

# Research Determination Worksheet (RDW) Submission Process

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A *Research Determination Worksheet* is submitted to the IRB for projects that do not include “research” or “research involving human subjects” ([45 CFR 46.102](#)). RDWs are submitted prior to project initiation and the IRB provides a determination and formal documentation that the project does not require further IRB review, approval or oversight.

- It is NOT necessary to submit an RDW if you know your project **includes** human subjects research. Instead, skip this step and submit a *Study Application* or *Exempt Study Application*, whichever is appropriate for your research.
- To reduce the chance of creating more work for yourself by inadvertently submitting the wrong application, please contact the IRB before submission if you are not sure which application to submit. IRB staff will be happy to assist you in selecting the appropriate application; please contact us via email ([irb@geisinger.edu](mailto:irb@geisinger.edu)) or phone (570-271-8663) with questions.

## Important information when submitting RDWs in iRIS

### iRIS User Account

- All individuals involved in the project must have an active iRIS user account and be listed on the RDW
  - If someone cannot access iRIS or you cannot add a person to your RDW application as study personnel, that means s/he does not have an active iRIS user account. To obtain access, please complete and email the [iRIS New User Account Request Form](#) to [irb@geisinger.edu](mailto:irb@geisinger.edu).

### Research CITI Training & COI Requirements for RDWs

- Unlike other iRIS submissions, individuals listed on your study application do not need to complete Geisinger’s researcher CITI education or COI requirements **before** RDW submission. (Even though you see the red box warning (*Training Validation failed*), the IRB will receive your RDW.)
- If, however, your project is determined to be “research” or “human subjects research”, you will receive one of the following stipulations in your IRB outcome letter:
  - *RDW Request for Modification* Letter - Your project was determined to be research that does not include human subjects. Therefore, XXX must complete Geisinger research education and COI requirements in order for the IRB to complete RDW review and send you a final determination letter; OR

- *IRB Determination* Letter - Your project was determined to be research including human subjects, so you CANNOT start your project. You will need to submit a Study Application or Exempt Study Application in iRIS, as appropriate. XXX must complete Geisinger research education and/or COI requirements prior to submission.

### Submitting RDW in iRIS

- Have/obtain an active iRIS User Account (see above)
- Open iRIS using your Username and Password
- Select *Study Assistant* → Add a New Study → Research Determination Worksheet
- Complete the application
- PI signs off on the application submission, which routes the RDW to the IRB
- You can track the status of your submission in iRIS by opening your project and selecting *Study Assistant* → *Notepad icon* next to your study → *Submission History*.
- IRB reviews your submission
- Once review is complete, you receive an *IRB Determination* letter
- You cannot begin your project until you receive an *IRB Determination* letter.

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