**WSU IRB HIPAA Authorization Worksheet**

This worksheet was created to help you ensure compliance with HIPAA authorization requirements and to convert to the new WSU IRB’s Authorization Template language. It is important to note that WSU normally is not the covered entity for research reviewed by the WSU IRB and so the authorization language must reflect who the covered entity (e.g., health care organization) is to be valid. When conducting a self-audit of current authorization language or when reviewing and utilizing new authorization forms that do not employ this research authorization template language, please carefully follow these five steps:

**Step 1:**

Determine whether your authorization contains all of the following core elements in sufficient detail (…*see authorization Template at end of worksheet for examples*). If you cannot use the WSU IRB template below then you must submit a copy of your consent with the authorization elements clearly labeled below to request permission to use alternate language. An easy way to do this is with the comments function in Word. Highlight the language that meets the element/statement, click add new comment and then type in Element or Statement # that applies.:

* **Element #1** - A description of the PHI to be used or disclosed, identifying the information in a **specific and meaningful** **manner**. This list of health information should be specific to the research study. For example, instead of “entire medical record” use “medical records related to your psoriasis.” An “entire medical record” could include psychotherapy notes, hemorrhoid care, HIV status…a lot of personal/sensitive information that you may not need for your study. You don’t have to list every data point, but be specific enough that a potential subject can understand and evaluate your request.
* **Element #2** - The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure (e.g., PI Name and his/her research staff members at Premier Health or other covered entity).
* **Element #3** - The names of individuals, organizations, companies, and/or class of individuals to whom (Select appropriate Premier/Dayton Children’s/Wright State Physicians or other covered entity) officials and researchers may disclose (share) or who may use the subject’s PHI in relation to the research study. Wright State University researchers should be included in this list, if applicable.
* **Element #4** - A description of the purpose(s) of the requested use or disclosure. For Premier research studies, the “purpose” would include the title of the research study and the overall purpose of the research. Authorization is a separate decision process, therefore, all of the information a subject will need to make that decision should be within the same section of the consent form or within the stand-alone authorization document. Consent forms can be lengthy and complicated – subjects should not be forced to go back through the document to find information related to authorization.
* **Element #5** - The 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).
* **Element #6** - Signature of the individual and date. If the subject's legally authorized representative signs the authorization, a description of the representative's authority to act for the individual must also be provided.

**Step 2:**

Determine whether authorization contains all of the following required statements:

* **Statement #1** - A statement of the subject's right to revoke authorization and how to do so, and, if applicable, the exceptions to the right to revoke authorization.
* **Statement #2** – A statement explaining whether non-research treatment, payment, enrollment, or eligibility of benefits can be conditioned on authorization. In addition, whether a subject can still participate in research study if they don’t provide authorization.
* **Statement #3** - A statement of the potential risk that PHI will be re-disclosed by the recipient and no longer protected by the Privacy Rule. This may be a general statement that the Privacy Rule may no longer protect health information disclosed to the recipient.

**Step 3:**

Confirm that the core elements and required statements contain plain language, if not, simplify appropriately. Understand that an authorization is not valid unless it contains all of the elements in Steps 1 and 2.

**Step 4:**

Provide a copy of the signed authorization to the research subject. This is required.

**Step 5:**

Properly store signed authorizations. Researchers must retain the authorization for at least six years from when it was signed or from the date when it was last in effect, whichever is later.

\*\*Additional information about research and the Privacy Rule can be found at [www.privacyruleandresearch.nih.gov](http://www.privacyruleandresearch.nih.gov).

**Authorization to Use and Disclose Your Health Information**

**This section is required if you will be accessing, using or creating PHI for this study via a covered entity (e.g., Premier Health, physician office, Dayton Children’s etc… and must be included at the end of your consent form including applicable signature lines.)**

State and Federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect the privacy of your health information. This section of the consent form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information (PHI) for this research study. **Please read this section of the consent form carefully.**

If you sign this document, you give permission to (**insert name of PI)** and his (or her) **Wright State/Premier Health/Dayton Children’s/Wright State Physicians** research team to use or disclose (release) the following protected health information: ***(List PHI to be used, created or disclosed for this study in a specific and meaningful way.)***

* **Your medical records for past medical conditions and medications related to your heart health**
* **All information (research records and medical records) created during your participation in this research study**
* **All information related to illness or hospitalizations that occur during your participation in this study**

The research team needs this information to conduct the study.This is a study to test **(add simple language describing the purpose of the study. For example,** **whether a device called an XYZ can increase the likelihood of survival in patients at risk of a stroke or heart attack.)**

To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally would have access to your health information.

**Disclosure of your protected health information**

If you sign this form, the researchers may share your health information during the conduct of the study with:

* Non-“Premier Health” (insert appropriate covered entity name) researchers or organizations working with (insert appropriate covered entity name) researchers, including Wright State University researchers
* Law enforcement or other agencies, when required by law
* WSU’s Institutional Review Board (or other IRB of record), which oversees our research
* The sponsor (the organization paying for) of this research study: **insert name(s) here**
* Representatives of government agencies in the United States and other countries (i.e. Food and Drug Administration and the Office of Human Research Protection)
* Other authorized WSU/(insert covered entity name) Officials who oversee research and clinical care

The people listed above will use and share your health information to review the quality, safety, and results of the research and may also do additional research.

Please understand that these persons/organizations who may receive your health information may not be required by U.S. Federal privacy laws (such as HIPAA) to protect it and may share your information with others without your permission.

This authorization does not have an expiration date*.*

However, you can change your mind and cancel this authorization at any time. To cancel this authorization, you must write the study investigator listed at the beginning of this consent form.

If you cancel this authorization, you will no longer be allowed to take part in the research study. If you cancel this authorization, health information you had already allowed us to obtain may still be used and disclosed by researchers in order to maintain the integrity and reliability of the research, and to report any adverse (bad) effects that may have happened to you.

If study involves optional activities use the following language, if not delete this highlighted section:

“You can cancel your authorization for the optional part(s) of the study and remain in the main study.”

**Right to refuse to sign this Authorization**

You have the right to refuse to sign and give your authorization. If you do not sign this form, your non-research related treatment, payment or enrollment in any health plans, or your eligibility for other medical benefits at Premier Health will not be affected in any way.

However, if you do not sign this form, you will not be able to participate in this research study.If study includes optional activities use the following language, if not delete highlighted section: “You can still be in the main part of the study even if you do not authorize the use and sharing of your information for the optional part(s) of the study.”

**Signature of Subject**

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research and authorize the use and disclosure of my protected health information for this study. I will be given a copy of this signed and dated form.

Signature Date

Printed Name

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Signature of Person Obtaining Consent and Authorization

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Obtaining Consent and Authorization

 \_\_\_\_\_\_\_\_\_\_\_

Signature of Legally Authorized Rep. Date

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Description of LAR’s Authority (delete highlighted section if LAR use not approved by IRB)