



EMORY  
UNIVERSITY

Institutional Review Board  
Research Administration

# HIPAA Applicability and Waiver Worksheet

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HIPAA COVERED ENTITIES,  
CONSENT WAIVERS, AND HIPAA  
WAIVERS OR ALTERATIONS

# Topics to be covered

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Brief Introduction to HIPAA

Emory's Hybrid Covered Entity

HIPAA Applicability for CHOA/Grady/VA

HIPAA Applicability Worksheet

Choosing an Informed Consent Template with HIPAA language

Informed Consent- waivers of consent and of documentation

HIPAA authorization- waivers and alterations

Using the Worksheet with Multiple Cohort Studies

Questions



A close-up photograph of several walnuts with their characteristic wrinkled, brown shells. A silver-colored metal nutcracker is positioned diagonally across the frame, with its two curved ends pressing against the shells of the walnuts. The lighting is warm, highlighting the textures of the nut shells and the metallic sheen of the tool.

# HIPAA in a nutshell

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- national standards to protect medical records and other personal health information
- requires safeguards to protect privacy
- sets limits on the uses and disclosures that may be made without patient authorization\*



# HIPAA Lingo

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Protected Health Information (PHI):  
Individually Identifiable Health Information that is held by a covered entity (or in a covered *component* of a hybrid entity, like Emory)

- Must first be *health* information (identifiers *by themselves* are not PHI)
- Must be [individually identifiable](#)

Individually Identifiable Health Information (IIHI): same information NOT (or no longer) covered by HIPAA



# Emory's Hybrid Covered Entity Units (2016)

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## The Emory University Health Plan

(governed by separate privacy and security policies)


## Emory University Student Health Services

(to the extent to which educational records subject to FERPA are not involved)

**Emory University School of Medicine health care providers** who are providing treatment (or Research that includes treatment) and collecting payment involving HIPAA-covered billing.





The background of the slide is a photograph of an outdoor patio area. In the foreground, there are several large patio umbrellas in various colors: a large orange one in the center, a smaller blue one to its left, and a white one to its right. The umbrellas are set against a backdrop of lush green trees and foliage. On the right side, a portion of a multi-story building with white siding and dark shutters is visible. The overall scene is bright and sunny, suggesting a pleasant outdoor environment.

Remember: Emory units are only covered components to the extent they perform “covered functions”

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- Provide Treatment AND bill insurance or a government benefits program (e.g., Medicare) for the Treatment; or
- Process Payment; or
- Perform Healthcare operations.



# HIPAA Applicability for CHOA/Grady/VA

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[HIPAA Changes FAQ and Decision Chart](#)

## For studies conducted at Emory or Grady:

- HIPAA will apply only to studies involving the use of PHI which also provide treatment (as part of the research study) billed to an insurance company, Medicare/Medicaid or another government benefits program

## For studies at the Atlanta VA (AVAHCS):

- HIPAA will always apply if identifiable health information is involved

## For studies at Children's Healthcare of Atlanta: Still under discussion

- HIPAA definitely applies when there is treatment AND billing *and/or* data is placed in medical record; HIPAA may or may not apply in other cases

# Introduction to the HIPAA Applicability worksheet

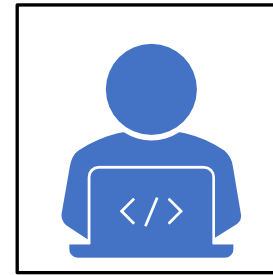
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Part I- Will HIPAA protect  
your research records?



Part II- Do you need HIPAA  
authorization or a waiver?



Part III- Do you need PHI  
for recruitment?



# IRB's HIPAA Applicability Worksheet- Part I

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Initializing...



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

1. **Is this study conducted solely at AVAHCS?**
    - ☐ Yes – *Skip to Part II; HIPAA will always apply to your research records*
    - ☐ No – *Continue*
  2. **Is this study conducted or partially conducted at an [Emory covered component](#), CHOA, Grady, or another institution that has defined itself as a covered entity?**
    - ☐ Yes
    - ☐ No
  3. **IF YES: Is medical treatment provided as part of your current protocol?**
    - ☐ Yes
    - ☐ No
  4. **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 2-4 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*.

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:

- Use the special ICF/HIPAA template here: [SaaS Emory Biomedical Consent/HIPAA Template - Obtaining PHI from a covered entity, but no treatment or billing for research](#)
- 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:

- Use the regular [consent/authorization](#) template that is appropriate for your study
- 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. Go to Part III.

# HIPAA Applicability and Waiver Worksheet

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PART II





### Part III: Accessing 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.**

You now have enough information to answer the HIPAA-related questions in eIRB!

# HIPAA Applicability and Waiver Worksheet

Part III





# Choosing an Informed Consent Template with HIPAA language

SaaS Biomedical Consent/HIPAA Template

SaaS Emory Biomedical Consent Template

- HIPAA does not apply

SaaS Emory Biomedical Consent/HIPAA Template

- Obtaining PHI from a covered entity, but no treatment or billing for research

## Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will be requesting health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) to provide us with health information that identifies you ("individually identifiable health information" or "IIHI"). Because the health care entities are covered by HIPAA, we must have your authorization to obtain your IIHI from them. However, the researchers who get your IIHI from the health care entities are not covered by HIPAA. Once they receive your IIHI from the health care entities, they will put it in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

Refer to these forms' HIPAA language as a model for other site-specific consent forms



# Waivers of One or More Elements of Informed Consent

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Can waive all elements or single elements individually

Option A includes 5 criteria

- all must apply and each requires protocol-specific comments
  1. 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
  2. The research or clinical investigation could not practicably be carried out without the requested waiver or alteration
  3. 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;
  4. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  5. Whenever appropriate, the subject or legally authorized representatives will be provided with additional information about their participation in the research/clinical investigation.



# A reminder about protocol-specific comments

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- Information in the worksheet serves as the IRB's documentation to back up granting the waiver.
- Tell us why it's really impracticable to obtain consent and why the study must be conducted with identifiers.
  - Don't just say "doing a chart review."
  - Don't use lack of study resources as rationale – we should always be concerned about participants' rights





# Waivers of One or More Elements of Informed Consent

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Option B is rarely used- only for public benefit or service programs

1. 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
2. The research could not practicably be carried out without the waiver or alteration

# Waiver of documentation (signature) of consent

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3 options, any can apply, each requires protocol-specific comments

- 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
- (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
- (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.

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.







# Heads Up!

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If you apply for a waiver of documentation of informed consent, and HIPAA applies at all to your study (Parts I, II, or III), you will also need to apply for an alteration of HIPAA authorization



**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<sup>3</sup>:** Click or tap here to enter text.

# HIPAA Waivers and Alterations

PART I- ADMINISTRATIVE  
INFORMATION



- ☐ 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

# HIPAA Waivers and Alterations

PART II- SOURCES OF PHI

# HIPAA Waivers and Alterations

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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):

- (A) 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:
  - i. An adequate plan to protect the identifiers from improper use and disclosure;
  - ii. 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
  - iii. 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;
- (B) That the research could not practicably be conducted without the waiver or alteration
- (C) That the research could not practicably be conducted without access to and use of the protected health information.

**Each criterion requires protocol-specific comments**



# Multiple Cohort Studies

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YOU CAN USE MULTIPLE  
WAIVER WORKSHEETS OR  
MULTIPLE RELEVANT PARTS OF  
THE WORKSHEET

MAKE THE WORKSHEET WORK  
FOR YOU!

MAKE SURE TO INCLUDE THE  
APPROPRIATE RATIONALE FOR  
EACH COHORT AND SELECT THE  
CORRECT INFORMATION IN  
EIRB



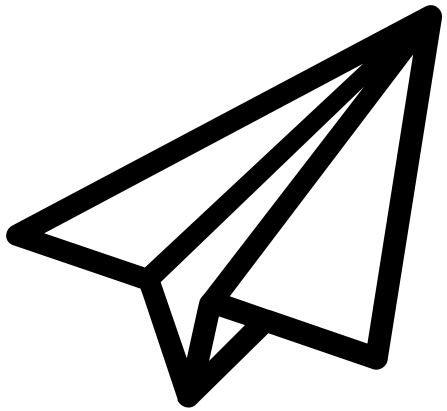
# Questions

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# Contact Us

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