

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

eProtocol IRB Reviewer Guidance Tool

eProtocol Tips:

- Use a supported web browser (Firefox 12, Safari 7)
- Make sure the Pop-Up Blocker is turned off
- Do not use the "Back button" or "refresh" in the system
- All IRB Reviewers must have a WSU Access ID & Password
- All Reviewer Assignments will be provided on the IRB Assignment & Deliberation Sheet (sent via e-mail and/or posted to Canvas)
- The Primary Reviewer is the leader in triggering a revision request to the PI/study team
- eProtocol Log in: https://ksprodweb.ovpr.wayne.edu

Reviewing a Protocol:

- Log on to eProtocol using WSU Access ID & Password
- Select the "Reviewer" role at the top of the dashboard under eProtocol
- Under "Protocol Event" select "Assigned as Reviewer"
- Select "Get Protocol" or select the IRB#'s Hyperlink (i.e.IRB-17-12-0427)
- Review the Protocol using your checklist

Primary & Secondary Reviewers must complete a REVIEWER CHECKLIST

- A paper copy reviewer checklist is provided to primary and secondary reviewers.
 - o For Amendments & Continuations primary reviewer only receives a checklist
- Please bring your checklist with you to the IRB meeting.
- Please complete all sections, sign and date.
- Secondary reviewers: Please email your comments to the Primary and the IRB.
 - o Secondary reviewers must still complete a reviewer checklist

Primary Reviewer Writing Comments/Requesting Revisions in eProtocol:

- Check with the secondary reviewer for any revisions
- Click "Write Comment(s)"
- Select Section in which revisions need to be made.
- Write Comment(s), for the section
- Select "Response is Necessary for Approval" Or "Suggestion Not Necessary for Approval"
- When comments are complete: Save & "Submit to IRB"
- If no comments: Click on **Review Decision/Recommend for Approval** to submit a review decision e.g. Recommended for approval
- The primary reviewer must submit a comment or recommend approval.

Reviewer Notes:

- Please review all sections of the eProtocol submission:
 - Consents, Assents, & Waiver requests are under the sections titled "Consent Information" & "Assent Information"
 - Protocol Information "Attachments" (section): Includes all other supporting documents: Protocol, IB, CV, Flyers, Scripts, Questionnaires, Administrative Approvals etc...
 - The PI must submit these documents for IRB Review.

If these items ae not provided, pleases request as part of your review.

- If the Protocol includes: Biological Specimens, Cognitively Impaired-Mentally Disabled Research Participants, Research Procedures Involving Radiation, or WSU is the Coordinating Center, these appendices/forms will be included for the "Attachments" section of eProtocol.
 - PSF Appendix D: Cognitively Impaired Mentally Disabled Participants
 - PSF Appendix F: Use of Drugs, Biologic Agents, or Devices
 - PSF Appendix H: The Use of Biological Specimens
 - PSF Appendix G: Imaging/Diagnostic Radiation Procedure
 - Coordinating Center Application (attached in study location section)

If these items are not provided, please request as part of your review.

- A review cycle ends when a response is received from the PI/study team.
- The **Primary Reviewer** must make comments in order for the RCA to have access to the protocol and forward to the PI/study team.
- When a comment has been sent to the PI/study team, the IRB Administration Office waits for response and forwards responses to the IRB Reviewer for review.
- Reviewers cannot see each other's comments in the system. This is why the secondary reviewer should email their comments to the primary and the IRB Office.

Sending Comments to PI/Coordinator outside of eProtocol:

The primary reviewer may choose to send an e-mail directly to the PI/Coordinator:

- 1. That e-mail must also be sent to the IRB Administration Office (see IRB email address below)
- 2. The primary reviewer still must complete a comment in eProtocol.
- 3. The PI/Coordinator still must make the requested revisions in eProtocol
- Please contact your **Research Compliance Administrator** if you need any assistance:

PH1board@wayne.edu MP2board@wayne.edu M1board@wayne.edu B3board@wayne.edu