**Statement on Use of Protected Health Information (PHI)**

This form must be completed and submitted with your application if you will be working with Protected Health Information (PHI). To use PHI in research you must have approval through one of the following methods. Check the appropriate one and submit the additional documentation as indicated. The forms referenced below are available at <https://research.ku.edu/human-subjects-research-forms>. Studies that are exempt from IRB review but that involve the use or disclosure of PHI will require a HIPAA compliant authorization or waiver of the authorization requirement as described further below.

1. \_\_\_\_\_ PHI will be fully de-identified and include none of the 18 HIPAA identifiers. **Submit the HIPAA De-identification Form.** If you are wishing to record data anonymously using existing medical records or other documentation containing PHI, you will have access to identifiable patient data when the data is collected. HIPAA compliant privacy authorization or a waiver of the authorization is required.
2. \_\_\_\_\_ The PHI will be obtained with written HIPAA authorization from individual subjects. **Submit a copy of the Authorization form.** When PHI is derived or obtained from or through a cooperating organization, that organization may require use of its own HIPAA authorization form. A copy must be submitted with the application.
3. \_\_\_\_\_ The PHI being used or disclosed constitutes a Limited Data Set as defined by HIPAA. **Submit a copy of the signed Data Use Agreement.**
4. \_\_\_\_\_ I wish to obtain an IRB waiver of, or alteration of the HIPAA authorization requirement. **Complete the Application for Waiver or Alteration of HIPAA Privacy Authorization Requirement.**
5. \_\_\_\_\_ The PHI is solely for preparation for research and no identifying information will be recorded or removed from the source. See list of 18 HIPAA “identifiers.” Please submit the supporting documentation to be provided to the Covered Entity.
6. \_\_\_\_\_ The research involves decedents and their information only. Please submit the supporting documentation to be provided to the Covered Entity.

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PI Name (Printed)

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Project Title

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PI Signature Date