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

IRB eProtocol Checklist & Guidance Tool

Full Board Review

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*)
- ☐ All Key personnel/users should update their CITI profile to include their WSU Access ID (*including the Dean/Authorized Signatory)*
- ☐ 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
- ☐ 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 Submission Form:

- ☐ Complete the eProtocol form section by section (in the order of appearance)
- ☐ Full Board Submissions check the WSU IRB Meetings and Deadlines website for the appropriate deadline. Submissions must be submitted 2 weeks before the upcoming meeting.
- ☐ Complete all applicable sections of the eProtocol form.
- ☐ Complete all applicable sections before starting the key personnel sign off process.

- ☐ Copying & Pasting is not advised. However, if copying & pasting text into eProtocol, use Plain text.
- ☐ It is recommended that you complete all sections of the submission before starting the key personnel sign off process.

Attachments:

Attach consents/assents:

- Attach Consents/Information Sheets to the "**Consent Information"** section
- Assents/Information Sheets attach to the "**Assent Information"** section
- Complete waivers/alterations of Consent or Assent, if applicable (see the waiver guidance tool click here)

Attach supporting documents to the Attachments section:

- Protocol/Proposal
- Data Collection Tools (Diaries, Questionnaires, Surveys, Assessments etc)
- Department Approvals (i.e. PRMC, DMC, Radiation Safety, Psychiatry, etc) other approvals (i.e. FDA IND/IDE letters, Sponsor Letters)
- CV/Resume, FCOI Plan, Letters of Support, External IRB Approvals etc.

Copying & Pasting text is not advised. If copying & pasting text into eProtocol, use Plain text.

Attach all applicable documents in the appropriate sections:

Consent Information section:	Research Informed Consent, Parental Permission, Research Information Sheets, Request for Waiver or Alteration of Consent
Assent Information section:	Adolescent Assent, Oral Assent Script, Request for Waiver of Assent
Protocol Information-Attachment section	
☐ CV/Resume	☐ Protocol, Protocol Addendums, Research Proposal
☐ Investigator Brochure/Package Inserts	☐ Data Collection Tools (Diaries, Questionnaires, Surveys, Assessments etc.)
☐ Participant Materials	☐ Recruitment Materials: Advertisements, Flyers, Scripts
☐ Department Approvals (i.e. PRMC, CIC, DMC, Radiation Safety, Psychiatry, etc.)	☐ Other documents (i.e. FDA IND/IDE letters, Sponsor Letters
☐ PSF Appendices: D, F, G, and H (see below)	

Full Board Submissions: If applicable the following Protocol Summary Form appendices must be uploaded and attached to the Protocol Information Attachments section

These appendices are available on the

WSU IRB's Forms and Submission Requirements Website

PSF Appendix D: Cognitively Impaired Mentally Disabled Participants	PSF Appendix F: Use of Drugs, Biologic Agents, or Devices
PSF Appendix G: Imaging/Diagnostic Radiation Procedure	PSF Appendix H: The Use of Biological Specimens
Coordinating Center Application (attached under the **Study Location** section)	

- ☐ Please refer to the "Labeling Attachments in eProtocol" reference information

Submitting the Application

- ☐ The first time "**Submit Form**" is selected it is routed to the Dean/Chair/Authorized Signatory.
- ☐ The Dean/Chair/Authorized Signatory is the **last** individual to complete Obligations, COI, & Department Certification before submitting to the IRB. This is a two-step process (**see Dean/Chair instructions**).
- ☐ After Department Certification is complete, the **PI or designee** must select "**Submit Form**" to route the submission to the IRB Office.

The Full Board Review & Approval Process

- ☐ Submit based on the IRB Deadlines & Meeting Dates Schedule
- ☐ The submission is placed on the applicable meeting's agenda if all required documents are provided
- ☐ The IRB Chairperson assigns the submission to the appropriate IRB reviewers
- ☐ IRB Members/Reviewer may request revisions **before** the IRB meeting.
- ☐ IRB Members/Reviewer will provide comments to the IRB Administration Office or contact the PI/study team directly
- ☐ The IRB Administration Office will forward comments on to the PI/Designee to make corrections.
    - Email notifications are sent to the WSU email alerting of IRB review activities.
- ☐ Corrections should be made to the sections indicated per the comments request.
- ☐ Please also indicate that revisions have been made in the comments section. Addressing each comment.
- ☐ Please complete revisions in the system **before** the IRB meeting date.
- ☐ If revisions cannot be completed before the please email the applicable IRB committee administrator (see email addresses below)
- ☐ Please "**Submit to IRB**" in order for revisions to be reviewed before the IRB meeting date.
- ☐ **After the Meeting**: An email alert is sent notifying the PI/Designee of the IRB's Determination.
- ☐ Please follow the instructions indicated on the e-mail.
- ☐ If ancillary reviews are not complete the IRB Administration Office will send a revision request for submission of the approval documents.
- ☐ Full Board Submissions Expiration Dates:
    - Greater than minimal risk studies are granted a 1 year continuing review expiration date
    - Minimal Risk studies that meet the flexible review criteria are granted a 3 year continuing review expiration date
- ☐ Upon granting approval, all IRB Approval letters are available in the eProtocol Events History section.
- ☐ Approval documents that require stamping are located for the Protocol Information-Attachments section
    - ***IRB stamps are not to be removed, deleted or tampered with in any manner***
    - If an IRB stamp or IRB stamped document requires revision, email the applicable IRB's email address.

Need eProtocol Training or Assistance, please email:
WSUIRBInfo@wayne.edu or contact the IRB Administration Office at 313 577-1628.

Need to email the assigned IRB Committee?

M1: m1board@wayne.edu	**MP2: mp2board@wayne.edu**
B3: b3board@wayne.edu	

For further contact information of the IRB Visit the WSU IRB's Contact Us Website