HIPAA Instructions for All IRB Applications

The Health Insurance Portability and Accountability Act (HIPAA) is designed by the federal government to protect the use and disclosure of Protected Health Information or PHI. **PHI** is defined as any of the 18 identifiers listed below* <u>in combination with</u> health information transmitted or maintained in any form (electronic, paper, or oral) that relates to the past, present or future physical or mental health or conditions of an individual.

You may need IRB approval to create, access, store, use or disclose PHI if you are employed outside the Covered Entity (CE) and obtaining PHI from a UK CE department or you are employed by a UK CE department and collecting PHI from subjects. A **CE** is defined as any department (or institution in some cases) that provides services that meets the definition of health care provider, health plan or health care clearinghouse. Contact UK Healthcare Corporate Compliance for a list of departments in the CE [http://ukhealthcare.uky.edu/compliance/ or 859-323-8002].

Note: If you are obtaining PHI from **another institution**, you must use its HIPAA forms and comply with its HIPAA requirements. Only complete this form if you are obtaining PHI from the University of Kentucky or in the CE.

This application will determine: 1) If your research falls under HIPAA; 2) Which HIPAA form (if any) should be completed; 3) Where to request/submit the HIPAA documents.

1. My research protocol involves creating, accessing, using, storing or disclosing PHI.

    ☐ Yes   Go to question two (2).

    ☐ No   STOP. Your research does not fall under HIPAA but you must follow federal/state privacy laws and IRB requirements when dealing with patient/subject information.

2. My department is listed as a University of Kentucky Covered Entity.

    ☐ Yes   Go to page two (2) and complete the HIPAA Application Form. You must comply with all of UK's regulations for creating, accessing, storing and disclosing PHI.

    ☐ No   If you are accessing PHI from UK Medical Records or any other source of PHI within the CE, complete the HIPAA Application Form. You must comply with the UK's HIPAA requirements for accessing PHI. Once PHI is removed from the CE, you must follow federal/state privacy laws and IRB requirements. If you are accessing PHI from another source, call ORI at 257-9084 to determine if HIPAA applies to your study.

If you have HIPAA Research questions, contact: Joe Brown, Research Privacy Specialist, at (859) 257-9084 or Joe.Brown@uky.edu or Helene Lake-Bullock, Research Compliance Officer, at (859) 257-5943 or hlbullo@email.uky.edu.

For questions regarding HIPAA Patient Rights, Data Use Agreement or Accounting of Disclosure, contact the UK Healthcare Privacy Officer, Richard Chapman, at 859-323-1184.

For questions regarding HIPAA agreements such as Data Use Agreements or Business Associate Agreements, contact: Shea Luna, Associate General Counsel, at (859) 323-1161.

<u>*HIPAA recognized identifiers:</u>
Names; All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes; All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; Telephone numbers; Fax numbers; Electronic mail addresses; Social security numbers; Medical record numbers; Health plan beneficiary numbers; Account numbers; Certificate/license numbers; Vehicle identifiers and serial numbers, including license plate numbers; Device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; Biometric identifiers, including finger and voice prints; Full face photographic images and any comparable images; Any other unique identifying number, characteristic, or code.

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☐ <u>De-identified Information</u>: De-identified Information is health information that cannot be linked to an individual. HIPAA lists 18 specific identifiers that must be removed to qualify as de-identified data. The following identifiers can be recorded: initial three digits of the zip code if population is greater than 20K, age if less than 90, gender and ethnicity.

If you are de-identifying protected health information (PHI) for your study and **your department is in the Covered Entity**, complete the de-identification certification form and take it to Medical Records to obtain PHI. Make a copy of the de-identification form and submit it with your IRB application.

If you are de-identifying PHI for your study and **your department is NOT in the Covered Entity**, complete the de-identification certification form <u>and</u> submit a Business Associate Agreement (BAA) to Medical Records to obtain PHI. Make a copy of the de-identification form and submit it with your IRB application. Contact: Shea Luna, Associate General Counsel, at (859) 323-1161 for assistance with BAAs.

☐ <u>Patient Authorization</u>: A patient authorization is a document signed by the subject that gives the researcher permission to use/disclose PHI collected during the research study for defined purposes.

An authorization should be signed by subjects when informed consent is obtained or when subjects are re-consented. If HIPAA Authorization is required for your research, you must use the *Informed Consent/HIPAA Combined Template* as a guide to develop your consent/authorization document, and submit it with your IRB application. For a copy of the template see the IRB application, or contact Joe.Brown@uky.edu, or (859) 257-9084. Take the IRB approved authorization form <u>signed</u> by the subject to Medical Records to obtain PHI.

☐ <u>Waiver of Authorization</u>: A waiver is a request to forgo the authorization requirement based on the fact that the disclosure of PHI is a minimal risk to the subject and the research cannot practically be done without access to/use of PHI. Please complete the waiver of authorization form and submit with your IRB application.

The IRB will issue you a waiver of authorization approval letter. Take this letter to Medical Records to obtain PHI.

For clinical trials only: If you plan to review PHI to identify subjects for recruitment purposes and your sponsor requires you to give them a screening log with PHI (and you have not obtained informed consent or authorization), submit a waiver of authorization form with your application. Note: The waiver of authorization will only be for recruitment purposes.

☐ <u>Limited Data Set</u>: A limited data set is a subset of identifiers that contain the following elements: city, state, zip code, date of birth, death or date of service.

If your department is listed in the Covered Entity, a Data Use Agreement must be completed and submitted to Medical Records to obtain PHI. Contact: Shea Luna, Associate General Counsel, at (859) 323-1161 for assistance with Data Use Agreements.

If your department is NOT listed in the Covered Entity, a Data Use Agreement and a BAA must be completed and submitted to Medical Records to obtain PHI. Contact: Shea Luna, Associate General Counsel, at (859) 323-1161 for assistance with this issue.

☐ <u>Preparatory Work for Research</u>: Preparatory work is PHI reviewed for the purpose of designing a research study or identifying potential subjects. Please go to Medical Records and complete their HIPAA Research Form to obtain PHI.

☐ <u>Decedent Research</u>: Decedent research is research where PHI is collected from a subject(s) that is deceased prior to the initiation of the study. Please go to Medical Records and complete their HIPAA Research Form to obtain PHI.