Research Determination Worksheet Submission Process

A *Research Determination Worksheet* (RDW) should be submitted for IRB review when research studies do not include human subjects or when projects do not include any activities that meet the Common Rule definition of research. RDWs should be submitted prior to project initiation and the IRB will provide a determination letter indicating that the project is either not research, or not human subjects research and does not require further IRB oversight, or that the project is human subjects research and requires a submission for human subjects research and IRB review.

It is NOT necessary to submit an RDW if it is already known that the project **includes** human subjects research. Investigators should skip to submitting either a *Study Application* or *Exempt Study Application*, whichever is appropriate for the research. To reduce the chance of creating unnecessary work by inadvertently submitting the wrong application, please contact the IRB before submission if you are not sure which application to submit. IRB staff will happily assist you in selecting the appropriate application; please contact us via email (irb@geisinger.edu) or phone (570-271-8663) with questions.

Important information when submitting RDWs in iRIS

iRIS User Account

At least one individual involved in the project will need an iRIS user account to submit the RDW. There is no need to include all individuals involved in the project on the RDW form, so not everyone will require an iRIS account. To obtain an iRIS user account, please complete and email the iRIS New User Account Request Form to irb@geisinger.edu.

Research CITI Training & COI Requirements for RDWs

Unlike other iRIS submissions, individuals listed on an RDW do not need to complete Geisinger's CITI research training or Conflict of Interest (COI) reporting requirements. If personnel without CITI training are included on an RDW, iRIS will identify this with a warning that indicates "Training validation failed" after submission of an RDW; however, the IRB will still receive the RDW, and no additional actions are required. Projects determined to be human subjects research, will receive determination letters that indicate the requirement to submit an application for human subjects research and IRB review. In this case, all individuals involved in

the research will need iRIS user accounts and need to complete CITI training. Those serving as an investigator will also need to complete COI reporting.

Submitting RDW in iRIS

- Have/obtain an active iRIS User account
- Open iRIS using your username and password
- Select *Study Assistant* →*Add a New Study* → *Research Determination Worksheet*
- Complete the application (RDW)
- Principle Investigator (PI) signs off on the RDW submission, which routes the RDW to the IRB
- Track the status of your submission in iRIS by going to *Study Assistant* → open the project by clicking on the *Notepad icon* next to it → *Outstanding Submission(s)* → click green cell that states *Routing in Progress* under the *Track Location* column
- IRB reviews RDW submission
- Once review is complete, IRB provides an *IRB Determination* letter
- Project *should* not begin until receipt of an *IRB Determination* letter requiring no further actions

Please contact the IRB via email (irb@geisinger.edu) or phone (570-271-8663) to request assistance or provide feedback related to the RDW process.