



eProtocol Guide Expedited & Exempt

Logging in to eProtocol:

- Website: <https://ksprodweb.ovpr.wayne.edu/>
- Use the most recent version of website browsers (FireFox, Chrome, Edge, Safari)
- 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 irbstatus@wayne.edu if you do not have one)
- All Key personnel must 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
- 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)
- Identify the appropriate submission type ([Expedited](#) or [Exempt](#)) Guidance Tools are available click on the links on this guide.
- Complete all applicable sections of the eProtocol form.
- For Exempt submissions their sections of the eProtocol application that are not required, however **Exempt** must be selected as the **Review Type**.
- Complete all applicable sections 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

Attach supporting documents to the Attachments section:

- Protocol/Proposal (**Not required for Exempt Submissions. Required for Expedited Submissions**)
- 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.

For Expedited Submissions: If applicable the following Protocol Summary Form appendices must be uploaded and attached to the submission.

(This is not required for Exempt Submissions)

- PSF Appendix H: The Use of Biological Specimens
- PSF Appendix G: Imaging/Diagnostic Radiation Procedure
- PSF Appendix D: Cognitively Impaired Mentally Disabled Participants
- PSF Appendix F: Use of Drugs, Biologic Agents, or Devices

Submission Tips:

- Note: There is not a deadline for Expedited or Exempt
- Protocol information – Study Details select the Identified Submission Type: (**Expedited** or **Exempt**)
- Research Categories will populate based on selected Submission Type
- Studies requiring DMC Review:
 - Select Print View tab:
 - 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.
 - DMC & VA affiliate review staff may be added to the “Other Personnel” section of the application. Indicate their role as “Affiliate”.

Review Process:

- Upon receipt of your submission in the IRB Office you will receive email notifications during the review process up until final approval (emails are sent to the WSU email address)
- Revision Requests:
 - Make changes to the sections indicated per the revision request
 - Attach any revised documents to the applicable sections
 - Consent & Assent Information section
 - Attachments section
- Minimal Risk Studies: Status Update or Continuing Review
 - A Status update/check-in date or Expiration Date is noted on the IRB Approval Memo
 - Please submit any modification to the IRB as an amendment

For submission status email irbstatus@wayne.edu