IRB eProtocol

Introduction

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IRB Administration Office
What is eProtocol?

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

“Electronic Submission”
What is eProtocol?

Research Compliance software package developed by Key Solutions

System is supported by WSU Division of Research IT & maintained by the software company Key Solutions
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

WSU IRB Administration Office began implementing eProtocol December 2017

With each board and review type activated in phases over the past 2 ½ years
Now Accepting
Social, Behavioral, & Education (SBE) & Biomedical

**NEW**

- **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

Note: The IRB is not currently accepting in person visits, email to eIRBManager@wayne.edu
Electronic Submission Enhancements

- WSU Access ID & Password is **required** and is the individual **key personnel’s signature**
- CITI Profile **must** include WSU Access ID
- Electronic Checks of Mandatory CITI Training*
- Required CITI Training completed **before** submitting
- Transparent listing of key personnel & CITI Training*
- Alerts & Notifications of IRB Review via WSU email
- Spell check
- Revision tracking

*(eProtocol refreshes every morning with previous day’s CITI training/content)*
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

• Completion of Mandatory CITI Training

• Update CITI Profile with WSU Access ID
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 IRBs website
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 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 should forward their WSU email to their primary email accounts to receive expiration notifications.
System Requirements

• Electronic sign offs by **ALL** study key personnel (including faculty advisor/supervisor/mentor)

• Completion of Obligations Statement:
  – Maintain CITI training
  – Follow direction of PI to adhere to the study protocol, institutional policies, & research regulations

• IRB Conflict of Interest (COI) Statement

Dean/Chair/ Authorized signatories

also log in to eProtocol to:

• Complete Obligations
• COI disclosure
• Complete Department/College Certification (Sign-off)

(pre-approval)
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)
How does eProtocol work?

### Before submission to IRB
- PI or designated coordinator completes electronic form
- Supporting documents are attached as word or pdf (see guidance tool for instructions)
  - Consents, Assents, Proposal, Flyers, Scripts, PI CV/Resume, Additional appendices, etc
- PI or designee contacts key personnel to complete Sign-offs (faculty sponsors/mentors must also Sign-Off)
- Key Personnel log-in and complete Obligations & COI (one person at a time)
- PI or designee selects “Submit Form” for Dean/Chair/Authorized signatory Sign-Off
- Check for completeness is activated
- System will provide list of certain missing items or incomplete *CITI training. Items will need to be completed before routing to chair
- Dean/Chair/Authorized Signatory receives email notification for Sign-off
- Dean/Chair/Authorized signatory Sign-Off or request changes
- Authorized Signatory completes COI, Obligations & Certification/Sign-off
- Email is sent alerting PI & designee of Sign-off completion
- PI or designee “Submits Form” to IRB Administration Office

### After submission to IRB
- IRB Administration Office intakes submission
  - Submission is assigned to a committee
  - Submission is assigned to a reviewer
- IRB Reviewer receives notification of submission ready for review
- Review Process begins:
  - IRB Review logs-in to review documents/submission
  - IRB Reviewer provides feedback/revision requests in eProtocol
  - Reviewers feedback/revision requests are forwarded to PI/designee
  - PI or designee completes revisions & “Submit Form” to IRB Administration Office
- IRB Administration Office forwards response to IRB Reviewer
- IRB Reviewer recommends approval, if all revisions and requirements are complete
- If revisions are not completed review process repeats again
- IRB Administrator Completes approval process

*Contact the IRB Office for Help with CITI & All Key Personnel Training must be completed and Access ID added to CITI profile.*

*Note: If Full Board Review: a convened IRB meeting is held and determination made by full board. Communications forward 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)

• 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)

Don’t forget to select Submit!
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 indicated on the approval letter
  – 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 continuation 4-6 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)
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.
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: 
[irb.wayne.edu]

Full training manuals & videos
available on your mobile device’s app store
Coming Soon!

Unanticipated Problem Reports
External IRB Requests

Currently submitted using paper forms available on the WSU IRB’s Forms website

irb.wayne.edu
Q&A

IRB Administration Office
Q&A

• **Question**: Is there a way to tell if someone has included if key personnel have added their WSU Access ID for their CITI Profile?
  
  – **Answer**: If someone has not entered 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:** 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.
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.
• **Question:** Can I submit multiple amendments
  
  – **Answer:** No
  
  • eProtocol only allows for 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.
Need eProtocol Assistance?

Email: WSUIRBIInfo@wayne.edu

or call

The IRB Administration Office
313-577-1628