

# II3D PR1 Authorization for Research Uses and Disclosures of Protected Health Information

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## Overview

University of Nevada, Reno (the University) and affiliate researchers who wish to create, use or obtain Private Health Information (PHI) as defined under the Health Insurance Portability and Accountability Act of 1996 (AKA: Privacy Rule), must comply with all requirements of the Privacy Rule. This guidance describes the ways in which covered entities can use or disclose PHI for research purposes and University and affiliate investigator responsibilities for same.

In general, the Privacy Rule allows covered entities to use and disclose PHI for research if authorized to do so by the subject in accordance with the requirements of the Privacy Rule. In addition, in certain circumstances, the Rule permits covered entities to use and disclose PHI without Authorization for certain types of research activities. For example, PHI can be used or disclosed for research if

1. a covered entity obtains documentation that a University of Nevada Institutional Review Board (IRB) has waived the requirement for Authorization or allowed an alteration;
2. a covered entity enters into a data use agreement with the investigator for sharing a limited data set; or
3. the proposed use or disclosed is for activities preparatory to research and for research on decedents' information, and the requisite provisions have been met.

(See IRB Policy II3D Privacy in Human Subjects Research for definitions of terms used in this guidance.)

## II3D1 Authorization

University investigators must obtain signed Authorization from the person to whom the PHI applies for uses and disclosures of her or his PHI not otherwise permitted. Individuals have the right to authorize a covered entity to use and disclose her or his PHI for research purposes. This requirement is in addition to the informed consent to participate in research required under the HHS Protection of Human Subjects Regulations and other applicable Federal and State law. The following table describes the relationships among the requirements of the Privacy Rule and regulatory requirements for the protection of human subjects.

***Note: For some research activities, Authorization may be waived. Details are provided below.***

Areas of Distinction	HIPAA Privacy Rule	HHS Protection of Human Subjects Regulations Title 45 CFR Part 46	FDA Protection of Human Subjects Regulations Title 21 CFR Parts 50 and 56
<b>Permissions for Research</b>	<b>Authorization</b>	<b>Informed Consent</b>	<b>Informed Consent</b>
<b>IRB/Privacy Board Responsibilities</b>	Requires the covered entity to obtain Authorization for research use or disclosure of PHI unless a regulatory permission applies. Because of this, the IRB or Privacy Board would only see requests to waive or alter the Authorization requirement. In exercising Privacy Rule authority, the IRB or Privacy Board does not review the Authorization form.	The IRB must ensure that informed consent will be sought from and documented for each subject or the subject's LAR* in accordance with and to the extent required by HHS regulations. If specified criteria are met, the IRB may waive the requirements for either obtaining informed consent or documenting informed consent. The IRB must review and approve the Authorization form if it is combined with the informed consent document. Privacy Boards have no authority under the HHS Protection of Human Subjects Regulations.	The IRB must ensure that informed consent will be sought from and documented for each subject or the subject's LAR* in accordance with and to the extent required by FDA regulations. If specified criteria are met, the requirements for either obtaining informed consent or documenting informed consent may be waived. The IRB must review and approve the Authorization form if it is combined with the informed consent document. Privacy Boards have no authority under the FDA Protection of Human Subjects Regulations.
*LAR: legally authorized representative			

### **II3D1a Elements of an Authorization**

A valid Privacy Rule Authorization is an individual's signed permission to allow a covered entity to use or disclose the individual's PHI for the purposes and to the recipient or recipients, as stated in the Authorization. Authorizations obtained for research purposes may pertain only to a specific research study, not to nonspecific research or to future, unspecified projects.

The Privacy Rule considers the creation and maintenance of a research repository or database as a specific research activity which means that the subsequent use or disclosure by a covered entity of information from the database for a research study requires a separate Authorization unless the PHI use or disclosure is permitted without Authorization (discussed later in this section).

If an Authorization for research is obtained, the actual uses and disclosures of the PHI must be consistent with what is stated in the Authorization. The signed Authorization must be retained by the covered entity for 6 years from the date of creation or the date it was last in effect, whichever is later.

### **II3D1b Authorization Versus Informed Consent**

An Authorization differs from an informed consent document in that an Authorization focuses on privacy risks and states how, why and to whom the PHI will be used or disclosed for research. Informed consent provides research subjects with descriptions of the study, its anticipated risks and benefits, and methods by which investigators will protect the confidentiality of research records.

## II3D1c Authorization Core Elements

An Authorization for the use, disclosure or both of PHI must include the following:

- a description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner;
- the names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure;
- the names or other specific identification of the person or persons (or class of persons) to whom the covered entity may make the requested use or disclosure;
- a description of each purpose of the requested use or disclosure;
- authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure ("end of the research study" or "none" are permissible for research, including for the creation and maintenance of a research database or repository); and
- signature of the individual and date. If the individual's legally authorized representative signs the authorization, a description of the representative's authority to act for the individual must also be provided.

## II3D1d Authorization Required Statements

The Authorization must include a statement informing the signer of her or his right to revoke the authorization and an explanation of how to do so. If the research involves exceptions to the person's right to revoke her or his Authorization, these must be described in the Authorization. Additionally, the Authorization must state if research-related treatment is contingent upon the Authorization and must include consequences of refusing to sign the Authorization, if applicable.

The Authorization must reference the potential risk that PHI may be re-disclosed by the recipient which may be a general statement that the Privacy Rule may no longer protect health information disclosed to the recipient.

University and affiliate investigators should use the University's Authorization to Use, Create and Share Health Information for Research Purposes form unless circumstances require the researcher to use a form from another institution or to draft a form. If the latter, investigators must write the Authorization in plain language and it must contain the core elements and required statements.

If a covered entity itself is seeking the Authorization, a signed copy of the form must be provided to the individual signing it.

There may be situations that permit disclosure of PHI to a person or organization that is not a covered entity or to a business associate acting on behalf of a covered entity (such as a sponsor or funding source of the research). In such cases, the Privacy Rule does not continue to protect the disclosed PHI

although other applicable Federal and State laws between the disclosing covered entity and the PHI recipient may establish continuing protections for the disclosed information.

Under HHS OHRP and FDA regulations an IRB may impose further restrictions on the use or disclosure of research information to protect subjects.

An Authorization for research uses and disclosures need not include a fixed expiration date or event; the form can list "none" or "the end of the research project." However, although such authorizations, need not expire, a research subject has the right to revoke, in writing, her or his Authorization at any time. The revocation is effective immediately but does not apply to previously authorized actions that the covered entity took before learning of the revocation. For example, a covered entity is not required to retrieve information that it disclosed under a previously valid but subsequently revoked Authorization. Investigators may continue the use and disclosure of PHI already obtained with the Authorization to the extent necessary to protect the integrity of the research (e.g., to account for a subject's withdrawal from the research study, to conduct investigations of scientific misconduct or to report adverse events).

## **II3D2 Waiver or Alteration of the Authorization Requirement**

Many health research projects and protocols cannot be undertaken using health information that has been de-identified or it may not be feasible for a researcher to obtain a signed Authorization for all PHI the researcher needs to obtain for the research study. As warranted by the proposed research, the University allows investigators to use the provisions in the Privacy Rule that allow for waivers or alterations of Authorizations, providing the requisite criteria are met.

Waivers or alterations of Authorizations do not affect the regulatory requirements or University policy for IRB for review and approval of protocols or consent documents. However, the Privacy Rule adds to such requirements when a researcher requests a waiver or an alteration of Authorization.

For acceptable uses and disclosures of PHI, the University IRB may approve a waiver or an alteration of the Authorization requirement in whole or in part. An IRB determination that no Authorization will be required for a covered entity to use and disclose PHI for a particular research project constitutes a complete waiver of Authorization. A partial waiver of Authorization occurs when an IRB determines that a covered entity does not need Authorization for all PHI uses and disclosures for research purposes, such as disclosing PHI for research recruitment purposes. An IRB may also approve a request that removes some PHI, but not all, or alters the requirements for an Authorization (i.e., an alteration of Authorization).

### **II3D2a Required Documentation for Waivers or Alterations of HIPAA Authorization**

The required documentation for waivers must indicate that the IRB followed normal or expedited procedures in reviewing and approving the waiver or alteration. Investigators requesting waivers or alterations of Authorization must also request a waiver of consent. Both waiver requests must be documented and sufficiently justified in the IRB protocol.

Documentation of the waiver or alteration of Authorization must include a statement identifying the IRB that made the approval and the date of approval, and statements that the IRB has determined that the waiver or alteration of Authorization, in whole or in part, satisfies the criteria itemized below.

- The use or disclosure of the PHI involves no more than minimal risk to the privacy of individuals and the waiver includes
  - an adequate plan to protect health information identifiers from improper use and disclosure;
  - an adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification or legal requirement for retaining them); and
  - adequate written assurances that the PHI will not be reused, disclosed to or shared with any other person or entity, with the following exceptions: disclosure is required by law or is necessary for authorized oversight of the research study, or involves use or disclosure that would be permitted under the Privacy Rule.
- The research could not practicably be conducted without the waiver or alteration.
- The research could not practicably be conducted without access to and use of the PHI.

*Note: The University IRB is not required to review the form or content of the Authorization a researcher or covered entity will use, or the proposed uses and disclosures of PHI made according to an Authorization. However, the IRB must review and approve requests to waive or alter the Authorization requirement.*

For multi-site research studies, a University or affiliate covered entity may rely on a waiver or an alteration of Authorization approved by any IRB without regard to the location of the approver, unless site-specific Authorization is required by the University or affiliate site. Such determinations will be made on a case-by-case basis.

### **II3D3 Limited Data Set and Data Use Agreement**

The University abides by the exception to the Privacy Rule that permits a covered entity, without obtaining an Authorization or documentation of a waiver or an alteration of Authorization, to use and disclose PHI included in a limited data set for research activities conducted by itself, another covered entity or a researcher who is not a covered entity if the disclosing covered entity and the limited data set recipient enter into a data use agreement (see IRB Policy for a definition of limited data set and data use agreement).

*Note: Limited data sets are still PHI when the sets contain identifiable information.*

A data use agreement is the means by which covered entities obtain satisfactory assurances that the recipient of the limited data set will use or disclose the PHI in the data set only for specified purposes. Even if the person requesting a limited data set from a covered entity is an employee or a member of the covered entity's workforce, a written data use agreement meeting the Privacy Rule's requirements must be in place between the covered entity and the limited data set recipient.

### **I13D3a Required Content for Limited Data Set and Data Use Agreements**

Data use agreements must describe the permitted uses and disclosure, identify who is permitted to use or receive the limited data set and must specify that the recipient will not use or disclose the information other than permitted by the agreement or otherwise required by law.

The document must address the investigators' responsibilities itemized below.

- The investigator agrees to use appropriate safeguards to prevent the use or disclosure of the information, except as provided for in the agreement.
- The investigator agrees to report to the covered entity any known uses or disclosures in violation of the agreement.
- The investigator agrees to insure that all members of the research team who may use the PHI will adhere to the standards, restrictions and conditions stated in the data use agreement.
- The investigator must agree to not seek to identify the information or contact the individuals.

When a University or affiliate covered entity receives a limited data set and violates the data use agreement, it is a violation of the Privacy Rule and must be reported to the IRB as potential noncompliance.