**HIPAA Covered Component/Covered Entity Determination**

**(Checklist for Waivers of Informed Consent and 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)

|  |
| --- |
| * **Part I, II, and III list factors that determine whether and how HIPAA applies in your study, and to your research records.**
* **Complete the Checklists that follow (starting on page 3) if:**
	+ **(1) you are requesting any waivers of informed consent, and/or**
	+ **(2) HIPAA does apply, and you are requsting any waivers of HIPAA authorization (other than “partial” HIPAA waiver)**
	+ **(3) you are requesting a waiver of signature on informed consent and/or authorization**
 |

## Part I: To determine if HIPAA will apply to your research records

1. **Is this study conducted partially or solely at AVAHCS?**

[ ]  Yes – *Skip to Part II; HIPAA guidelines will apply to your research because of the VA involvement*

[ ]  No – *Continue*

1. **Is this study conducted or partially conducted at an** [**Emory covered component**](http://irb.emory.edu/documents/HIPAA_changes_FAQ_plus_decision_chart.pdf)**, CHOA, Grady, or another institution that has defined itself as a covered entity?**

[ ]  Yes

[ ]  No

1. **IF YES: Is medical treatment provided as part of your current protocol?**

[ ]  Yes

[ ]  No

1. **IF YES: Is any treatment described in the protocol being billed, electronically, to an insurance company or a benefits program (e.g., Medicare/Medicaid)?**

[ ]  Yes

[ ]  No

* **If the answer to all of the above is “YES,” then HIPAA will apply to your *research records*.**
* **If the answer to any of 2-4 of the above is “NO”, then HIPAA will not apply to your *research records***
	+ (Unless the research is within the AVAHCS, in which case HIPAA *will* apply and it was not necessary to complete this Part I – go to Part II)
* **Complete Parts II and III below to see if HIPAA applies to *other parts of your study and to determine the HIPAA or confidentiality language to insert into the consent*.**

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

1. **Will you use and/or record protected health information from Emory Healthcare or an external covered entity (e.g., collection of data from medical records)? (Note: by definition, PHI *includes identifiers*.)**

[ ]  **Yes**, and I am requesting a complete consent waiver and waiver of HIPAA authorization.

Instructions:

* **Skip Part III and complete both Checklists.**

[ ]  **Yes**, and I will obtain consent and HIPAA authorization from the participant/LAR, but **HIPAA** **does not apply to my research records** (see Part I above).

Instructions:

* Insert ‘*Obtaining PHI\_No treatment and Billing\_HIPAA doesn’t apply to research records*’ language in to the consent from the [consent toolkit page](https://www.irb.emory.edu/forms/consent/index.html). Complete Part III, and do not complete the Checklists that follow unless you need a waiver of signature (i.e. verbal consent/authorization)

[ ]  **Yes**, and I will obtain consent and HIPAA authorization from the participant/LAR in a study, and **HIPAA** **does** **apply to my research records** (see Part I above).

Instructions:

* Insert ‘*HIPAA Applies to Research Records*’ language in the consent from the [consent toolkit page](https://www.irb.emory.edu/forms/consent/index.html). Complete Part III, and do not complete the Checklists that follow unless you need a waiver of signature (i.e. verbal consent/authorization)

[ ]  **No,** I am not accessing, *using* or *storing* any PHI from a covered entity. Insert *confidentiality language* from the [consent toolkit page](https://www.irb.emory.edu/forms/consent/index.html). Go to Part III.

## Part III: Accesing data for recruitment purposes only - requesting a partial HIPAA waiver (PHW)

[ ]  I will access PHI within a covered entity for **recruitment purposes** **ONLY** (i.e. identifying potentially eligible subjects). As subjects are contacted, I will obtain HIPAA authorization

[ ] I will not access PHI for recruitment purposes prior to obtaining subject consent and authorization

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

**Checklist for Waiver of Consent/ Elements of Consent, or Waiver of Documentation of Consent[[1]](#footnote-1)**

To be filled out by researcher or analyst, and made part of the eIRB study application by uploading it under the Protocol section in the smartform. The HIPAA waiver included in this document should only be completed if applicable. See the [IRB website](http://www.irb.emory.edu/forms/Waivers/index.html) for additional waiver guidance.

**Instructions**: **Fill the questions in gold as applicable. Select between option A (waiver of certain elements), B (for waiver of consent) or C (for waiver of documentation of consent), and provide additional information for each selection.**

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

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

Mode of Review (**IRB Use Only**): [ ] Expedited [ ] Full Board

**The PI requests the waiver of:**

* [ ]  ALL or [ ]  SOME elements of informed consent for this research study.

If SOME elements, list the corresponding numbers here: Click or tap here to enter text. **(See the numbered list on the** [last page](#_Elements_of_Informed_1)**)** or

* [ ]  Waiver of Documentation/Signature only (**Skip to Option C**)

**Waiver of Elements of Informed Consent**

The IRB may waive the above elements of informed consent if the Designated Reviewer of Full Board finds (choose ONE of the following two options):

**Option A** (*Board must find that all 5 criteria apply*)

[ ] The research or clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects

Protocol-specific comments: Click or tap here to enter text.

[ ] The research or clinical investigation could not practicably be carried out without the requested waiver or alteration;

Protocol-specific comments: Click or tap here to enter text.

 [ ]  If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

Protocol-specific comments: Click or tap here to enter text.

[ ] The waiver or alteration will not adversely affect the rights and welfare of the subjects;

Protocol-specific comments: Click or tap here to enter text.

[ ] Whenever appropriate, the subject or legally authorized representatives will be provided with additional information about their participation in the research/clinical investigation.

Protocol-specific comments: Click or tap here to enter text.

**Option B**

[ ] The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; **and**

[ ] The research could not practicably be carried out without the waiver or alteration.

Protocol-specific comments: Click or tap here to enter text.

**Option C: Only for Waiver of Documentation of Consent (i.e. Signature)**

An IRB may waive the requirement for the investigator to obtain a signed informed consent form from some or all subjects if it finds any of the following:

[ ]  (i) That the only record linking the subjects and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject or legally authorized representative will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or

Protocol-specific comments: Click or tap here to enter text.

[ ]  (ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

Protocol-specific comments: Click or tap here to enter text.

[ ]  (iii) If the subject or legally authorized representative are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Protocol-specific comments: Click or tap here to enter text.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

#

**HIPAA Alteration and/or Waiver Checklist (if applicable)[[2]](#footnote-2)**

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**): [ ] Expedited [ ] Full Board

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

or [ ]  Alteration of HIPAA authorization (meaning that some elements of the authorization will be waived, for example, a signature in the HIPAA authorization for verbal authorizations).

**If alteration - description of the alteration[[3]](#footnote-3)**: Click or tap here to enter text.

**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

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:** Click or tap here to enter text.

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

**Describe how the request meets this criterion:** Click or tap here to enter text.

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:** Click or tap here to enter text.

Reference

# **Elements of Informed Consent**

1. A statement that the study involves research, an explanation of the purpose of the research, expected duration of the participation, description of the procedures, and identification of research procedures v. non-research
2. Description of any reasonably foreseeable risks or discomforts
3. Description of any benefits to the subject or to others that may be reasonably expected from the research
4. Disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the subject
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and what records may be examined by the research staff, IRBs, sponsor, their representatives, and possibly the FDA or OHRP.
6. For research involving more than minimal risk, a statement that emergency medical care will be arranged for a study-related illness or injury, and an explanation of whether funds are set aside to pay for this care and/or compensation, and if so by whom (e.g., sponsor, subject, insurer). Language must not be exculpatory (i.e. “In case of injury” language)
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
	1. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
	2. (ii) A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
1. 45 CFR 46.116 (f) and (d); 45 CFR 46.117 (c); FDA Guidance: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects. [↑](#footnote-ref-1)
2. Title 45, Subchapter C, Part 164 (E) [↑](#footnote-ref-2)
3. The most frequent alteration is for verbal HIPAA Authorization when the IRB has also waived the requirement for written consent under 45 CFR 46.117(c)(1)(ii). Another alteration to obtain verbal HIPAA Authorization is issued when consent is not required for screening procedures limited to: (a) obtaining information through oral or written communication with the prospective subject or legally authorized representative, or (b) obtaining identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. Demonstrating that the "research could not practicably be conducted without the waiver or alteration" is the main obstacle to approving an alteration. If the subject is physically present, it is usually practicable to obtain written HIPAA Authorization. [↑](#footnote-ref-3)