



## eProtocol Guide Expedited & Exempt

### 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](mailto: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)
- 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.
- **Exempt submissions do not require completion of vulnerable population addendums, Data Safety Monitoring, and Drugs & Devices sections.**
- 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 ([see the waiver guidance tool click here](#))

### 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 staff may be added to the “Other Personnel” section of the application

## 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

- **Need eProtocol Training or Assistance, please email: [WSUIRInfo@wayne.edu](mailto:WSUIRInfo@wayne.edu) or call 313 577-1628.**