Wayne State University
Institutional Review Board (IRB)

WSU IRB Administration Office
87 East Canfield, Second Floor
Detroit, MI, 48201
313-577-1628
irb.wayne.edu

IRB eProtocol Amendment Submission Checklist

☐ **EXPEDITED** **If there are changes that reflect full board revisions the submission will need to reviewed as a full board submission.**	☐ **FULL BOARD**
☐ **Change in Principal Investigator (Submit new PI's CV as an attachment)** ☐ **Key Personnel Deletions or Additions**	☐ N/A
☐ **Recruitment Methods & Participant Materials:** ○ Flyers, Advertisements, Brochures, recruitment letters & scripts	☐ N/A ☐ Included attachment(s)
☐ **Protocol Document and/or Protocol Changes:** ○ 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)	☐ N/A ☐ Included attachment(s)
☐ **Consent/Assents/ Scripts/Information Sheets:** ○ 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	☐ N/A ☐ Included attachment(s)
☐ **HIPAA** ○ Revising or adding PHI, changing USES or Disclosures, who will have access to PHI, Requesting Waiver of HIPAA Authorization	☐ N/A
☐ **Investigator's Brochure/Package Inserts:** ○ Investigator's Brochure or Package Insert	☐ N/A ☐ Included attachment(s)
☐ **Other Changes** ○ Funding source ○ Data Safety Monitoring Minutes/Memo ○ Sponsor Annual Reports ○ Study off-hold, Study on-Hold (*provide supporting documentation*) ○ Study Closed to Accrual	☐ N/A ☐ Included attachment(s)
☐ Review Addendums to check for changes to any applicable areas ☐ Update IRB Appendices (Appendix H, Appendix G, Appendix D, Coordinating Center Application)	☐ completed ☐ N/A
☐ Include **ALL** attachments ○ Consent, Assents, Participant Materials, Data Collection Tools, IB/Package Insert… ○ IRB Appendices (if applicable) ○ PI Change (new PI's CV/Resume)	☐ completed ☐ N/A

eProtocol Amendment Submission 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 applicable sections have been revised (i.e. personnel information, participant checklist, study location, protocol checklist, Consent, Assent, HIPAA, etc.)
- As changes are made and saved to each section the system will generate a list of sections revised for the amendment form.
- Describe the modifications for the "summary section of proposed changes" section:
    - State if the Amendment is **Full Board** **or** **Expedited** *(as there is only one amendment form for both types of submissions)*
    - Indicate the following: PI change, key personnel, consent/Assent/Script, protocol, IB, risk changes, recruitment materials, etc.

- Describe why the changes are being made for the "explanation of changes" section

- Please refer to the "Labeling Attachments in eProtocol" reference sheet for assistance. Provide Highlighted versions of attachments to indicate revisions.

- 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
- PSF Appendix F: Use of Drugs, Biologic Agents, or Devices
- Coordinating Center Application

Please also HIGHLIGHT revisions made to the appendices