OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #505.1 Revision 1	**TITLE: HIPAA in Research**	Effective Date: 11/27/2017
Approved By: OIRB Director	Signature 	Date 11/27/2017
Approved By: IRB Chair	Signature 	Date 11/27/2017

PURPOSE

To describe UNM Institutional Review Board (IRB) policy and procedures for conducting reviews of research covered by the Health Insurance Portability and Accountability Act (HIPAA) including research authorization forms, waiver of authorization requests, and coordination with the UNM Privacy Office (PO).

REVISIONS FROM PREVIOUS VERSION

Update to identify HIPAA Privacy Board and define, clarify the difference between research health information and Protected Health Information (PHI).

POLICY

The UNM IRB serves as a HIPAA Privacy Board and reviews HIPAA authorizations and authorization waiver requests for human research projects that obtain PHI from a covered entity (CE) as defined at 45 CFR 160.103. All other HIPAA research issues such as preparatory work, decedent research, limited data sets, public health activities, privacy notices, and accounting of disclosures fall under the jurisdiction of UNM's PO. The UNM HSC Human Research Review Committee reviews projects requesting access to UNM HSC PHI.

Definitions

Protected health information is defined as any of the 18 identifiers listed in the HIPAA Privacy Regulations in combination with health information that is created or maintained by a CE that relates to the past, present, or future physical or mental health or conditions of an individual.

Research health information (RHI) is identifiable health information collected directly from the individual (not from a medical record or covered entity, including the UNM HSC) and used solely for research. RHI does not meet the definition of PHI and is not regulated by HIPAA.

A UNM *hybrid covered entity* is a department/center that provides services that meets the definition of health care provider, health plan, or health care clearinghouse and bills patients/subjects electronically. Regents' Policy Manual Health Sciences Center Institutional Compliance Program details which UNM departments fall within UNM's hybrid CE.

Options for Obtaining PHI

Researchers have the following six options for obtaining PHI from a covered entity for research purposes:

1. De-identified Information - health information that cannot be linked to an individual;
2. Authorization - a document signed by the participant that gives the researcher permission to use/disclose PHI collected from a covered entity during the research study for defined purposes;
3. Waiver of Authorization - a request to forgo the authorization requirement based on the fact that the disclosure of PHI is a minimal risk to the participant and meets all of the requirements at 45 CFR Part 160 and Subparts A and E of Part 164.
4. Limited Data Set - a subset of identifiers that contain the following elements: city, state, zip code, date of birth, death, or date of service (requires data use agreement);
5. Preparatory Work - PHI reviewed for the purpose of designing a research study or identifying potential subjects. PHI cannot be removed from the CE during the review; or
6. Decedent Research - research on PHI from a participant(s) that is deceased prior to the initiation of the study.

RESPONSIBILITIES

Execution of SOP: Researchers, IRB, OIRB Staff, UNM Privacy Office.

PROCEDURE

General Procedures

1. IRB members who review research authorizations and waiver of authorization requests received annual training on the HIPAA Privacy Rule.
2. IRB members do not review any authorizations or waiver of authorization requests for which they have a conflict of interest. (See IRB Member and Consultant Conflict of Interest SOP for additional information.)

HIPAA Authorization Review Procedures

1. The PI makes a preliminary assessment to determine whether his/her protocol requires signed HIPAA authorization or whether they will request a waiver of authorization (see next section). A PI may call the OIRB if he/she needs assistance in determining whether HIPAA is applicable.
2. The PI submits an IRB application and an authorization form to the OIRB. If HIPAA is applicable, the PI uses the IRB's template HIPAA authorization language, which includes all federally and institutionally mandated criteria, embedded in the informed consent document or as a standalone document.
3. OIRB staff reviews the protocol and determines whether the HIPAA Privacy Rule if applicable and if a signed HIPAA authorization is appropriate for the study. Staff also reviews the authorization form/language to ensure that all federally and institutionally mandated criteria are in the document using the HIPAA Authorization Checklist.
4. If there are any HIPAA questions or concerns, OIRB staff consult with the OIRB Director, who will consult with the UNM PO as needed.
5. OIRB forwards the HIPAA Authorization Checklist and any comments from the PO, if applicable, to the IRB or IRB member to assist them with their authorization review.

6. The IRB requests revisions to any authorization form that does not contain all the federally and institutionally mandated criteria.
7. The IRB and/or IRB reviewer make the final determination as to whether the HIPAA Privacy Rule is applicable.
8. The OIRB sends requests for revisions to the authorization to the PI, who in turn makes the necessary corrections and resubmits the revised document to OIRB. The IRB reviews revisions to the authorization and determines whether all the federally and institutionally mandated criteria for authorizations are satisfied.
9. Once the IRB determines the HIPAA Authorization meets the federal regulations and institutional requirements, no further IRB review is necessary unless the PI makes subsequent changes to the authorization. The PI obtains IRB review prior to implementing changes in the authorization.
10. The OIRB maintains copies of all versions of the PI's HIPAA authorization form for a period of no less than six (6) years after the study closure. (See IRB Records Management and Retention SOP.)
11. The OIRB revises the IRB's template authorization form/template as appropriate.

Waiver of HIPAA Authorization Review Procedures

1. The PI makes a preliminary assessment to determine whether his/her protocol meets the criteria for a waiver of HIPAA authorization.
2. The PI submits an IRB application and a waiver request using the HIPAA Waiver of Authorization Request Form, which includes all federally and institutionally mandated criteria, to the OIRB.
3. OIRB staff reviews the protocol and determines whether the study includes PHI and a research waiver of authorization request is appropriate for the study. OIRB staff also reviews the waiver request to ensure that all federally and institutionally mandated criteria are addressed and provides the form to the IRB and/or IRB reviewer.
4. IRB members review the justifications provided by the PI in the HIPAA Waiver of Authorization Form and makes the final determination as to whether the HIPAA Privacy Rule regulates the study and whether the waiver of authorization is granted.
5. The IRB requests revisions of any waiver of authorization request that does not adequately address the questions/issues in the Waiver of HIPAA Authorization Request Form.
6. The OIRB sends requests for revisions to the PI, who in turn makes the necessary corrections and resubmits the revised form to the OIRB. The IRB reviews the revisions and determines whether all the federally and institutionally mandated criteria for waiver of authorization are satisfied.
7. Once the IRB reviews the waiver, the IRB reviewer signs the waiver of authorization form and uploads the document in IRBNet. The OIRB publishes the signed Waiver of HIPAA Authorization form and notes the waiver decision in the letter sent to the PI.
8. The OIRB maintains copies of all versions of the PI's HIPAA Waiver of Authorization Request Forms for a period of no less than six (6) years after the study is closed. (See IRB Records Management and Retention SOP.)
9. The OIRB revises the HIPAA Waiver of Authorization Request Form as appropriate.

REFERENCES

45 CFR 164.512
45 CFR 164.532
45 CFR 164.530
45 CFR 164.508
45 CFR 164.514

NIH's Research Repositories, Databases, and the HIPAA Privacy Rule
NIH's Privacy Boards and the HIPAA Privacy Rule
UNM Regents' Policy Manual - Section 3.7: Health Sciences Center Institutional Compliance Program
HIPAA Authorization Checklist
HIPAA Waiver of Authorization Request Form