WAYNE STATE UNIVERSITY

Human Investigation Committee

HIPAA Tip Sheet for Investigators

DO NOT SUBMIT THIS TIP SHEET TO THE HIC. THIS IS A GUIDANCE DOCUMENT ONLY.
*HIPAA Documents must be submitted to the HIC when medical records (electronic or paper), clinical databases, and specimen or tissue banks or repositories at Wayne State University or its affiliate institutions are being accessed for research purposes.

*If a data set received by a researcher has no elements of PHI within it and no link is available to the researcher that would connect the participant to the information, HIPAA does not apply to that research protocol.

*When health information is collected directly from the participant in a research study through interviews, questionnaires, surveys and if the research team will never access medical records to verify that information, HIPAA oversight by the HIC is not required.

HIPAA Documentation Required for Initial Submission of Protocols

Protocol Summary Form-
- Check the appropriate boxes regarding sources of data.
- Indicate who will be doing the initial contact of the participant to introduce the study. (Requires someone with a clinical relationship)

Informed Consent Document-
- WSU Research-
  - The required HIPAA Authorization language and signature lines are now included in the WSU informed consent template. Separate signatures are required for both the informed consent and the HIPAA Authorization sections of the template.
  - The HIPAA Authorization follows the signature page on the informed consent template.
- VAMC Research-
  - Use the VA consent template which includes the required HIPAA Authorization language. Separate signatures are required for each section in the template.

HIPAA Summary Form-
- This form provides the IRB committees with information needed to oversee application of HIPAA requirements to research projects being conducted within the institution.
- Submit one copy of the HIPAA Summary Form with the protocol submission.

HIPAA Waiver of Authorization-
- To request a waiver or alteration of Authorization, Section F of the HIPAA Summary Form must be completed in detail and the request for a waiver signed by the PI on the last page.
- The Waiver of Authorization must be reviewed and approved by the HIC and documented in the approval memo for the protocol.

- In order for the HIC to approve the waiver or alteration of the Authorization,, the request must satisfy the following criteria:
    - The use or disclosure involves no more than minimal risk to the privacy of individuals based on the presence of the following elements.
    - 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.
    - Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research, or for other research for which the use or disclosure of the PHI would be permitted.
    - 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.

HIPAA Authorization-

- The HIPAA Authorization is now a part of the Informed Consent Template. It follows the signature page of the consent and must be included in the protocol submission along with the required consent document content.
- This required language provides specific information to the research participant regarding the use and or disclosure of their PHI for research purposes and their rights under the law.
- The PI must complete all of the required sections of the authorization and must indicate which PHI will be used or disclosed.
- When research participants sign this form, they are authorizing use/and or disclosure of the PHI specified within the document for a particular research study.
- The participant must sign separately at the end of the HIPAA section of the consent template in order to authorize use or disclosure of PHI for research purposes.
- The John D. Dingell Veterans Administration Medical Center (JDD VAMC) also has required HIPAA language contained within the consent template, and a separate authorization signature is required on the VAMC template.
- Submit two clean copies with the protocol submission.
- If changes are made to the content in the Authorization (e.g. new or altered uses or disclosures, new recipients of PHI), the revision must be submitted to the HIC as an amendment.

Please refer to the "HIPAA Flow Chart" and the HIC Policy/Procedure "HIPAA Requirements in Research" located under the HIPAA Link at www.hic.wayne.edu for additional information.