emory HIPAA-Covered Components: [*http://irb.emory.edu/documents/HIPAA\_changes\_FAQ\_plus\_decision\_chart.pdf*](http://irb.emory.edu/documents/HIPAA_changes_FAQ_plus_decision_chart.pdf)

List of PHI identifiers: [http:www.irb.emory.edu/documents/phi\_identifiers.pdf](http://www.irb.emory.edu/documents/phi_identifiers.pdf)
§46.104(d)(1-4) Exempt research categories conducted at AVAHCS: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html>

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| --- |
| * **Part I and II list factors that determine whether and how a complete HIPAA waiver request applies in your exempt study, and to your research records.**
* **Complete the Checklists that follow if:**
	+ **HIPAA does apply and you are requesting a waiver of HIPAA authorization.**
	+ **This study will be conducted only at the Atlanta VA.**
	+ **The Emory IRB serves as the Privacy Board for your Atlanta VA research.**
	+ **The study meets one or more of the 45CFR46.104(d) Exempt categories 1, 2, 3, and/or 4.**
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## Part I: To determine if HIPAA will apply to your research records

**Is this an Exempt study conducted only at AVAHCS?**

[ ]  Yes – HIPAA guidelines will apply to your research. *Please complete Part II.*

[ ]  No – *Quit this application and complete the Emory University IRB Combined Waiver Consent HIPAA Element.*

## Part II: To determine what kind of HIPAA *authorization* or *waiver* will be needed

**Will you use and/or record protected health information from the Veterans Administration only (e.g., collection of data from medical records)? (Note: by definition, PHI *includes identifiers*.)**

[ ]  **Yes**, and I am requesting a complete waiver of HIPAA authorization. The VA considers this study to be outside of the informed consent requirement as such studies are exempt from the requirements of 45CFR46, except as noted in 45CFR46.104.

[ ]  **No,** I am not accessing, *using,* or *storing* any PHI from a covered entity. End this application here. A waiver of HIPAA authorization is not required for your study.

**After completing this form (including the Checklist below if applicable), please save and upload in the last page of your IRB application, under “HIPAA Applicability and Waivers Requested” section, question 4.**

**HIPAA Alteration and/or Waiver Checklist (if applicable)[[1]](#footnote-1)**

To be completed by researcher or IRB staff, and made part of the eIRB study application

**Study Number**: Click or tap here to enter text.

**PI Name:** Click or tap here to enter text.

Mode of Review (**IRB Use Only**): [ ] Exempt

**The PI requests a**  [ ]  Waiver of authorization (meaning that an authorization will not be obtained).

 **Which of the following sources of PHI will be requested?:**

[ ]  Physician records

[ ]  Hospital records

[ ]  Billing records

[ ]  Clinical records

[ ]  Mental health records

[ ]  Laboratory results

[ ]  Biological or tissue samples

[ ]  Pathology results

[ ]  Radiology results

[ ]  Interviews, surveys or questionnaires

[ ]  Data previously collected for research purposes

[ ]  Other - please describe: Click or tap here to enter text.

[ ]  No PHI will be utilized

[PLEASE NOTE: Response guidance has been supplied for the following justifications. (A) Text in *italics* should be tailored to your specific study. (B) **BOLD** text must be retained or have minimal changes. (C) Yellow highlighted information needs to be provided by the study team.]

**The IRB, sitting as a privacy board, must determine that the waiver of authorization satisfies ALL of the following (may refer to protocol and eIRB submission):**

1. **That the use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:**
	* 1. **An adequate plan to protect the identifiers from improper use and disclosure;**
		2. **An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and**
		3. **Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, or for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by this subpart.**

**Describe how the request meets this criterion (edit the following to meet the specifics of your study):** *i: Study team will protect PHI by keeping all PHI in a locked and secure location (physical and/or electronic). PHI will not be removed in any fashion from the VA while the HIPAA waiver is in use. The PHI will only be accessed by study personnel on approved VA computers which are password protected.* **Databases and electronic records will be stored on the Principal Investigator’s assigned VA Research drive study file.****All paper documents will be kept in a locked filing cabinet in a locked office located xxxxxx.****ii. The study team will store research records containing PHI in a VA approved storage facility (physical and/or electronic) per current VA research records storage guidelines. The VA does not permit self-destruction of any VA records.iii. Study team will not reuse or disclose PHI while the HIPAA waiver is in use. VA records, including those containing identifiers, must be destroyed in accordance with the Federal Records Retention Schedule, and/or FDA approval, and/or end of any record keeping requirements; and will not be used outside what is outlined in the research study protocol***.*

1. **That the research could not practicably be conducted without the waiver or alteration.**

**Describe how the request meets this criterion (edit the following to meet the specifics of your study):** **We will need access to PHI to determine potential eligibility for the study and for recruitment purposes. We will also need PHI to determine the past medical history of participants in the study as xxxxxx is a necessary requirement to be included in the study.**

1. **That the research could not practicably be conducted without access to and use of the protected health information.**

**Describe how the request meets this criterion (edit the following to meet the specifics of your study):** *Could not determine pre-screening eligibility requirements without access to PHI outlined above. It is not practical to contact all potential record owners because xxxxxxxx.*

1. Title 45, Subchapter C, Part 164 (E) [↑](#footnote-ref-1)