**Wayne State University**
**Institutional Review Board (IRB)**

**WSU IRB Administration Office**
87 East Canfield, Second Floor
Detroit, MI, 48201
313-577-1628
irb.wayne.edu

# External IRB Submission Guidance

When engaged in multi-site research, research involving external collaborators, or research that is otherwise under the jurisdiction of more than one IRB, WSU acknowledges that each organization is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal regulations. This guidance tool provides information for the initial submission, amendment/modification, and unanticipated problem reporting for studies that are under the oversight of an external IRB. Initial submissions are accepted via the eProtocol system. Submissions that were previously approved before the implementation of eProtocol use the submission forms that are available on the WSU IRB's respective reliance agreement websites.

## Logging in to eProtocol:

- ☐ Website: https://ksprodweb.ovpr.wayne.edu/
- ☐ Use a supported web browser (recommended browsers: Firefox 12, Safari 7)
- ☐ Make sure the Pop-Up Blocker is turned off
- ☐ Do not use the web browsers "Back button" or "refresh"
- ☐ All Key Personnel must have a WSU Access ID & Password

(*email WSUIRBInfo@wayne.edu if you do not have one*)

- • **Note:** Only add local research personnel who are affiliated with Wayne State University or are WSU affiliate institutions (DMC, VAMC, Karmanos Cancer Institute). Researchers from external institutions are responsible for adhering to their own IRB's requirements and **should not** be added to the eProtocol application.
- ☐ All Key personnel/users should update their CITI profile to include their WSU Access ID
- ☐ All Key Personnel including the Dean/Chair/ Authorized Signatory must complete IRB required training modules. See the WSU IRB's Mandatory CITI Training Website.

## Electronic Sign-Off:

- ☐ The role for **All** Key Personnel & the Signatory in eProtocol is "**Investigator.**"
- ☐ All Key Personnel must log-in to eProtocol and complete the Obligations & COI sections.
  - o For the Initial submissions include: the PI, Study Coordinator(s)/Study Manager.
  - o All other key personnel can be submitted via an amendment before study initiation.
- ☐ Only **"ONE"** individual can log in at a time to complete the Obligations & COI:
- ☐ Identify appropriate Dean/Chair/Authorized Signatory.
  **(Dean/Chair/Authorized Signatory will need to log into system with their WSU Access ID & Password)**
- ☐ The first time "**Submit Form**" is selected it is routed to the Dean/Chair/Authorized Signatory for their sign off.
- ☐ After Department Certification is completed the **PI or designee** will then select "**Submit Form**" to the IRB.

# Completing the Initial Submission Form:

## Complete the following eProtocol form sections (in the order of appearance)

☐ **Personnel Information** section
  - All key personnel must complete with **COI** and **Obligations** sections.
  - An amendment can be submitted at a later date to include additional key personnel

| ☐ **Participant Checklist** | ☐ **Study Location**<br>  - Select location of research activities & complete items 1& 2<br>  - Select if this is a multi-site study. |
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☐ **Funding**
  *If the funding source is not currently included for eProtocol, this can be completed concurrently with the WSU IRB review.*

☐ **VAMC Checklist** (Complete if applicable)

☐ **Protocol Checklist**: Select "**Request to Rely on Another IRB-External IRB Submission**" and all other applicable boxes.
  - If a clinical trials number is not available indicate "pending"
  - Select if PHI is being used or disclosed and if yes select "HIPAA Authorization."
  - Select all Ancillary reviews that are applicable.

☐ **Study Details**: drop down menu:
  - Select: "External IRB"
  - Select the Review Type:  Full Board, Expedited, or Exempt
    - Exempt submissions may not be accepted for external IRB review.
    - If unsure regarding the review type, please contact the reviewing IRB for assistance.

## eProtocol- Protocol Information sections

☐ **Summary & Purpose**:
  - Provide the estimated start and end date. The start date is for the local WSU sites.
  - **Note:** This is the section is where you can make changes to the study title, if needed.

☐ **Participant Population:**
  - Complete the PI's experience question.
  - If enrolling non-English-speaking individuals, please state.

☐ **Consent Information**:
  - Attach the Consent(s) ONLY.  Use the approved consent templates available on the WSU IRB reliance agreement website.
  - State N/A, no response is required for all other items requested for eProtocol.

☐ **Assent Information**:
  - Attach the Assents (s) ONLY
  - State N/A, no response is required for all other items requested for eProtocol.

☐ **HIPAA** (if applicable):
  - If PHI will be collected attach the HIPAA Authorization with the Consent.
  - For NCI CIRB submissions the HIPAA Authorization is a separate document

☐ **Drugs and Devices** (if applicable):
  - The appropriate boxes must have been selected for the **Protocol Checklist** (i.e. investigational drug, commercially available drug, investigational medical device, chemotherapeutic drug, etc)
  - Include the IND/IDE/HDE numbers and Phase of Treatment.

**NOTE:  Addendums or Appendices are not required for External IRB Submissions-**

| Sections and documents that are <u>NOT</u> required.  DO NOT COMPLETE/SUBMIT | |
|---|---|
| • **Summary & Purpose (start and end date ONLY)**<br>• **Background, Rationale, Data Analysis, and Procedures**<br>• **Participant Population (PI's Expertise ONLY)**<br>• **Recruitment Process, Participant Compensation, and Costs** | • **Risks**<br>• **Data Safety Monitoring**<br>• **Addendums & Appendices**<br>• **Recruitment Materials & Data Collection Tools** |

## Attachments:

**Attach consents/assents:**

- o Attach Consents/Information Sheets to the "**Consent Information**" section.
- o Assents/Information Sheets attach to the "**Assent Information**" section.

**Attach supporting documents to the Attachments section:**

- o Initial External IRB Worksheet
- o PI's CV/Resume
- o Research Protocol/Research Proposal
- o Reviewing IRB Local Context Form (if applicable)
- o Reviewing IRB Reliance Agreement or Smart IRB Acknowledgement (if applicable)
- o NCI CIRB HIPAA Authorization Form (if applicable)
- o Ancillary Reviews/Approvals (DMC, FCOI Committee, PRMC, FCOI, IBC, Radiation Safety, VA CIC, McLaren, etc.)

## Initial Submission Review Process:

- ☐ Upon receipt of your submission in the WSU IRB Office you will receive email notifications
- ☐ If the IRB Administrator request revisions:
  - o Revision requests are forwarded via eProtocol to the PI & Study Coordinators' WSU email account.
    - ▪ To make changes to the sections indicated per the revision request complete the following:
      - • Open the application in edit mode.
      - • Attach the ==highlighted==/track changes revised documents to the applicable sections.
      - • Label the documents as revised with the revision date.
  - • Corrections should be made to the sections indicated per the comments request.
  - • Indicate that revisions have been made in the comments section by addressing each comment.
  - • Select "Submit to IRB" to return the revisions back to IRB.
- ☐ Revisions are reviewed, if no additional requests or pending ancillary reviews, authorization will be provided.
- ☐ Authorization will be provided in the form of an email to the PI and coordinators WSU email account.

**Note: Studies requiring DMC Review:**

- o DMC review can occur concurrently with IRB review.  Please contact the [DMC Clinical & Translation Research Office](#) for DMC submission instructions.
- o DMC personnel may be added to the IRB application for DMC reviewer view access.
- o To forward a copy of your IRB Application to the DMC Clinical & Translation Research Office
  - ▪ Select Print View tab:
    - • Select applicable sections of the eProtocol form
    - • Save form as a PDF to provide for DMC Review
    - • Consent & Assents and other participant documents will need to be saved separately and forward to DMC for review.

# Amendments/Modifications:

- Modifications requests are only submitted to the IRB for local context changes.
  - Changes include:
    - Change in PI & Key Personnel
      - If changing the PI update the PI's expertise information for the Participant Population section.
    - HIPAA Authorization (changes to PHI use and disclosure), HIPAA Waiver
    - Changes to the protocol or consent documents that affect the local context of the study.
    - Changes to injury language in the consent form.
    - Changes to reliance agreement or transfer of the study to another outside IRB.
- **eProtocol Submissions:**
  - Submit request using the eProtocol Amendment form by selecting "Start an Amendment" for active protocols and follow the External IRB Instructions for the Amendment Form.
  - **Attach revised documents per the Attachments instructions above.**
- **Non eProtocol submissions**:
  - Submit using the External Modification Worksheet available on the WSU IRB's reliance agreement websites (see below).
  - Follow the submission instructions per the External Modification Worksheet

# Unanticipated Problem & Event Reporting:

## Protocol Violations/Deviations submitted to the Reviewing IRB:

- **eProtocol Submissions:**
  - Submit by selecting the eProtocol "**Protocol Violation" Form** and attach documents submitted to the reviewing IRB.
  - A follow-Up submission should be provided once the reviewing IRB has made a determination.
- **Non eProtocol submissions:**
  - Submit using the External Modification Worksheet available on the WSU IRB's reliance agreement websites. A follow-Up submission should be provided once the reviewing IRB has made a determination.

## Local Context Protocol Violations/Deviations

- This includes HIPAA, key personnel, and breach of confidentiality are submitted to the WSU IRB
- Submit using the Unanticipated Problem & Event Reporting form available on the IRB's website and follow instructions for the Unanticipated Problems & Event Reporting Form.
- eProtocol Submission: Complete the UP & Event Reporting Form, complete a **Protocol Violation** for eProtocol and submit.
- Non eProtocol Submissions: Complete the UP & Event Reporting Form and email to eIRBManager@wayne.edu

- **Site Visits:** Upon notification of an impending regulatory site visit, hold notification, and/or external audit, the WSU IRB Administration Office must be contacted immediately. Please e-mail Monica Malian, Director HRPP at monica.malian@wayne.edu.

# WSU IRB Reliance Agreement Websites:

- **NCI CIRB  https://research.wayne.edu/irb/cirb**
- **WCG IRB https://research.wayne.edu/irb/wirb**
- **All Other External IRB's https://research.wayne.edu/irb/reliance-agreements**

Process questions? email: irbquestions@wayne.edu

To inquire about WSU IRB submission status email: irbstatus@wayne.edu