PROTECTED HEALTH INFORMATION (PHI) AND INSTITUTIONAL REVIEW BOARD (IRB) APPLICATIONS

To see a definition of PHI, visit https://bit.ly/2HMBBbT

Where will your study obtain PHI from?

	From a Purdue Covered Component	Directly from a Healthcare Provider or other HIPAA Covered Entity	Directly from a study participant in the human subjects research	Fully de-identified from a repository, biobank, or databank
What permissions will I need to show the IRB for review of my application?	• Permission via the Purdue Covered Component to access PHI. • Please see www.purdue.edu/hipaa to connect with the Purdue Covered Component's access procedures.	• Contact the Provider's HIPAA privacy department to obtain permission to access their PHI. • Researchers must obtain written permission from the HIPAA Privacy Officer at each study site.	• Participant should give permission to send you this information directly. • The participant may need to work with their HIPAA-covered provider to obtain PHI necessary for the study.	• Contact the provider to determine the process that must occur for access to the de-identified data. This may include contracts or terms required by the repository. • Contracts or Data Use/Access Agreements for datasets must be signed by SPS Contracting. Contact spscontr@purdue.edu to begin the process.
What do I need to include in the IRB application materials ?	• A draft of the Purdue Authorization for Release of PHI. You must include a draft that details the reason for disclosure, personnel, and specific medical records for each study. • If you request a waiver of this authorization,you must provide specific justification to the IRB. See the IRB application narrative form for the criteria required for these requests.	• Include a statement in all consent forms to notify participants that participation in the study requires separate release of PHI from the Covered Entity. • A description of the process required to access PHI from the Provider written into the application. • Write a detailed description of the process required to access PHI from the Provider.	• A description of how data are transferred (i.e. paper, electronic) from the participant to the researcher. This process must appear in the application. • A statement in all consent forms to notify participants that release of their PHI is [required] or [optional] for participation in the study.	• Information about any links to identifiers, direct or indirect that may be exchanged. Explain the process that must take place to access the data or samples. • You will not need to draft a consent form for repository/biobank data.

Research records utilizing PHI must be retained for six years following study closure.

Questions? Contact irb@purdue.edu