

eProtocol IRB Reviewer Guidance Tool

eProtocol Tips:

- Use a current web browser
- 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(s)

Primary & Secondary Reviewers must complete a **REVIEWER CHECKLIST**

- Reviewer checklists are emailed to primary and secondary reviewers.
 - For Amendments & Continuations a primary reviewer only receives a checklist
- Please bring your checklist with you to the IRB meeting.
- Please complete all sections of the checklist, sign and date.
- Secondary reviewers: Please email your comments to the Primary and the IRB.
 - *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.
 - *Secondary reviewers please also include your comments for eProtocol. The primary reviewer must first submit a comment in the system. A notification will appear if this has not been done.*

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 are not provided, please request as part of your review.
- If the submission includes any of the following vulnerable populations or research areas, please complete the additional reviewer forms for the following:
 - [IRB Reviewer Form - Children as Research Participants - September 2012](#)
 - [IRB Reviewer Form - Pregnancy, Fetuses, Neonates - May 2011](#)
 - [IRB Reviewer Form - Studies Conducted At or By The VA](#)
 - [IRB Reviewer Form - Department of Defense - May 2011](#)
 - [IRB Reviewer Form - Prisoners as Research Participants - October 2013](#)
 - [IRB Reviewer Form-NIH Genomic Data Sharing \(December 2019\)](#)
- If the submission includes any of the following below these appendices/forms must 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.

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 and send your completed checklist to:

M1board@wayne.edu

B3board@wayne.edu

MP2board@wayne.edu