The IRB Submission Process for First Time Users
Steps to IRB Approval

Plan Ahead
- Complete the Human Subjects Training, prepare CV/resumes and Investigator Agreement forms
- Create your InfoEd Account using the InfoEd Global Access Request Form under forms and templates

Prepare your Submission
- Create your protocol in InfoEd
  - Note - the Initial Application eForm is pre-loaded in InfoEd
- Download informed consent and any other needed templates from the RU IRB Forms and Templates website
- Complete your documents, including the Initial Application eForm in InfoEd
- Upload completed forms and any supporting documents where indicated in the Initial Application eForm

Submission and Review
- Submit your project in InfoEd
- Pre-Review, Review, and Approval Processes
- Modifications, Continuations, and Closures after Approval

What Happens After IRB Approval?
- What forms to use and when approval expires, and more
Definitions

- **CITI** - The Collaborative Institutional Training Initiative (CITI Program) is the online training service Radford University uses for Human Subjects Research and other research compliance training.

- **InfoEd Global** - The online software service that Radford University uses for submitting IRB Protocols. Note: you must have valid RU credentials and an account in InfoEd (see next slide).

- **Protocol** - Your submission to the IRB for review in order to conduct research using human subjects, which includes the initial application and any supporting documents needed, such as consent forms and recruitment flyers.

- **PI** – Principal or Primary Investigator – must be an RU faculty member. Please note that the PI CANNOT be a student researcher.

- **IRB** - Institutional Review Board.
Steps to IRB Approval – Plan Ahead

InfoEd Access:

- If necessary, request your InfoEd account by completing the InfoEd Global Access Request Form located on the RU IRB Forms and Templates webpage:

  - All students wishing to submit a protocol will need to request access to InfoEd

  - All faculty wishing to submit a protocol who were hired by RU after mid-July 2015 will need to request access to InfoEd

- Please allow 24-28 hours for processing time
Steps to IRB Approval – Plan Ahead

Complete Your Human Subjects Research Training in CITI:

• Review the CITI Program New User Log-in Tutorial and create your account

• Select the correct CITI IRB training course:
  • Faculty - “Social and Behavioral Research Investigators” course
  • Students - “Students conducting no more than minimal risk research” for Exempt and Expedited research, or “Social and Behavioral Research Investigators” for protocols that will be reviewed by the Full Board.

• Complete the selected IRB CITI Training Course
  • Learners may stop and start throughout the training and retake quizzes as needed.
  • Protocols will not be reviewed until all research team members have completed his or her CITI training.
Steps to IRB Approval – Plan Ahead

Required Documents to be Uploaded by All Members of the Research Team:

• CV/Resume

• Investigator Agreement form
  • Please see the Investigator Agreement form Instructions for guidance on how to correctly complete this form for every member of the research team.

• NOTE – Human Subjects training certificates are only required to be uploaded if the training was completed outside of CITI or the training was completed in CITI but the person’s account is not affiliated with Radford University in CITI.

• Affiliations are easy to add in CITI. For more information, please see the CITI tutorial How to add/change your affiliated institution.
Steps to IRB Approval - Prepare your Submission

• Create a new protocol in InfoEd to begin your initial application

• Go to the RU IRB Forms and Templates website for informed consent templates and other resources, as needed

• Complete your application in InfoEd

• Upload consent forms, survey instruments, letters of support (to be completed by hosting organization), and/or any other documents needed for your protocol into the Initial Application form

  • The Initial Application eForm has locations labeled within it for you to upload your documents throughout the application
Steps to IRB Approval - Prepare your Submission

For more information, please see the D2L Self-Registration Course titled “IRB User Resources” for the following tutorials, among others, with detailed screenshots*:

- Creating and Submitting a New Protocol in InfoEd
- Protocol Content Information - Initial Application Form content tutorial
- Instructions for PI’s to Approve Student or Colleague Submitted Research in InfoEd

*InfoEd requires that we only show screenshots of their proprietary content behind a firewall that requires an RU log-in.
Steps to IRB Approval - Submission and Review

• **Submit Your Protocol** - Complete and submit your protocol in InfoEd

• **The Pre-Review Process** - work with the IRB Office as needed to make requested revisions to your protocol in the pre-review phase of the review process

• **The Review Process** - work with the IRB Office as needed to revise your submission based upon reviewer comments during the review process

• **Approval Letter** - Receive and retain your IRB Approval Letter and any stamped and signed documents required to implement research on your protocol
  • You must use any stamped consent forms, flyers, etc., that you receive from the IRB Office
  • You must make sure to only use those documents with current dates on the stamps
Steps to IRB Approval - Submission and Review

Submit Your Protocol

Create, complete and submit your protocol in InfoEd

- For more information, please see the D2L Self-Registration Course titled “IRB User Resources” for the following tutorials, among others, with detailed screenshots:
  - Creating and Submitting a New Protocol in InfoEd
Steps to IRB Approval - Submission and Review

The Pre-Review and Review Processes

You will use the InfoEd Action Item to return your protocol from this point forward

- There is no “Submit” button after the initial submitting of your protocol
- Action items are sent to you when you receive reviewer comments for your protocol revisions
- They are located on your InfoEd Home Page under “Things to Do”

For more information, please see the D2L Self-Registration Course titled “IRB User Resources” for the following tutorial, among others, with detailed screenshots:

- Returning a Protocol After Revisions are Completed
Steps to IRB Approval - Submission and Review

Approval Letter

Receive and retain your IRB Approval Letter and any stamped and signed documents sent with your Approval Letter that you need to implement your research on your approved protocol

- You **must use** copies of any stamped consent forms, flyers, etc., that you receive from the IRB Office when recruiting and consenting participants

- You must make sure to only use documents with current dates on the stamps and you may not work on an expired protocol

- IRB protocols expire in one year. Please be sure to renew or “Continue” your protocol prior to expiration to ensure there is no gap in coverage and no resulting non-compliance

- PLEASE NOTE – you must keep your protocol open while you are working with identifiable data
What Happens After IRB Approval?

• Photocopy or print and use your stamped consent forms or other documents, if any, with your participants

• Apply for a modification request when adding or deleting personnel or making other changes to your protocol

• Exempt studies do not currently expire

• Expedited and Full Board protocols expire in one year

• Continue (e.g., renew) your Expedited or Full Board protocol just before it’s one year expiration date
  • You MUST have an open protocol during analysis of your raw data