PURPOSE
To describe Institutional Review Board (IRB) policy and procedures for conducting reviews of Health Insurance Portability and Accountability Act (HIPAA) research authorization forms, waiver of authorization requests, de-identification forms, and coordination with the UNM HIPAA Privacy Officer.

REVISIONS FROM PREVIOUS VERSION
None

POLICY
The IRB reviews HIPAA research authorization and authorization waiver requests for any investigator obtaining protected health information (PHI) from a UNM covered entity (CE) department. Although federal regulations do not require IRBs to review authorization forms or waiver requests, UNM IRB made a decision to review authorization forms and waiver requests for human research studies to assist researchers in complying with the HIPAA Privacy Rule. All other HIPAA research issues such as preparatory work, decedent research, limited data sets, public health activities, business associate agreements, privacy notice, and accounting of disclosures fall under the jurisdiction of UNM’s Privacy Officer.

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 UNM CE department that relates to the past, present, or future physical or mental health or conditions of an individual.

A UNM covered entity department is defined as any department 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 Section 3.7 details which UNM departments fall within UNM’s CE.

A business associate agreement is defined as a contract where a person or entity performs certain functions or activities that involve the use and/or disclosure of PHI.
Options for Obtaining Protected Health Information

Researchers have the following six options for obtaining PHI from UNM for research purposes:

- **De-identified Information** - health information that cannot be linked to an individual;
- **Authorization** - a document signed by the subject that gives the researcher permission to use/discard PHI collected during the research study for defined purposes;
- **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 the research cannot practically be done without access to/use of PHI;
- **Limited Data Set** - a subset of identifiers that contain the following elements: city, state, zip code, date of birth, death, or date of service;
- **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
- **Decedent Research** - research where PHI is collected from a subject(s) that is deceased prior to the initiation of the study.

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

PROCEDURE

*General Procedures*

1. IRB members who review research authorizations and waiver of authorization requests comply with the UNM’s HIPAA educational requirements.
2. IRB members do not review any research authorizations or waiver of authorization requests in 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. A PI may call the OIRB if he/she needs assistance in determining whether HIPAA is applicable.
2. The PI submits his/her IRB application and authorization form to the OIRB. The PI uses the IRB’s template HIPAA language, which includes all federally and institutionally mandated criteria, and can be incorporated into the informed consent document or a standalone authorization form can be used.
3. OIRB staff reviews the protocol and determines whether the study is regulated by the HIPAA Privacy Rule and if 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 forward the submission to the OIRB Director for review, who will consult with the UNM Privacy Officer (PO) as needed.
5. OIRB forwards the HIPAA Authorization Checklist and any comments from the PO, if applicable, to the IRB or IRB member assist them with their authorization review.
6. The IRB may review authorizations during initial full review, expedited review, or continuation review. The IRB requests revisions to any authorization form that does not contain all the federally and institutionally mandated criteria for authorization forms.

7. The IRB and/or IRB reviewer make the final determination as to whether the study is regulated by the HIPAA Privacy Rule and whether the researcher must modify the authorization form.

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 authorization forms are satisfied.

9. Once the IRB determines the HIPAA Authorization Form meets the federal regulations and institutional requirements, no further IRB review is necessary unless the investigator makes subsequent changes to the authorization form. The PI obtains IRB review prior to implementing changes in the authorization form.

10. The IRB does not review authorization forms for research activities conducted at sites outside of UNM’s CE.

11. The IRB does not review authorizations under the following circumstances:
   - PHI that was created or received either before or after the compliance date (April 14, 2003) may continue to be used and disclosed for research purposes, if any one of the following was obtained prior to the compliance date:
     - An authorization or other express legal permission from the subject to use or disclose PHI for the research; or
     - The informed consent of the subject to participate in the research; or
     - A waiver of informed consent by the IRB in accordance with the federal regulations pertaining to human subject research protection commonly known as the Common Rule or in accordance with an exception under the FDA’s human subject protection regulations.
   - If the PI obtains a waiver of informed consent prior to the compliance date, but subsequently seeks informed consent after the compliance date, he/she must obtain the participant’s authorization at the time he/she obtains the new informed consent. It is the PI’s responsibility to submit a copy of the authorization form for IRB review.

12. 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.)

13. The OIRB revises the IRB’s template authorization form/template as appropriate.

Research Waiver of Authorization Request Review Procedures

1. The PI makes a preliminary assessment to determine whether his/her proposal needs a HIPAA research waiver of authorization.

2. The PI submits his/her IRB application and research waiver of authorization request to the OIRB. A PI submits a waiver request using the HIPAA Waiver of Authorization Request Form, which includes all federally and institutionally mandated criteria.

3. OIRB staff reviews the protocol and determines whether the study is regulated by the HIPAA Privacy Rule and if 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 in the document and submits 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. The IRB and/or IRB Reviewer make the final determination as to whether the study is regulated by the HIPAA Privacy Rule and whether the waiver of authorization is granted.

5. The IRB may review the waiver of authorization request during initial full review, expedited review, continuation review, or exemption review. The IRB requests revisions of any waiver of authorization request that does not adequately address the questions/issues in the HIPAA Waiver of 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 ORI. The IRB reviews revisions to the HIPAA Waiver of Authorization Request Form 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 Chair or the IRB reviewer signs the waiver of authorization form and uploads the document in IRBNet. The OIRB notes the HIPAA decision in the letter sent to the PI.

8. The IRB does not review a research waiver of authorizations for research activities conducted at sites outside of UNM’s CE.

9. The IRB does not require a research waiver of authorizations under the following circumstances:
   - A PI may use and disclose for research purposes PHI that was created or received either before or after the compliance date (April 14, 2003) if a waiver of informed consent was reviewed by the IRB in accordance with the federal regulations and obtained prior to the compliance date.
   - If the PI obtains a waiver of informed consent prior to the compliance date, but subsequently seeks informed consent after the Compliance Date, he/she must obtain the subject’s authorization at the time he/she obtains the new informed consent.

10. The OIRB maintain 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.)

11. 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
Regents’ Policy Manual - Section 3.7: Health Sciences Center Institutional Compliance Program, Adopted Date: 12-14-2010, Amended: 09-12-2014
HIPAA Authorization Checklist
HIPAA Waiver of Authorization Request Form