INDIANA UNIVERSITY

# HIPAA-P03
# Authorization Requirements for Use and Disclosure of PHI

**FULL POLICY CONTENTS**



**Effective:** July 1, 2014
**Last Updated:** January 13, 2016

**Responsible University Office:**
*Vice President for University Clinical Affairs*

**Responsible University Administrator**
*Associate Vice President for Research Administration*

**Policy Contact:**
*IU HIPAA Privacy Officer*

## Scope

This policy applies to all personnel, regardless of affiliation, who have access to Protected Health Information ("PHI") under the auspices of Indiana University (IU), including IU HIPAA Affected Areas.

## Reason for Policy

To establish when a valid Authorization using, requesting or disclosing PHI is required, what a valid Authorization must contain and when uses and disclosures may be made without an Authorization.

## Definitions

See HIPAA Glossary for a complete list of terms.

# Policy Statement

IU HIPAA Affected Areas shall obtain a valid, signed Authorization from an Individual prior to using or disclosing the Individual's protected health information (PHI), unless the use or disclosure is otherwise permitted or required by federal and/or state law.

### A. General Authorizations

Except as otherwise permitted or required by HIPAA, IU HIPAA Affected Areas may not use or disclose PHI without a valid Authorization.

When IU HIPAA Affected Areas obtain or receive a valid Authorization for its use or disclosure of PHI, such use or disclosure shall be consistent with such authorization.

### B. Psychotherapy Notes

Use and disclosure of Psychotherapy Notes is subject to a heightened level of privacy/security under HIPAA/HITECH. Hence, Psychotherapy Notes may not be disclosed without first obtaining the patient's authorization except under specific circumstances.

### C. Marketing

1. Notwithstanding any other provision of HIPAA, IU HIPAA Affected Areas shall obtain an Authorization for any use or disclosure of PHI for all communications, whether for "treatment" or "health care operations" purposes, where the IU HIPAA Affected Area receives payment (direct or indirect) for making the communication from a third party whose product or service is being marketed. Unless the communication is:
    a. a refill reminder or other communications that are about a drug or biologic that is currently being prescribed for the individual;
    b. a face-to-face communication made by the IU Affected Area to the Individual; or
    c. a promotional gift of nominal value provided by the IU HIPAA Affected Area.
2. If the IU HIPAA Affected Area will be paid by a third party for the marketing activity the Authorization must include a statement the marketing involves payment by a third party.
3. The following communications are exempt from the marketing requirements:
    a. communications promoting health in general, which do not promote a product or service from a particular provider
    b. communications about government and government-sponsored programs, such as Medicare, Medicaid, or the State Children's Health Insurance Program.

### D. Research

IU HIPAA Affected Areas shall obtain an Authorization or an IRB-approved waiver of Authorization for use or disclosure of PHI for research purposes, unless an exception applies and in accordance with [*Section II: SOP's 3.3.1.3 Authorization from the Research Participant:* http://researchadmin.iu.edu/HumanSubjects/hsdocs/IRB_SOPs_1_3_2013.pdf

### E. Authorizations by Minors

1. In situations where the parent or guardian of a minor has the authority to act on behalf of the minor as the minor's legally authorized representative, and an Authorization to use or

disclose the minor's PHI is required, the Authorization may be signed by the minor's legally authorized representative.

2. If the minor has the authority to act on his or her own behalf in receiving health care services, then the minor must sign his or her own Authorization. In this situation, the minor must authorize any disclosures to parents or guardians. IU HIPAA Affected Areas shall refer to relevant state law for information about the legal rights of minors to act on his or her own behalf.

**F. Required Contents of Authorization**

1. Authorizations shall be written in plain language and shall include, at a minimum, the following required elements:
    a. A specific description of the PHI to be used or disclosed – must identify the information in a specific fashion (e.g. not just entire chart or all medical records);
    b. The name of the organization or other specific identification of the person(s) or class of persons (e.g., billing office, human resources department, medical director, etc.) being authorized to make the requested use or disclosure;
    c. The name of the organization or other specific identification of the person(s) or class of persons being authorized to receive the requested disclosure;
    d. A description of the purpose for each use or disclosure being requested. "At the request of the Individual" is sufficient description when the Individual initiates the request;
    e. A specific expiration date or expiration event relating to the purpose; and
    f. Individual signature and date. If signature is by the personal representative, a description of the representative's authority (e.g., custodial parent, executor, conservator).
2. A valid Authorization shall also include the following required statements to notify an Individual of:
    a. The right to revoke the Authorization at any time in writing; that the revocation is effective upon receipt, but a use or disclosure that has already occurred cannot be withdrawn;
    b. How to revoke an Authorization;
    c. Whether or not the Individual's treatment or payment is conditioned on the Authorization (see Prohibition on Conditioning of Authorization below); and
    d. The potential for re-disclosure of PHI by a recipient who is not required by HIPAA to protect PHI.
    e. Individual's signature and date
3. Authorizations are not valid, if:
    a. The expiration date has passed or the expiration event is known by the covered entity to have occurred;
    b. The Authorization has not been filled out completely, if applicable;
    c. The Authorization is known to have been revoked;
    d. The Authorization violates any state or federal law, if applicable;
    e. Any material information in the Authorization is known by the covered entity to be false.

**G. Compound Authorizations**

1. An Authorization for use or disclosure of PHI may not be combined with any other document to create a compound Authorization, except as follows:
    a. Authorization to use or disclose PHI for a research study may be combined with other types of written permission for the same research study provided the conditions for a valid Authorization are satisfied.
    b. Authorization to use or disclose psychotherapy notes may only be combined with another authorization for the same psychotherapy notes.
2. Authorizations may be combined with other authorizations, except in the instance where a covered entity has conditioned the provision of treatment, payment, health plan enrollment or health benefits eligibility upon one of the Authorizations.

**H. Prohibition on Conditioning of Authorization**

IU HIPAA Affected Areas shall not condition an Individual's treatment or payment on whether the Individual signs a requested Authorization, except for:

1. Research related treatment may be conditioned on an Authorization to use or disclose PHI for the research project; and
2. Healthcare provided solely for the purpose of creating PHI for disclosure to a third party may be conditioned on an Authorization to disclose to the third party (e.g., pre-employment examinations, research treatments, school physicals).

**I. Copy to Individual**

IU HIPAA Affected Areas shall provide a copy of the signed Authorization to the Individual.

**J. Revocation of Authorization**

IU HIPAA Affected Areas shall permit an individual to revoke an Authorization at any time, provided that the revocation is in writing, except to the extent that the IU Affected Area has taken action in reliance of the Authorization.

**K. Authorization Not Required**

As provided in the IU HIPAA Policy on Uses and Disclosures, IU HIPAA Affected Areas may use and disclose PHI without an authorization:

1. to carry out treatment, payment or health care operations;
2. for its own training programs;
3. to defend a legal action or other proceeding brought by the Individual;
4. as required by the Secretary of HHS;
5. for health oversight activities;
6. as required by law;
7. as required to public health authorities; or
8. to prevent or lessen a serious and imminent threat to the health or safety of a person or the public.

# Attachments

Attachment A – Description of the Authorization for Research Purposes

Attachment B – Instructions for Completing Authorization for Research Purposes

# Related Information

**HIPAA Privacy and Security Rules**

45 CFR §§ 160 and 164

**HITECH Act - Amended**

45 CFR §§ 160 and 164

**Related IU Policies**

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|---|---|
| HIPAA-A03 | Hybrid Designation |
| HIPAA-G01 | HIPAA Sanctions Guidance |
| HIPAA-P01 | Uses & Disclosures of Protected Health Information Policy |
| HIPAA-P02 | Minimum Necessary Policy |
| IT-12.1 | IU Mobile Device Security Standard |
| PA/SS 6.4 | Corrective Action Policy (non-union)<br>University HIPAA Privacy and Security Compliance Plan |
| IRB SOPs | IU Standard Operating Procedures for Research Involving Human Subjects – Section 3.3.1.2 Limited Data Set |

# History

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|---|---|
| 11/12/2013 | Draft Sent to HIPAA Privacy and Security Compliance Council |
| 07/01/2014 | Final |
| 01/13/2016 | Updated Definition Section |

# Attachment A

# Requirements of an Authorization for Research Purposes

A Privacy Rule Authorization is an individual's signed permission to allow a covered entity to use or disclose the individual's protected health information (PHI) that is described in the Authorization for the purpose(s) and to the recipient(s) stated in the Authorization. In contrast, an informed consent document is an individual's agreement to participate in the research study and includes a description of the study, anticipated risks and/or benefits, and how the confidentiality of records will be protected, among other things. An Authorization can be combined with an informed consent document or other permission to participate in research. If a covered entity obtains or receives a valid Authorization for use or disclosure of PHI for research, it may then use or disclose the PHI for the research, but the use or disclosure must be consistent with the Authorization.

The Authorization must be written in plain language. A copy of the signed Authorization must be provided to the individual signing it if the covered entity itself is seeking the Authorization. The Privacy Rule does not specify who must draft the Authorization, so a researcher could draft one. The Privacy Rule specifies core elements and required statements that must be included in an Authorization. An Authorization is not valid unless it contains all of the required elements and statements. An Authorization form may also, but is not required to, include additional, optional elements so long as they are not inconsistent with the required elements and statements and are not otherwise contrary to the Authorization requirements of the Privacy Rule. An Authorization, whether prepared by a covered entity or by a person requesting PHI from a covered entity, must include the following core elements and required statements:

**Authorization Core Elements** (see Privacy Rule, *45 C.F.R.* §164.508(c)(1))

- Description of PHI to be used or disclosed (identifying the information in a specific and meaningful manner).
- The name(s) or other specific identification of person(s) or class of persons authorized to make the requested use or disclosure.
- The name(s) or other specific identification of the person(s) or class of persons who may use the PHI or to whom the covered entity may make the requested disclosure.
- Description of each purpose of the requested use or disclosure. Researchers should note that this element must be research study specific, not for future unspecified research.
- Authorization expiration date or event that relates to the individual or to the purpose of the use or disclosure (the terms "end of the research study" or "none" may be used for research, including for the creation and maintenance of a research database or repository).
- Signature of the individual and date. If the Authorization is signed by an individual's personal representative, a description of the representative's authority to act for the individual.

**Authorization Required Statements** (see Privacy Rule, *45 C.F.R.* § 164.508(c)(2))

- The individual's right to revoke his/her Authorization in writing and either (1) the exceptions to the right to revoke and a description of how the individual may revoke Authorization or (2) reference to the corresponding section(s) of the covered entity's Notice of Privacy Practices.
- Notice of the covered entity's ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and, if applicable, consequences of refusing to sign the Authorization.
- The potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule. This statement does not require an analysis of risk for re-disclosure but may be a general statement that the Privacy Rule may no longer protect health information.*

A research subject may revoke his/her Authorization at any time. However, a covered entity may continue to use and disclose PHI that was obtained before the individual revoked Authorization to the extent that the entity has taken action in reliance on the Authorization. In cases where the research is conducted by the covered entity, this would permit the covered entity to continue using or disclosing the PHI as necessary to maintain the integrity of the research, as, for example, to account for a subject's withdrawal from the research study, to conduct investigations of scientific misconduct, or to report adverse events.
Indiana University, Office of Research Compliance has developed the Authorization for the Release of Health Information for Research which includes all core elements and required statements listed as well as it is designed to meet the minimum necessary requirement.

# Attachment B

# Instructions for Completing IU's Authorization for Research Purposes

The HIPAA Privacy Rule generally prohibits health care providers from using or releasing protected health information for research purposes without written authorization from the subject/patient ("participant"). A HIPAA authorization must contain specific core elements and required statements to be valid under the regulations.

The IU template research authorization was prepared to comply with the HIPAA privacy regulations and Indiana statute. This includes the requirements to obtain a participant's permission to use health information for research purposes and to request, use and disclose only the ***minimum*** amount of information necessary to accomplish the intended purpose or goal.

The Office of the VP for Research, Research Compliance Offices of Clinical Research Compliance and Human Subjects and the Interim University HIPAA Privacy Officer have approved this document for use. It should be provided to the research participant during the informed consent process. The investigator should obtain the signature of the participant (or his/her personal representative) and the date of signature, as indicated on the last page of the document. If the authorization for research purposes is not properly completed, signed and dated, it would not be considered a valid authorization and could adversely impact your research.

## Specific Instructions

Instructions for completing specific sections of the authorization are in italics in the authorization document. **Please delete the instructions and examples** in italics in your final version of the document.

**1. <u>This authorization relates to the following study:</u>**

***Please insert Study Information:***

Title of the Research
IBB Protocol #
Name of the Principal Investigator
Sponsor #

***Please insert Participant Information:***

Name of Research Participant
Birthdate
Address (Required by the State of Indiana)

## 2. Health Information Covered by this Authorization

***This permission is for health care provided to you*** _____

Use this field to describe a date range or time period and/or specific medical conditions. Understand this refers to the information needed and recorded for research purposes only, not for treatment purposes.

***I understand the information listed below will be released and used for this research study:***

Delete any information that is not applicable.

- Only information provided by you, no other information will be requested
  *If you select this option, please delete the all the following options*
- All records *[If you select this option, you may be required to justify this request including providing documentation during a HIPAA Privacy audit.]*
  *If you select this option delete the first option & "other" then add language that states:*
  *This may include, but is not limited to: (the remainder of this list)*
- Hospital discharge summary
- Radiology records
- Medical history / treatment
- Medications
- Consultations
- Radiology films (like X-rays or CT scans)
- Laboratory / diagnostic tests
- EKG reports
- EEG reports
- Psychological testing
- Pathology reports
- Operative reports (about an operation)
- Pathology specimen(s) and/or slide(s)
- Diagnostic imaging reports
- Dental records
- Other: [specify other here]

## 3. Specific Authorization

*If you selected: Only information provided by you, no other information will be requested*
*You may delete this section, but only in this situation*

HIPAA and Indiana Law require we allow a participant to restrict the use of certain sensitive information. We are also required to tell the participant if that restriction will affect their ability to participate in the research study.

I understand that this release also pertains to records concerning hospitalization or treatment that may include the categories listed below. I have the right to specifically request that records **NOT** be released from my health care providers to the Research Team. However, I understand that if I limit access to any of the records listed below, I [***will not*** *OR* ***will still***] be able to participate in this research study. Check limitations, if any, below:

*Select: **will not** or **will still** and delete the one that does not apply*

Records that may be restricted include:

- ☐ Mental health records
- ☐ Psychotherapy Notes
- ☐ HIV (AIDS)
- ☐ Other: _____
- ☐ Sexually transmitted diseases
- ☐ Alcohol / Substance abuse
- ☐ Sickle Cell Anemia

## 4. Who will be requested to release this information?

Since IU is an academic medical center that sees participants from all over the world and IU does not own the affiliated hospitals or physician practices, it is important we make it clear to the participant who we will contact to request records. Also this ensures the provider(s) know the participant specifically gave them permission to release the records to you for research purposes.

- Only information provided by you, no other information will be requested
  *If you select this option,* ***delete the remaining options***
  *If you will be requesting information for any health care provider,* ***delete this option***
- Indiana University Health: Riley Hospital, Methodist Hospital, or University Hospital
- Indiana University Health Physicians*[Include Specialty]*
  *For Example: Indiana University Health Physicians, Neurology and Neurosurgery*
- Eskenazi Health/Wishard Hospital
- IUMG – Primary Care Physicians
- Eskenazi Health Physicians
- Roudebush VAMC (See VA Authorization form)
- Indiana Network for Patient Care (INPC)
- *[Name of health care organization(s) or provider(s)]*
- *[Insert the name or leave a space for the participant to write in the name(s)]*

## 5. Who can access your PHI for the study?

This information is required and informs the participant who will have access to their information for this research purpose. The first seven (7) primary bullets must not be deleted as they apply to all studies conducted at IU when an authorization is required. The remaining items may or may not be applicable, but be sure you include **all** that apply.

- The researchers and research staff conducting the study at *Indiana University* and *IU Health*
  *Delete IU or IUH if one does not apply, but do not delete this line*
- The Principal Investigator: ***[Insert Name]***
- The members and staff of the Indiana University Human Subjects Office
- The members of the Indiana University Institutional Review Boards (IRB) that approve this study
- Indiana University and/or Indiana University affiliated institutions or offices with compliance and financial oversight including but not limited to:
  - Research Compliance
  - HIPAA Privacy and Security Compliance
  - Billing and Payment Activities
  - Clinical Trials Billing Compliance
  - General Compliance Activities
  - General Counsel's Office

- Internal Audit
- US or foreign governments or agencies as required by law
- Federal Agencies with Research oversight responsibilities including but not limited to:
  - The United States Department of Health & Human Services (HHS)
    - Office for Human Research Protections (OHRP)
    - Office for Civil Rights (OCR)

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*The remaining lines can be deleted if they do not apply to this study*

- The United States Food and Drug Administration (FDA)
  *If research is FDA regulated, must include this option*
- Research teams at other institutions or research site(s): ***[list]***
  *If research involves researchers at other institutions or sites, must include this option*
- The following research sponsor(s): ***[list]***
  *If research is a sponsored study, must include this option*
- Contract Research Organization ***[Name]***
  *If research involves a contract research organization, must include this option*
- Data and Safety Monitoring Boards
  *If research requires data and safety monitoring, must include this option*

## 6. Expiration date of the authorization

HIPAA requires information related to the end date of an authorization or expiration criteria. You must enter one of the following; delete those that do not apply.

- ☐ Date: __/__/____
- ☐ When the research ends and required monitoring of the study has been completed.
- ☐ When *[insert description of event or other circumstance. Examples: one year after death; one year after you reach age 50]*.
- ☐ None, this authorization is valid indefinitely

## 7. Participant's Rights

Participants must understand their rights under HIPAA which include:

- The right to refuse to sign this authorization
  It must be clear to the participant they can refuse to sign an authorization and if they do not sign the form it will not affect their treatment, payment, enrollment or eligibility for benefits. However, but not signing it will prevent them from participating in the research study

- Review and obtain a copy of their personal health information
  While participants have a right to access their health information under HIPAA, access to the research records can be delayed if it is determined access could be harmful to the quality of the research. This should be communicated to the participant if they make such a request during the study. You must comply with the request or provide in writing an explanation as to why you are not providing a copy at the time of the request.
  Sample Response:
  You have a right to review and obtain a copy of your personal health information collected during the study. However, the Dr. [PI's name] has determined releasing records prior to the completion may affect

the success and integrity of this study. Therefore your request for a copy of your records will be delayed until this study is completed.

- Right to cancel or revoke the release of their information and who they must contact and that cancelling the authorization may end their participation in the study.

  To cancel this release of information/authorization at any time. If I choose to cancel this release of information/authorization, I must notify the Principal Investigator for this study **in writing** at: _____ *(provide organization name and address)*. However, even if I cancel this release of information/authorization, the Research Team, Research Sponsor(s) and/or the Research Organizations may still use information about me that was collected as part of the research project between the date I signed the current form and the date I cancel the authorization. This is to protect the quality of the research results. I understand that canceling this authorization may end my participation in this study.

  Enter the Study Contact's name and address for written notification.

- Right to receive a copy of this authorization
  The participant must be provided a signed copy of this authorization

## 8. Participant's Signature

Finally you must give the participant the opportunity to ask questions about the authorization. The participant must also sign and date the form and be provided a copy with signature.

If the form is signed by someone other than the participant, you must mark why the participant is unable to sign as well as the legal authority that allows them to sign.

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If any of the required elements of this document are missing, it is not considered a valid authorization and your research would not be in compliance with HIPAA requirements.

**No Modifications**

This authorization may not be modified except as described above. Any other modifications of this document must be approved by the Human Subjects Office.

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