Research HIPAA Waiver Authorization Guidance

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This guidance document is to inform individuals involved in research at GWU MFA on the process of identifying when and what type of HIPAA authorization is required for research and the process of submitting the waiver. A HIPAA Authorization Waiver is an IRB requirement that allows researchers to forgo the authorization requirement based on the fact that the disclosure of Protected Health Information (PHI) involves minimal risk to the participant and the research cannot practically be done without access to/use of PHI.

HIPAA Waiver Templates can be located here: https://humanresearch.gwu.edu/hipaa-forms-0

What HIPAA Waiver Should the Researcher Use:

Partial HIPAA Waiver

The Partial HIPAA Waiver should be used when a PI is requesting a waiver of Research Subject Authorization to access PHI for the ***sole purpose*** **of obtaining information to pre-screen and recruit prospective subjects as part of a research protocol** (e.g., a MFA employee requesting access to GW Hospital billing records).

If a PI wishes to review medical files strictly to determine whether there are enough patients to justify a research study but does not wish to extract/document any PHI, the PI must complete a Request for Review Preparatory to Research form and obtain the signature of the Privacy Officer(s) of the covered entity(ies) holding the PHI. The form does not need to be submitted to the IRB.

Full HIPAA Waiver

Under HIPAA, a research authorization may be waived, or required elements of research authorizations may be altered, by an IRB if the proposed research activity meets the following criteria:

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

Waiver of the Research Subject Authorization Process: In practical terms, this means that a waiver will *not* be approved for research involving interaction with live subjects (because it is possible for the investigator to obtain an authorization from subjects). Requests for waivers are appropriate for studies of *existing* data or tissue and when access to subjects is not feasible.

Alteration of Research Subject Authorization Elements: An alteration of the required elements for an authorization may be appropriate for research involving interaction with live subjects and highly sensitive information (e.g., HIV/AIDS, domestic abuse, drug use) for which subjects may not want to sign an authorization form.

Waiver of informed consent: As a general matter, a waiver of or alteration to Research Subject Authorization may be granted only when a waiver of informed consent is also granted. In other words, in order to qualify for one of the waivers (informed consent or authorization) you must request and qualify for both of the waivers.

2. **The use/disclosure of PHI involves *no more than minimal risk* to the PRIVACY of the subjects.**

HIPAA requires the IRB to consider at least the following three factors to determine if the proposed research poses no more than a minimal risk to the subjects' privacy:

a. There is an adequate plan to *protect the identifiers* from improper use and disclosure;
b. There is an adequate plan to *destroy the identifiers* at the earliest opportunity, ***and***
c. The investigator provides adequate written assurances that *PHI will not be reused or disclosed* except as permitted under HIPAA. By signing this form, you are providing your written assurance that PHI will not be reused or redisclosed except as permitted under HIPAA.

3. **The research could not practicably be conducted without PHI.**

The investigator must explain to the IRB why either a limited data set or de-identified data would not be sufficient to achieve the study's research objectives.

Process for Submitting a HIPAA Waiver

1. Researchers will decide on what waiver is appropriate for their study and complete the HIPAA Waiver Templates that can be located on the GWU IRB's website (listed above).
2. Upload the completed HIPAA Waiver to the iRIS initial submission (if applicable)
    - If WCG is the IRB of record: Send the HIPAA Waiver to WCG with the submission and also email it to the privacy officer along with the documents listed in 3.
    - If Advarra is the IRB of record: Make the selection in the initial submission noting the use of a HIPAA waiver and send the completed HIPAA waiver to the privacy officer along with the documents listed in 3.
    - If iRIS is the IRB of record: Upload the completed HIPAA waiver for signatures with the initial IRB submission, email the waiver along with the documents listed in 3 to the privacy officer and upload it once the officer has signed off.
3. If the researcher will be using MFA subjects, send an email to privacyofficer@mfa.gwu.edu with the following documents attached:

    - IRB Outcome letter
    - HIPAA waiver reviewed by the IRB
    - Protocol or application
    - List of relevant data points

    NOTE: Turn-around is approximately one week. **Do NOT send the email directly to Scott Intner.**

4. Upload the completed HIPAA Waiver with the privacy officer's signature to the IRB website and maintain it in the regulatory binder.
5. If the researcher will be using GWU Hospital subjects, send an email to GWUHResearch@gwu-hospital.com with the following documents attached:

    - IRB Outcome letter
    - HIPAA waiver reviewed by the IRB
    - Protocol or application
    - List of relevant data points

6. Upload the completed HIPAA Waiver with the privacy officer's signature to the IRB website and maintain it in the regulatory binder.

Contacting Potential Research Subjects

Partial HIPAA Waivers allow the researcher to pre-screen and recruit potential subjects, saving time and resources by identifying the correct subject population. Using EPIC, researchers may go into the potential subjects' chart and review records and contact information. All communication should be done through the messaging function of EPIC. Do not directly email the potential subjects asking them if they want to participate in research, but it is acceptable to call the potential subjects to see if they would be interested in participating in the clinical trial.

Storing Research Subject Information Collected via HIPAA Waivers

Subject information should be stored securely where only research members have access to the information. Secure ways to store the information include: Sharepoint, on the Department ShareDrive, RedCap and Florence. Unacceptable platforms include: GoogleDocs, Box, and GoogleDrive. Information collected via the HIPAA Waiver, under any circumstances, should not be shared with anyone who is not IRB approved.