



IRB eProtocol Amendment Submission Checklist

<input type="checkbox"/> EXPEDITED If there are changes that reflect full board revisions the submission will need to reviewed as a full board submission.	<input type="checkbox"/> FULL BOARD
<input type="checkbox"/> Change in Principal Investigator (Submit new PI's CV as an attachment) <input type="checkbox"/> Key Personnel Deletions or Additions	<input type="checkbox"/> N/A
<input type="checkbox"/> Recruitment Methods & Participant Materials: <ul style="list-style-type: none"> ○ Flyers, Advertisements, Brochures, recruitment letters & scripts 	<input type="checkbox"/> N/A <input type="checkbox"/> Included attachment(s)
<input type="checkbox"/> Protocol Document and/or Protocol Changes: <ul style="list-style-type: none"> ○ Administrative/editorial, Project Title, Accrual numbers (increase or decrease enrollment), Enrollment Criteria, Adding Vulnerable Participants, Study Procedures, Risks and/or Benefits, Data collection Tools, Participant Compensation, Adding or Removing Research Site(s) 	<input type="checkbox"/> N/A <input type="checkbox"/> Included attachment(s)
<input type="checkbox"/> Consent/Assents/ Scripts/Information Sheets: <ul style="list-style-type: none"> ○ Informed Consents, Information Sheet, Oral Consent Scripts, Parental Permissions Consent, Adolescent Assent Form, Oral Assent Script, Addendum to Consent ○ Requesting Waiver of consent, Waiver of written documentation of consent 	<input type="checkbox"/> N/A <input type="checkbox"/> Included attachment(s)
<input type="checkbox"/> HIPAA <ul style="list-style-type: none"> ○ Revising or adding PHI, changing USES or Disclosures, who will have access to PHI, Requesting Waiver of HIPAA Authorization 	<input type="checkbox"/> N/A
<input type="checkbox"/> Investigator's Brochure/Package Inserts: <ul style="list-style-type: none"> ○ Investigator's Brochure or Package Insert 	<input type="checkbox"/> N/A <input type="checkbox"/> Included attachment(s)
<input type="checkbox"/> Other Changes <ul style="list-style-type: none"> ○ Funding source ○ Data Safety Monitoring Minutes/Memo ○ Sponsor Annual Reports ○ Study off-hold, Study on-Hold (<i>provide supporting documentation</i>) ○ Study Closed to Accrual 	<input type="checkbox"/> N/A <input type="checkbox"/> Included attachment(s)
<input type="checkbox"/> Review Addendums to check for changes to any applicable areas <input type="checkbox"/> Update IRB Appendices (Appendix H, Appendix G, Appendix D, Coordinating Center Application)	<input type="checkbox"/> completed <input type="checkbox"/> N/A
<input type="checkbox"/> Include ALL attachments <ul style="list-style-type: none"> ○ Consent, Assents, Participant Materials, Data Collection Tools, IB/Package Insert... ○ IRB Appendices (if applicable) ○ PI Change (new PI's CV/Resume) 	<input type="checkbox"/> completed <input type="checkbox"/> N/A

eProtocol Reminders

- Use a supported web browser (Firefox 12, Safari 7, Internet Explorer 10)
- Make sure the Pop-Up Blocker is turned off
- Do not use the “Back button” in the system
- If adding Key personnel, key personnel should update their CITI profile to include their WSU Access ID
- All Key Personnel must log in to complete the Obligations & COI sections
- Only one individual can log in at a time to complete the Obligations & COI
- Go through the form section by section to make sure all sections have been revised as applicable

- Please refer to the “Labeling Attachments in eProtocol” reference sheet for assistance

- If copying & pasting text into eProtocol, use Plain text. Copying & Pasting is not advised.

- If amending information associated with the following appendices be sure to upload as attachments:

(available on the IRB’s website):

- PSF Appendix H: The Use of Biological Specimens
- PSF Appendix G: Imaging/Diagnostic Radiation Procedure
- PSF Appendix D: Cognitively Impaired Mentally Disabled Participants
- Coordinating Center Application

Please also HIGHLIGHT revisions made to the appendices