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

   IRB Protocol #

   Name of the Principal Investigator

   Sponsor #

   Please insert Participant Information:

   Name of Research Participant

   Street Address (Required by Indiana Law)

   City/State/Zip (Required by Indiana Law)

2. **<u>Health Information Covered by this Authorization</u>**

   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]

In the event of an adverse event, such as injury related to the research, other records may be accessed for the purposes of your treatment and/or for reporting purposes. This may include records from other health care providers from which you have received medical care, but who are not specifically listed in this Authorization.

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
☐ Sexually transmitted diseases
☐ Alcohol / Substance abuse

☐ HIV (AIDS) ☐ Sickle Cell Anemia
☐ Other: _____

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:
  - Office of Research Compliance
  - Office of Research Administration
  - HIPAA Privacy and Security Compliance Office
  - 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)

- National Institutes of Health (NIH) [for NIH sponsored research]

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]*.

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 - required.

- 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.

Sponsors are not permitted to change this authorization. This documents meets the requirements under HIPAA as well as Indiana State Law.

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