IRB eProtocol

External IRB Submissions

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IRB Administration Office

Summer 2022
Sessions Agenda

• Implementation Date
• Initial Submission Requirements/Components
• Modification Submission Requirements
• Questions
eProtocol External IRB

Implementation Date:

August 1, 2022

Last day to accept paper based forms:

August 15, 2022
What is eProtocol?

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

“Electronic Submission”
External IRB Implementation
Accepting Only
NEW Submissions Via eProtocol
Previously Authorized Submissions will continue to submit modifications using the External Modification Report Form available on the WSU IRB’s external IRBs websites

- NCI CIRB
- WCG
- All other External IRBs: Advarra, Academic IRBs

Modifications are emailed to the respective external IRB email boxes:
- NCI CIRB: cirb@wayne.edu
- WCG: wirb@wayne.edu
- All others: relyirb@wayne.edu
Completing the IRB Submission

4 components to the Submission:

1. Initial Submission External Worksheet/Guide
2. Mandatory CITI Training
3. eProtocol System Requirements & Submission Form
4. Modification Submissions of local context changes
Completing the IRB Submission

Component #1

Initial Submission External Worksheet/Guide

- The Initial External IRB Worksheet and Guide must be completed and attached to the eProtocol Submission.
- The worksheet includes instructions for eProtocol & reliance agreement guidance.
- The worksheet is available on the WSU IRB’s reliance agreement websites:
  - NCI CIRB
  - WCG/formerly WIRB
  - Reliance Agreements

An update version of the External Worksheet/Guide will be available July 30th
Completing the IRB Submission

Component #2

Mandatory CITI Training

Local context requirement that all key personnel must maintain CITI training

This is checked at initial submission and at the point of a modification.

For more information visit the WSU IRB’s Mandatory CITI training website
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)
eProtocol System Requirements & Form

Component #3
Completing the IRB Submission

Component #3

eProtocol System Requirements & Form

• System Requirement & Access
• Creating a New IRB Protocol
• Completing the required sections
• Completing Electronic Sign-Off Steps
• Attaching documents
How to Access eProtocol?

www.irb.wayne.edu

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

Log in using WSU Access ID & Password
Web Browser Requirements

Supported by Firefox 12 & Safari 7 web browsers

(please disable the pop-up blocker)
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)

- **Completion of Mandatory CITI Training**
  *(component #2)*

- **CITI Profile with WSU Access ID**
  - Access ID Connects CITI training to eProtocol
  - Entry in lower case no extra characters or spaces
  - Must affiliate CITI profile with WSU

- **Electronic Sign-Off by Key Personnel**
System Requirements

❌ Does not require registration by users

✅ Does require a WSU Access ID & Password

WSU Access ID’s are assigned to:

- WSU Faculty
- Staff
- Students

A WSU Access ID & Password opens the door to eProtocol

Use the IRB’s Key Personnel Guidance Tool
to determine key personnel for your study
WSU Access ID Requirement

- If the submission will include individuals that are **not** WSU faculty, staff, or students.

**A guest WSU Access ID will need to be requested for the non WSU key personnel**

DMC Staff/Clinicians, Karmanos Cancer Institute, & John D. Dingell VA personnel that are **not** a WSU faculty, staff, or student will need a guest access ID
System Requirements

Only key personnel that will conduct research activities at WSU/WSU Affiliate should be included as key personnel for a submission.

DO NOT Include:
- Other sites’ Principal Investigators
- Key Personnel from other non-affiliate sites
- McLaren Personnel (they are listed for the McLaren authorization). The McLaren Approval and Authorization documents are submitted and attached to the eProtocol application.

WSU Affiliates include:
Detroit Medical Center, Karmanos Cancer Institute, & John D. Dingell VA Medical Center
Guest Access ID Request

- 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.
eProtocol System Requirements & Form

Completing the IRB Submission
Completing the IRB Submission

• Individual that creates protocol is listed as the PI
  – Coordinator can complete the submission and switch the PI
  – Complete this switch before requesting key personnel to sign off on submission

• Complete all the required sections of the form
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.
Completing the IRB Submission

Arrive at Main Dashboard

Select “Create Protocol”
Completing the IRB Submission

Select the IRB Form radio button

Type the Title do not cut and paste
Completing an IRB Submission

Search for the authorized signatory & add

Wayne State

Find User

<table>
<thead>
<tr>
<th>User ID:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name:</td>
<td></td>
</tr>
<tr>
<td>Last Name:</td>
<td></td>
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</tbody>
</table>
Completing the IRB Submission

The following tabs are required:

- Personnel Information
  - Obligations & COI
- Study Location
- VAMC Checklist, if VA
- Protocol Checklist (Select: Request to Rely on Another IRB)
- Funding
- Protocol Information
  - Study Details (Review Categories)
  - Summary (Proposed Start and End Date ONLY)
  - Participant Population (PI’s Expertise)
  - Consent/Assent Information sections
  - HIPAA (if PHI will be collected)
  - Drugs & Devices (if applicable)
- Attachments
Completing the IRB Submission

**eProtocol Attachments**

- Attach supporting documents
- Consent Information section: Attach all consents
- Assent Information section: Attach Assents (child participants)
- Attachments section:
  - Initial External IRB Submission Worksheet & Guide
  - PI’s CV/Resume
  - Local context forms
  - Ancillary Reviews (DMC, PRMC, CIC, Radiation Safety, etc.)
Completing the IRB Submission

**eProtocol Attachments**

- **Initial External IRB Submission Worksheet and Guide**
  - Obtains preliminary identifiable information
  - Provides guidance regarding External IRB Submissions
    - i.e. type of submissions accepted
    - For NCI-CIRB submission it documents the sites
  - Collections information regarding transferring a study to an External IRB
  - Provides sites’ COVID-19 health precautions
  - Provides eProtocol submission guidance and instructions
  - Provides information regarding the eProtocol Review Process
Electronic Sign-Off

• Key Personnel Sign Off
  – PI or assigned/designee contacts key personnel to complete the 2 step sign-off process
  – **Only one person can log-in at a time to complete Obligations & COI**
  – IRB Office can provide assistance with CITI checks or use the eProtocol Training Checklist

• Selecting “Check for Completeness”
  – Will show currently missing items for the application
  – Will indicate CITI training is not completed for key personnel
  – Will not allow for submission to the authorized signatory until items are completed
Electronic Sign-Off

- 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”

Only use supported web browsers: Firefox or Safari

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

Principal Investigator (PI)

Log into eProtocol as Investigator (ksprodweb.ovpr.wayne.edu) complete the following:

- Obligations (PI Responsibility Statements):
  - Maintain CITI training
  - Submit Modifications to the IRB for review and approval
  - Provide participants informed consent, if applicable
  - Agree application is accurate
  - Responsible for management and conduct of the study
  - Submit Closure

- Conflict of Interest (COI) Statement:
  »Disclosing any financial interest or non financial interest

The student Principal Investigator must select their role as: "Student/Resident/Fellow"

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

 Faculty Sponsor/Mentor

Log into eProtocol as Investigator (ksprodweb.ovpr.wayne.edu) complete the following:

- Review the submission for consistency per guidance and instructions provided to the student/resident.

- Obligations (Faculty Sponsor/Mentor Responsibility Statement):
  - Faculty Sponsor will maintain CITI training
  - Faculty Sponsor has reviewed the research plan
  - Faculty Sponsor has approved the scientific and ethical aspects
  - Faculty Sponsor will supervise all compliance with IRB guidelines

- IRB Conflict of Interest (COI) Statement:
  » Disclosing any financial interest or non financial interest

The PI must contact their Faculty Sponsor to sign off on the submission.
Electronic Sign-Off

Key Personnel (coordinator, co-investigators, other personnel)

Log into eProtocol as investigator (ksprodweb.ovpr.wayne.edu) complete the following:

- Obligations (Key Personnel Responsibility Statement):
  - Maintain CITI training
  - Follow direction of the PI to adhere to the study protocol, institutional policies, and research regulations

- IRB Conflict of Interest (COI) Statement:
  » Disclosing any financial interest or non financial interest

The PI or assigned coordinator must contact their key personnel to complete electronic sign-offs.
Only one person can log in at a time.

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

 Authorized Signatory (Dean or Chair role) (3 steps)

 After receiving email notification:
Log into eProtocol as investigator (ksprodweb.ovpr.wayne.edu) complete the following:

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

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

– (Step 3) Department Certification (pre-approval)

The listed Authorized signatory is notified of sign off when the PI or assigned coordinator selects “Submit Form” the first time

Only use supported web browsers: Firefox or Safari
External IRB Submission & Review Process
Submission Process Overview

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

*Coordinators (PI designee) please complete the PI assignment before key personnel sign offs began
Submission Process

IRB Intake

Check for:
• Correct Authorized Signatory
• Study Location completed
• Request to Rely on another IRB

• Assign to External IRB Review
• Assign to IRB Reviewer

• Review Conducted
• Revisions Requested
Authorization Review Process

Review Cycles

A review cycle consists of the IRB administrator reviewing the submission and submitting the comments to the PI/Designee for response and updates to the application.

IRB Administrator sends comments to PI/designee

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

PI/designee submits revisions to IRB Office

By selecting “Submit to IRB”

IRB Administrator reviews the revisions.

If all items have been addressed authorization is provided.

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

If ancillary reviews are required and/or not received. The IRB Administrator will request approval documentation as a revision request. (Includes: DMC, McLaren, PRMC, CIC, etc.)
System Alerts & Notifications

• Alerts Dean/Department Chair for sign off (certification/approval)
  – Confirm appropriate dean/chair/authorized signatory before submitting for sign off.
    • This will eliminate pitfalls of incorrect routing and resetting the pre-approval by the IRB Office.

• Alerts IRB of Submission

• Alerts PI/Designated Key Personnel of revision requests

• Alerts IRB of Response and edits to application

• Completion of IRB review notification & Authorization

Guest Access ID Users:
Email Alerts are sent to the WSU email account. The IRB recommends forwarding your WSU email to a preferred email account.
WSU IRB External Authorization

Email is sent notifying PI /Key Personnel of WSU IRB authorization.

The email notification will have language that authorizes the PI to submit to an External IRB.

- No paper documents
- No stamped documents
- No signed authorization or reviewer form
Component #4
Modification/Amendment Submission
Submitting an eProtocol
External IRB Modification/Amendment

Only key personnel listed on study with edit rights can create and submit an amendment.
Submitting an eProtocol
External IRB Modification/Amendment

Key Personnel with Edit Rights

- Principal Investigator
- Faculty Sponsor/Mentor
- Co-Investigator/Other Investigator
- Study/Regulatory Coordinator
- Administrative Contact

Key personnel listed as “Other Personnel” do not have edit capability.
Submitting an eProtocol
External IRB Modification/Amendment

• The initial protocol/submission must have been previously reviewed and approved in eProtocol.
• Only one modification/amendment can be submitted at a time.

If not the modification must be submitted to the appropriate external IRB’s email box:
• NCI CIRB: cirb@wayne.edu
• WCG: wirb@wayne.edu
• Advarra & All Others: relyirb@wayne.edu

If you wish to transfer a study to eProtocol a new application must be created and submitted in eProtocol
External IRB Modification/Amendment

Modification Steps

• **Complete the External IRB Modification Worksheet and Guide**
• Start an Amendment in eProtocol
• Attach the External IRB Modification Form to the eProtocol Amendment
• Attach any updated consent/assents to the:
  – Consent Information section
  – Assent Information section
  – Label the revised documents as revised with the new revision date
  – Provide highlighted versions of the documents
Submitting an eProtocol
External IRB Modification/Amendment

Scroll down to the **Approved Protocols** section on your IRB Dashboard

**Approved Protocols**

<table>
<thead>
<tr>
<th>Protocol ID</th>
<th>Principal Investigator</th>
<th>Approval Date</th>
<th>Expiration Date</th>
<th>Review Decision</th>
<th>Form Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB-22-06-4516</td>
<td>Jointer, Amanda</td>
<td></td>
<td>08/29/2025</td>
<td>Panel Manager Review</td>
<td>NEW</td>
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<tr>
<td>IRB-22-04-4490</td>
<td>Jointer, Amanda</td>
<td></td>
<td></td>
<td>Designated Review</td>
<td>NEW</td>
</tr>
</tbody>
</table>

**Click on the Protocol’s ID Number**

Key Personnel that have edit capability for a submission can start and submit an amendment:

- Those listed under **Personnel Information** as: PI, Co-Investigator, Study Coordinator, Administrative Contact have edit capability.
- Key personnel listed as “Other Personnel” **do not** have edit capability.
Submitting an eProtocol
External IRB Modification/Amendment

Select “Start an Amendment”
Only complete the top portion of the eProtocol amendment form.
Attach the Revised Consent/Assent documents
Label as Revised with the revision date

- Do not delete previous versions of documents
- Label the revised documents as “Revised” with the new revision date
**External IRB Modification/Amendment**

Please Do Not attach Consents Forms, Assent Forms, or Research Information Sheets (unsigned consent) here. Those documents must be attached under the Consent Information or Assent Information sections.

Please do not use "IRB Only" labels. These labels are used by the IRB Administration office to indicate instructions to the PI or provide IRB stamped/approved materials.

<table>
<thead>
<tr>
<th>Attachment</th>
<th>Add</th>
<th>Delete</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CV / Resume</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Document Name</strong></td>
<td><strong>Attached Date</strong></td>
<td><strong>Submitted Date</strong></td>
</tr>
<tr>
<td>[ ] PI CV</td>
<td>04/21/2022</td>
<td>04/21/2022</td>
</tr>
</tbody>
</table>

| **External IRB Modification Worksheet** |     |        |
| **Document Name** |     |        |
| [ ] external_irb.modification.worksheet and guide June 2022 |     |        |

Attach the External IRB Modification Form
External IRB Modification/Amendment

**eProtocol Attachments**

- **External IRB Modification Worksheet and Guide**
  - Obtains preliminary identifiable information
  - Provides guidance regarding the modification submission process
    - i.e. type of modifications that require review by the WSU IRB
    - For NCI-CIRB submission it documents the sites
  - Addition and Deletion of Key Personnel Instructions
  - Provides sites’ COVID-19 health precautions
  - IRB of Record Changes or Lead Site Changes
  - Ancillary Reviews
  - Change in PI Instructions
  - Modification Authorizations

Unanticipated Problems are submitted on the UP form available on the WSU IRB’s Forms and Submissions website.
Modification/Amendment Process

IRB Intake

- Received by Administrative Reviewer
- Review Conducted
- Revisions Requested
Authorization Review Process

Review Cycles

A review cycle consists of the IRB administrator reviewing the submission and submitting the comments to the PI/Designee for response and updates to the application.

1. IRB Administrator sends comments to PI/designee
2. PI/designee responds with making changes to applicable sections & addressing comments
3. PI/designee submits revisions to IRB Office. By selecting “Submit to IRB”
4. IRB Administrator reviews the revisions. If all revisions requests are complete authorization is provided

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

If ancillary reviews are required and/or not received. The IRB Administrator will request the approval documentation as a revision request. (Includes: DMC, McLaren, PRMC, CIC, etc.)
WSU IRB External Authorization

- Email is sent notifying PI / Key Personnel of WSU IRB modification authorization.
- The email notification will have language that authorizes the local context change.

- No paper documents
- No stamped documents
- No signed authorization or reviewer form
How to prepare for eProtocol Implementation?

• *Key Personnel Complete/Update CITI Training
• *Non WSU Faculty/Staff request an access ID
• Update your web browsers
• *If needed, forward your WSU email to your main email account
• Sign up for the listserv
  – Receive notification of updated WSU IRB External Forms
    • wsuirbinfo@wayne.edu

*Links to Guidance Tools provided
Tips & Tools

• Start Early

• 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 including the External IRB Worksheet

• Remember Administrative/Ancillary Approvals (DMC, McLaren PRMC, Psychiatry, Radiation)

Don’t forget to select Submit!
Questions?