



IRB eProtocol Frequently Asked Questions

Have an IRB eProtocol question not listed below? Send an email to WSUIRBInfo@wayne.edu

How can I tell if CITI Training is complete for key personnel?

- The Principal Investigator's CITI Training appears under the Personnel Information section.
- To check all other key personnel training click on the individual's name and all completed trainings will appear.
- If an individual has not entered their WSU Access ID for their CITI profile a message will appear stating "**no training data is available**".

When does CITI training populate/update in eProtocol?

- The next business morning.
- When a user updates their CITI training (i.e. adding your WSU access ID, completing a CITI module, etc) these actions will update in eProtocol early the next business morning.
- The new information/training status will not automatically update the same day.

Does key personnel receive alerts to sign-off on Obligations & COI?

- No
- The PI or designated personnel (i.e. research coordinator), will need to reach out to individual key personnel to request Obligations & COI sign off.

Can more than one key personnel log-in and complete Obligations & COI?

- No
- only one person can log in at a time. Each person should completely log out of the system when they have completed Obligations & COI.

Will the selected Department Chair/Dean/Authorized signatory receive notification for sign-off?

- Yes
- Upon the PI or coordinator selecting "Submit Form" if there are no check for completeness items an email alert is sent to the authorized signatory and the submission is routed to the authorized signatory's dashboard for sign-off.

If the Department Chair/Dean/Authorized signatory completes COI & Obligations is their sign off complete?

- No

- The Department Chair/Dean/Authorized signatory must also complete "Department Certifications" which is authorizing submission of the application to the IRB.

Can the Principal Investigator or faculty supervisor/mentor also be listed as the authorized signatory?

- No
- An individual can only have one assigned role for an eProtocol application.
- A Principal Investigator that is also is the department chair may need to list the authorized signatory at college/dean level for the submission.
- A faculty supervisor who is also the Dean or Chair for their College or Department will need to list another individual designated as an authorized signatory for research within their college/department.

How can I revise/modify the study title for a submission?

- A study title can be modified while the user is in edit mode.
- Go to the Protocol Information-Summary & Purpose section.
- The study title appears in a text box for this section. This text box content can be modified.
- Once changes have been made select "Save" on the Summary & Purpose page and the title will change throughout the application.

For exempt submissions are the addendums for vulnerable populations required?

- No
- when a submission is indicated as exempt, the vulnerable populations addendums will disable in the eProtocol system. However, the applicable CITI training is still required.

Can I submit multiple amendments at the same time?

- No
- eProtocol only allows for one submission/action request at a time.

Are administrative approvals still required for an eProtocol submission (PRMC, DMC, Psychiatry, WSU Dean of Students, Export Control-International Research, Radiation Review)?

- Yes
- All applicable administrative approvals are still required
- **DMC submissions:** DMC personnel are administratively added on the eProtocol submission as "Other Personnel" for designated DMC personnel to have access to the eProtocol submission. The DMC application must also be completed. Contact the [DMC's Clinical & Translation Research Office](#) for the DMC submissions. The DMC approval letter should be attached to the Protocol Information-Attachments section.
- **PRMC** approval is required for cancer studies. This approval should be attached for the Protocol Information-Attachments section.
- All other Administrative Approvals should be attached to the Protocol Information-Attachments section.

How do I request a waiver of consent or alteration of consent?

- Protocol Checklist section select the appropriate waiver
- Consent Information section select "Add" and complete the pop-up window
 - type the name of the requested waiver:
 - Waiver of Consent
 - Waiver of Consent for Screening
 - Waiver of Written documentation of consent
 - Alteration of Consent.
 - select the appropriate waiver type for the pop-up window:
 - Waiver of Consent
 - Waiver of Written documentation of Consent
 - Alteration of Consent
 - Respond to the listed waiver/alteration statements

How do I request a waiver of HIPAA Authorization?

- Go to Protocol Checklist section and select the following:
 - Protected Health Information will be viewed, created, accessed, used, or disclosed
 - HIPAA Authorization
 - Waiver of Authorization
- Then go to Protocol Information-HIPAA section
 - Complete HIPAA section and select Waiver of HIPAA Authorization for HIPAA
- *please note, a waiver of consent may also be required when requesting a waiver of HIPAA Authorization.*

How do I clone a protocol?

- Log into the eProtocol system under the Investigator Role
- make sure the IRB tab is selected
- select "**Clone Protocol**"
- select the radio button for the protocol ID to be cloned
- select "**Clone Protocol**" again
- Select "**Yes**" to the question "**Do you want to clone the selected Protocol?**"
- the protocol will then copy and assign a new IRB number
- All key personnel will need to sign off on the submission including the PI.
- The submission can then go through the "check for completeness" and authorized signatory sign-off process by selecting "Submit Form"

Need eProtocol Training or Assistance, please email:

WSUIRBInfo@wayne.edu or contact the IRB Administration Office at 313 577-1628.