Wayne State University
Institutional Review Board (IRB)

WSU IRB Administration Office
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# eProtocol IRB Expedited & Exempt Reviewer Guidance Tool

## eProtocol Getting Started 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**
- ☐ An email notification is sent when you are assigned as a Reviewer
- ☐ eProtocol Log in: **https://ksprodweb.ovpr.wayne.edu**

## Reviewing a Protocol:

- ☐ Log on to eProtocol using your 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 & "**Write Comment(s)"**
- ☐ Reviewers must complete the **"Checklist"** **Do Not use the Checklist tab in eProtocol**
  - Current checklists are available on the IRB Reviewer forms and tools website.
  - The main checklist will guide the reviewer through any additional reviewer checklist that are required.

## The eProtocol Form:

- ☐ **Study Location**: Appropriate approval letters must be included for the attachments section (McLaren, DMC, VA, PRMC) or letters of support for non-affiliate sites or the research is not conducted the PI's assigned department.
- ☐ **Protocol Information (section) –** Includes the majority of information for the submission (background, rationale, participant population, risks, benefits, HIPAA, attachments etc.) Select this tab to open the remainder of the application.
- ☐ **Study Details**: includes Review Type of IRB submission (Full Board, Expedited, Exempt)
- ☐ **Consent Forms** located under **Protocol Information: Consent Information** section
- ☐ **Assent Forms** located under **Protocol Information**: **Assent Information** section
- ☐ **Waiver of Consent/Assent Requests -** waiver requests completed under the Consent Information & Assent Information sections.
  - Note waivers of documentation of consent/assent are needed for use of Research Information Sheets.

- Note: If a study is requesting waiver of consent and there is use/collection of PHI, a waiver of HIPAA Authorization must also be completed for the submission under the HIPAA section.

- ☐ **Protocol Information** – **Attachments Section** should include the following:
  - Protocol/Proposal (***Not required for Exempt Submissions. Required for Expedited Submissions***)
  - Data Collection Tools (Diaries, Questionnaires, Surveys, Assessments etc)
  - Recruitment Materials (flyers, emails, social media messages)
  - Department Approvals (i.e. PRMC, DMC, Radiation Safety, Psychiatry, etc) other approvals (i.e. FDA IND/IDE letters, Sponsor Letters, letters of support)
  - CV/Resume, FCOI Plan, Letters of Support, External IRB Approvals etc
- ☐ **eProtocol Addendums:**
  - Children as Research Participants (***Not required for Exempt Submissions)***
  - Pregnant Women Neonates, & Fetuses(***Not required for Exempt Submissions)***
  - Prisoners as Research Participants (***Not allowed for Exempt Submissions)***
  - International Research (Export Control Review and approval must be attached)
  - Internet Use (if recruiting or collecting data via the internet, this includes Zoom & Teams)
  - NIH Genomic (Institutional Certificate must be submitted and signed by the PI and forwarded to the Associate VP for research)

- ☐ **Additional Appendices**: If research 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 in 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 to Study Location eProtocol section)

## Writing Comments-Requesting Revisions/Approval in eProtocol:

- ☐ Click "**Write Comment(s**)"
- ☐ Select "**Section**" in which revisions need to be made. Write the comment(s), for that section.
- ☐ Select "**Response is Necessary for Approval**" or "**Suggestion Not Necessary for Approval**"
- ☐ **Ready to Approve?**
  - Click on "**Recommend for Approval"** and indicate time frame of approval or status check-in. See the approval period guidance at the end of this guidance tool.
- ☐ When "**Write Comments**" or "**Recommend for Approval**" are complete select "**Submit to IRB**"

- ☐ Upon Approval: Email your completed reviewer sheets to: IRBReview@wayne.edu
- ☐ You may also contact the expedited/exempt **Research Compliance Administrator** directly if you need assistance: Samantha Scheer el4716@wayne.edu
- ☐ If you need to recommend a change to the study's review type (i.e. expedited to exempt, expedited to full board, or exempt to expedited, etc) please follow the notes on the reviewer checklist and include the justification for the change. Then send an email and attach the checklist to IRBReview@wayne.edu

# Approval Period Guidance

| ☐ Approved 12 months<br>Continuing Review<br>364 days | ☐ Status Update-Minimal Risk Studies<br>No Continuing Review | ☐ Approved Flexible Review<br>36 months<br>Continuing Review (3 years) |
|---|---|---|
| • Full Board Risk Category 2 and 3<br>• FDA Minimal Risk Studies<br>• studies where flexible review or status update will not apply<br>• Full board or IRB reviewer has determined and justified annual review is required | • Exempt Studies<br>• Expedited Revised Common Rule Studies (Federally Funded-Common Rule Agencies) | • Expedited Studies & Full Board Studies Category 1.<br>• Unfunded, WSU Department Funded and meets flexible review policy<br>• No more than minimal risk<br>• Risks to participants are minimized<br>• Risks to participants are reasonable in relation to anticipated benefits<br>• Adequate plan for monitoring<br>• Adequate provisions for protecting privacy and confidentiality<br>• Safeguards are in place to protection participants who are vulnerable to coercion or undue influence<br><br>**Examples of research projects that are ineligible include:**<br>• Federally sponsored research projects<br>• Federal training and program project grants<br>• Student projects supported by a faculty sponsor's federal funding<br>• Veterans Affairs (VA) projects<br>• Federal no-cost extensions<br>• FDA-regulated projects<br>• Data repositories containing data intended to support applications to the FDA<br>• Clinical trials involving interventions<br>• Projects that target enrollment of prisoner participants<br>• Projects where non-federal sponsors require annual review |