IRB eProtocol Checklist & Guidance Tool

Full Board Review

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 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)
- Full Board Submissions check the WSU IRB Meetings and Deadlines website for the appropriate deadline. Submissions must be submitted 2 weeks before the upcoming meeting.
- Complete all applicable sections of the eProtocol form.
- Complete all applicable sections before starting the key personnel sign off process.

updated 10/2022
Copying & Pasting is not advised. However, if copying & pasting text into eProtocol, use Plain text.

It is recommended that you complete all sections of the submission 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
- 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.

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**Attach all applicable documents in the appropriate sections:**

<table>
<thead>
<tr>
<th>Consent Information section:</th>
<th>Research Informed Consent, Parental Permission, Research Information Sheets, Request for Waiver or Alteration of Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assent Information section:</td>
<td>Adolescent Assent, Oral Assent Script, Request for Waiver of Assent</td>
</tr>
<tr>
<td>Protocol Information-Attachment section</td>
<td></td>
</tr>
<tr>
<td>CV/Resume</td>
<td>Protocol, Protocol Addendums, Research Proposal</td>
</tr>
<tr>
<td>Investigator Brochure/Package Inserts</td>
<td>Data Collection Tools (Diaries, Questionnaires, Surveys, Assessments etc.)</td>
</tr>
<tr>
<td>Participant Materials</td>
<td>Recruitment Materials: Advertisements, Flyers, Scripts</td>
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**Full Board Submissions:** If applicable the following Protocol Summary Form appendices must be uploaded and attached to the Protocol Information Attachments section

These appendices are available on the

**WSU IRB’s Forms and Submission Requirements Website**

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

- Coordinating Center Application (attached under the Study Location section)

- Please refer to the “Labeling Attachments in eProtocol” reference information

updated 10/2022
Submitting the Application

- The first time “Submit Form” is selected it is routed to the Dean/Chair/Authorized Signatory.
- The Dean/Chair/Authorized Signatory is the last individual to complete Obligations, COI, & Department Certification before submitting to the IRB. This is a two-step process (see Dean/Chair instructions).
- After Department Certification is complete, the PI or designee must select “Submit Form” to route the submission to the IRB Office.

The Full Board Review & Approval Process

- Submit based on the IRB Deadlines & Meeting Dates Schedule
- The submission is placed on the applicable meeting’s agenda if all required documents are provided
- The IRB Chairperson assigns the submission to the appropriate IRB reviewers
- IRB Members/Reviewer may request revisions before the IRB meeting.
- IRB Members/Reviewer will provide comments to the IRB Administration Office or contact the PI/study team directly
- The IRB Administration Office will forward comments on to the PI/Designee to make corrections.
  - Email notifications are sent to the WSU email alerting of IRB review activities.
- Corrections should be made to the sections indicated per the comments request.
- Please also indicate that revisions have been made in the comments section. Addressing each comment.
- Please complete revisions in the system before the IRB meeting date.
- If revisions cannot be completed before the please email the applicable IRB committee administrator (see email addresses below)
- Please “Submit to IRB” in order for revisions to be reviewed before the IRB meeting date.
- After the Meeting: An email alert is sent notifying the PI/Designee of the IRB’s Determination.
  - Please follow the instructions indicated on the e-mail.
- If ancillary reviews are not complete the IRB Administration Office will send a revision request for submission of the approval documents.
- Full Board Submissions Expiration Dates:
  - Greater than minimal risk studies are granted a 1 year continuing review expiration date
  - Minimal Risk studies that meet the flexible review criteria are granted a 3 year continuing review expiration date
- Upon granting approval, all IRB Approval letters are available in the eProtocol Events History section.
- Approval documents that require stamping are located for the Protocol Information-Attachments section
  - IRB stamps are not to be removed, deleted or tampered with in any manner
  - If an IRB stamp or IRB stamped document requires revision, email the applicable IRB’s email address.

Need eProtocol Training or Assistance, please email: WSUIRBInfo@wayne.edu or contact the IRB Administration Office at 313 577-1628.
### Need to email the assigned IRB Committee?

<table>
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<tr>
<th>M1: <a href="mailto:m1board@wayne.edu">m1board@wayne.edu</a></th>
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For further contact information of the IRB Visit the WSU IRB’s [Contact Us Website](#)