IRB eProtocol

Introduction

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What is eProtocol?

Is a web based system used to submit track, review, and approve research protocols in a paperless format.

“Electronic Submission”
WHY?

Electronic Submission

- Over 3 million pages of text scanned
- Vast amount of paper required for IRB Submission
- Transparency of Submission & Review
- Access to Information
- Goal to decrease turn around time
Implementation


With each board and review type activated in phases over the past 3 years.
Now Accepting
Social, Behavioral, & Education (SBE) &
Biomedical

Full Board (greater than minimal risk)
Expedited (minimal risk)
Exempt (minimal risk)

via eProtocol

Excluding VA Submissions
IRB Submissions
Submissions approved **before** eProtocol continue to submit:

• **Continuations**
• **Amendments**
• **UP reports**
• **Closures**

Via the forms available on the IRB’s website

[irb.wayne.edu](http://irb.wayne.edu)

Note: The IRB is not currently accepting in person visits, email to eIRBManager@wayne.edu
System Requirements

• WSU Access ID & Password is **required** for log-in
  If you do not have an access ID & Password please sign up for a guest WSU Access ID (note guest ID’s require annual renewal)

• Supported by Firefox 12 & Safari 7 web browsers
  *(please disable the pop-up blocker)*

• Completion of Mandatory CITI Training
• CITI Profile must include the WSU Access ID
• Electronic Signatures/Sign-Off
System Requirements

- Does **not** require registration by users
- Does require a WSU Access ID & Password

**A WSU Access ID & Password opens the door to eProtocol**

Use the IRB’s Key Personnel Guidance Tool to determine key personnel.

Guidance tools available on the [IRB’s Education website](#)
eProtocol System Requirements

Guest WSU Access ID

- Submit an e-mail request to WSUIRBInfo@wayne.edu
- Include in email guest users:
  - First Name, Middle Name, Last Name
  - Birthdate
  - Previous Access ID (if applicable)
  - Guest user’s Email address

Guest Access ID users will receive an email with ID activation instructions.

- Guest IDs are for 1 year and must be re-activated yearly
- Guest IDs include a WSU Academica account with email
- Guest users can forward their WSU email to their primary email accounts to receive eProtocol notifications.
CITI Training Profile

Adding the WSU Access ID

- Connects key personnel’s CITI training to eProtocol
- If the WSU Access ID is not added the IRB Application cannot be submitted and will cause submission delays
- Incorrect ID or incorrectly added ID will also not allow for the IRB Application to be submitted
- See Guidance Tool for instructions on adding the WSU Access ID to a CITI profile
Mandatory CITI Training

(3) Required CITI Training Modules for

ALL Key Personnel & Authorized Signatories

(I) Basic Course in Human Subjects Research: Biomedical or Social Behavioral Investigators (Refresher course is required every 3 years)

(II) Responsible Conduct of Research Biomedical or Social Behavioral Investigators

(III) Health Information Privacy and Security (HIPS) Module (per research role)
Mandatory CITI Training

Additional CITI Modules based on Research Type

• Children included as participants (CITI module: 152332 or 152335)
• Pregnant Women, Fetuses or Neonates included as participants (CITI module: 152332 or 152335)
• Prisoners included as participants (CITI module: 152333 or 152336)
• Students included as participants (CITI module: 152334 or 152337)
• Internet Research (CITI module: 152338)
• International Research (CITI module: 153207)
System Requirements
Electronic Sign-Off

• Principal Investigator (PI)
• Faculty Sponsor/Supervisor/Mentor
• Key Personnel (co-investigator, Study Regulatory, Other Personnel)
• Authorized Signatory (Dean or Chair) select the correct signatory. Confirm with your dept./college
Electronic Sign-Off Overview

- Principal Investigator (PI)
- Faculty Sponsor/Supervisor/Mentor
- Key Personnel (co-investigator, Study Regulatory, Other Personnel)
- Authorized Signatory (Dean or Chair)

All Key Personnel will log-in with the role of “Investigator”

This includes the Dean/Chair/Authorized signatory

Only use supported web browsers: Firefox or Safari

Disable the pop-up blocker for your web browser
Electronic Sign-Off Overview

- Principal Investigator (PI)
- Key Personnel (including faculty supervisor/mentor)
  - Completion of Obligations (Responsibility & Policy Statements)
  - Completion of IRB Conflict of Interest (COI) Statement

The PI or assigned coordinator must contact their key personnel to complete electronic sign-offs.

Notifications are **not** sent via the system

Only one person can log in at a time.

A student Principal Investigator must select their role in eProtocol as:

“Student/Resident/Fellow”

Only use supported web browsers: Firefox or Safari
Electronic Sign-Off

Authorized Signatory (Dean or Chair) (3 steps)

– (Step 1): Completion of Obligations (Responsibility Statements):
  – Maintain CITI training
  – Scientific Review (elements of sound research design)
  – Provide appropriate support and adequate facilities and staff for the conduct of research

– (Step 2): Completion of IRB Conflict of Interest (COI) Statement:
  – Disclosing any financial interest or non financial interest

– (Step 3): Department Certification (pre-approval)
  Approving submission to be reviewed by the IRB

Upon the PI or assigned coordinator selecting “Submit Form” the first time. The listed Authorized signatory is notified via email of sign-off. Sign-off by the authorized signatory should not take place until “Submit Form” is selected.

Only use supported web browsers: Firefox or Safari
Electronic Sign-Off Overview

- Complete IRB Form & Training Requirements
- PI Sign-Off
- Faculty Mentor & Key Personnel Sign-Off
- PI or designee submits Form to Authorized Signatory
- Authorized Signatory Sign-Off
- PI or Designee submits Form to IRB

Completed in this Order
See the Initial Submission Guidance Tool for instructions
System Requirements

Electronic Sign-Off

- To learn more about Electronic Sign-Off attend an upcoming IRB Education Session on The Electronic Sign-Off Process.
Completing the IRB Form

• Answer all questions completely
• Follow instructions given throughout the form
• Use IRB Guidance tools for assistance
• Make sure training by all key personnel is completed
• Be mindful of vulnerable population requirements (children, pregnant women, fetuses, neonates, cognitively impaired)
  – CITI modules completed by all personnel & addendums completed
• Attach supporting documents
  – Consents & Assents (if applicable) in Consent & Assent Sections
  – CV/Resume
  – Protocol/Proposal
  – Advertisements/Participant Materials
  – Administrative Approvals

Wayne State
Submit
The Submission/Review Process

**IRB Application is Submitted**
By PI or designee selecting “Submit Form”

**IRB Application receives application and completes intake:**
assigns to committee & IRB reviewer

**PI/designee responds with making changes to applicable sections & addressing comments**

**PI/designee submits revisions to IRB Office**
By selecting “Submit to IRB”

**IRB Admin. forwards revisions to reviewers for review/approval**

The Cycle repeats if the IRB reviewer request additional revisions. Cycles are numbered and labeled accordingly (i.e. cycle 1, cycle 2)

The IRB reviewer may also send revision requests via email directly to PI. However the revisions still must be completed in eProtocol
Approval

What happens after IRB approval?

• Email is sent notifying PI of IRB approval
  – No paper approval documents are mailed or e-mailed

• Approval letters are located in eProtocol “Events History” Tab
  – Make note of your expiration date or status check in date indicated on the approval letter
  – Expiration Courtesy reminders are generated 90 days, 60 days, 30 days before expiration

• IRB Stamped Documents
  – located under Protocol Information – Attachments Tab

• Modifications are submitted via an amendment (via eProtocol)

• Submit continuations 6 weeks before expiration (via eProtocol)

• UP reports currently submitted using UP form on IRB’s website

• Submit Final Report (Closure) when all research activities & identifiable data analysis are complete (via eProtocol)
Tips & Tools

• Start Early
  – IRB Full Board Submission Deadline Dates (Schedule is Available at irb.wayne.edu)
  – No deadlines for Expedited & Exempt Reviews

• All Users must complete the Mandatory IRB CITI Training
  (before submitting Dean/Chair Sign-Off)

• Check with your dept/college for the correct authorized signatory

• All Users **must** add WSU Access ID to their CITI Profile
  (6 character letter number combination, for example: aa1234)
  – Work with your research personnel NOW to get this completed

• Make sure the correct individual is listed as PI

• **Only one person can log-in at a time to complete Obligations & COI**

• Use IRB Guidance Tools for Assistance (available on IRB website)

• Remember Administrative Approvals (DMC, PRMC, Psychiatry, Radiation)

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Don’t forget to select Submit!
For assistance with submitting to eProtocol e-mail

WSUIRBIInfo@wayne.edu

or call the IRB Office 313-577-1628

Stay Updated:

Sign up for the IRB listserv

Email: WSUIRBIInfo@wayne.edu
Guidance Tools available on the IRB’s website:

research.wayne.edu/irb/education

Full training manuals & videos available on your mobile device’s app store
How to Access eProtocol?

www.irb.wayne.edu

https://ksprodweb.ovpr.wayne.edu/

Log in using WSU Access ID & Password
Welcome to the Wayne State University eProtocol system - a powerful and efficient way to submit, track and approve research protocols and Conflict of Interest disclosures.

Browser Requirements: This site requires Firefox 12 and higher or Apple Safari. Using older browsers, non-compatible browsers or disabling browser features, such as Javascript, cookies and SSL, will reduce site functionality.
Q&A

IRB Administration Office
Q&A

• **Question:** Does key personnel receive alerts to sign-off on Obligations & COI?
  
  – **Answer:** 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.
    
    • Only one person can log in at a time to complete the sign off steps
    
    • Upon selecting the “Submit Form” option the first time the submission is routed to the indicated authorized signatory and that person does receive an email notification.
• **Question:** Is there a way to tell if someone has included/added their WSU Access ID to their CITI Profile?

  – **Answer:** If someone has not entered their Access ID for their CITI profile when you click on their name it will state “**no training data is available**”.

    • The software company is currently working on the Training Checklist to provide a listing for completion of the 3 major modules.
    • If you need assistance with checking training for your key personnel, please contact the IRB Administration Office.
    • There is IRB staff dedicated to checking eProtocol CITI training compliance.
Q&A

• **Question:** How do I change a study title in eProtocol?
  
  – **Answer:** A study’s title can be modified while a user is in edit mode.
    
    • The study can be modified by going to the Protocol Information – “Summary & Purpose” section.
    
    • The Study Title: that appears in the text box can be modified.
    
    • Once saved the new title will appear throughout the application.
**Q&A**

- **Question:** Can I submit multiple amendments
  - **Answer:** No
  - eProtocol only allows for one submission/action request at a time.
  - This includes submission of amendments and continuation.
  - The system is designed for one amendment to be reviewed at a time. You may add multiple modifications to an amendment, however that amendment must be reviewed and approved before submission of another.
Q&A

• **Question:** How do I request Waiver of Consent and Waiver of HIPAA Authorization for eProtocol?

  – **Answer:**

    • **Protocol Checklist** - Select that the appropriate Waivers that are needed for the study:
      - Waiver of Consent or Waiver of Written documentation of Consent
      - Waiver of consent to screen for eligibility
    
    • **Protocol Checklist** – Select that Protected Health Information will be viewed, created, accessed, used or disclosed.
      - Select HIPAA Authorization
      - Select Waiver of Authorization
    
    • **Consent Information** section – Select “Add” and complete the pop up window indicating the Waiver or Alteration of Consent
    
    • **HIPAA** section – Complete HIPAA section as well as completing the Waiver of HIPAA Authorization portion of the form.
Q&A

• Your Questions?
Q&A

- Additional IRB FAQs on the education website

research.wayne.edu/irb/education
Need eProtocol Assistance?

Email: WSUIRBIInfo@wayne.edu

or call

The IRB Administration Office
313-577-1628