WSU IRB Member Guidance - October 2019

Understanding the IRB Electronic Submission Forms

**Initial Review Application:**

This form is used for all new research involving human subjects, including research that is exempt from IRB review. Members can be assigned this form for both expedited and full board reviews. The IRB Office staff can act the Reviewer for exempt research.

**Amendment:**

This form is used to request review and approval of changes to fully approved studies or HUDs. Members can be assigned this form for both expedited and full board reviews. Minor changes to full board studies can also be expedited under Category 10. “Minor changes” are defined in the Expedited Policy. Expedited approval of amendments of expedited studies (minimal risk) should be approved under that same expedited category as the overall study.

Exempt research involving PHI must also be amended using this form if the PI changes the data collected or changes study personnel.

**Continuing Review/Administrative Update:**

For full board (greater than minimal risk) studies, continuing review must occur at least once per 364 days. Three Reviewers are assigned to each continuing review. The PI can also include amendments to the study with the form. In the Reviewer dashboard, each Reviewer must select whether to approve, table or require modifications.

Expedited studies (minimal risk), that were approved via expedited review before or after January 21, 2019 and are not federally funded, funded by DOJ or FDA regulated, then these forms can be reviewed and approved for two years by the IRB Office via Administrative renewal.

Expedited studies (minimal risk), that were approved via expedited review before January 21, 2019 that are federally funded, funded by DOJ or FDA regulated, must be reviewed and approved by at least one Reviewer and given a 1-year approval period. Expedited category should be the same as initial review.

Expedited studies (minimal risk), that were approved via expedited review after January 21, 2019 and are federally funded must receive 2-year Administrative renewal via IRB Office review.

Any expedited study in which an amendment is requested at the time of continuing review must be reviewed by at least one Reviewer who can approve the amendment and continuing review at the same time regardless of funding.

**Reportable Event:**

The IRB Office will screen this form to ensure that the event reported meets one of the defined events that requires prompt reporting. Reportable event forms are screened by the IRB Chair and then assigned to next full board meeting. If the report is acceptable, then the Reviewer would select “approved.” If the PI needs to take additional actions, then the Reviewer would select “Mods Required” as a determination.

**Miscellaneous Submission:**

The purpose of this submission is to provide a way for investigators to submit documents that do not require IRB review, but for which the sponsor or other entity requires acknowledgement of receipt by the IRB office. IRB Office staff act as Reviewers for these items via Administrative review.

**HUD Initial Submission:**

This form is for a new request to utilize a Humanitarian Use Device that under FDA regulations requires full board review. For the full board meeting, three voting members will be assigned as Full Board Reviewers, and each should evaluate the submission based on the requirements in the HUD policy.

**HUD Continuing Review:**

Continuing review of an active HUD application is required at least every year. HUD Continuing Review Forms can be reviewed either via expedited (1 member) or full board (3 members) review depending on the last determination at a convened meeting and is not based on minimal risk vs. more than minimal risk. Assigned Reviewers can determine whether to approve or require modifications for these submissions.

**Study Closure:**

Closing a study is considered a change to the study that requires IRB review and approval. Almost all study closures are reviewed via expedited review, unless the Chair, the IRB Office or Reviewer refers the submission to the full board. If the submission is acceptable, the single reviewer should select “Closed” from the drop-down Reviewer Determination found on the Reviewer Dashboard. The study closure letter will be processed based on the date of the Reviewer’s determination.

**External IRB Reliance Application:**

This form is for a PI to request permission to use an external IRB of Record. WSU IRB members do not review these submissions. These forms receive institutional review and approval only.

HIPAA Waivers of Authorization

**Full and Partial Waiver of HIPAA Authorization – Initial Review Application Question**

To request a waiver of HIPAA Authorization, please answer the following questions:

**Explain why the study cannot be practicably conducted without the waiver:**

*To obtain written authorization, the study team would need to collect more identifiable private information than is needed to conduct the study. Therefore, we are requesting a waiver as it is not practicable to obtain written authorization.*

*Or*

*We are collecting data from the medical records of 500 patients that were seen for diabetes care from 2000-2015. As the contact information for the majority of these patients may not be current, it is not practicable to obtain written authorization.*

**Describe the plan to protect identifiers from improper use and disclosure:**

*Data collected from medical records will stored in a password-protected Excel file that is stored on a password-protected computer that will not leave the premises of the hospital. These records will be coded with a code that does not contain any identifier or part of an identifier. The code and the list of identifying information associated with that subjects records (except for dates) will be kept as a paper file in a locked drawer in the PI’s office….or The code and the list of identifying information associated with that subjects records (except for dates) will be kept as a separate Excel file that will be password protected and only accessible to the PI. This file will be stored in a separate location on the shared drive that has a different password than the research file itself.*

**Describe the plan to destroy the identifiers at the earliest opportunity:**

*At the completion of our data collection and analysis, the code containing subject identifiers will be destroyed via… After the code is destroyed the data will be maintained in a de-identified format and stored in accordance with data maintenance/storage requirements applicable to this study.*

*Or*

*Identifiers will be maintained indefinitely so that the data set may be used for future research. However, no other research will be conducted with the identifiable data set without prospective IRB review and approval and the data will be maintained in accordance with the data security plan detailed above.*

**Explain why this research could not be carried out without access to and use of PHI:**

*Access to and use of the PHI listed below (and or requested in this application) is the minimum necessary to answer the research question(s) for this study.*

**Please list all PHI that will be create, used or disclosed for this study:**

*PHI = Identifiers + Health information*

*Investigators should not just list identifiers here. However, if there are hundreds of data points to be collected, then not every data point needs to be listed here – just a representable sample.*