Wayne State University
Institutional Review Board (IRB)

WSU IRB Administration Office
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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)** –For PI Change amendment the System requires Dean/Chair/Authorized signatory certification. ☐ **Key Personnel Deletions or Additions**	☐ N/A ☐ New PI's CV Attached
☐ **Recruitment Methods & Participant Materials:** o Flyers, Advertisements, Brochures, recruitment letters & scripts	☐ N/A ☐ Included attachment(s)
☐ **Protocol Document and/or Protocol Changes:** o 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:** o Informed Consents, Information Sheet, Oral Consent Scripts, Parental Permissions Consent, Adolescent Assent Form, Oral Assent Script, Addendum to Consent o Requesting Waiver of consent, Waiver of written documentation of consent	☐ N/A ☐ Included attachment(s)
☐ **HIPAA** o 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:** o Investigator's Brochure or Package Insert	☐ N/A ☐ Included attachment(s)
☐ **Other Changes** o Funding source o Data Safety Monitoring Minutes/Memo o Sponsor Annual Reports o Study off-hold, Study on-Hold (*provide supporting documentation*) o 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 o Consent, Assents, Participant Materials, Data Collection Tools, IB/Package Insert… o IRB Appendices (if applicable) o PI Change (new PI's CV/Resume)	☐ completed ☐ N/A

Attach all applicable documents in the appropriate sections:

Consent Information section:	Research Informed Consent, Parental Permission, Research Information Sheets, Request for Waiver or Alteration of Consent
Assent Information section:	Adolescent Assent, Oral Assent Script, Request for Waiver of Assent
Protocol Information-Attachment section	
☐ CV/Resume	☐ Protocol, Protocol Addendums, Research Proposal
☐ Investigator Brochure/Package Inserts	☐ Data Collection Tools (Diaries, Questionnaires, Surveys, Assessments etc)
☐ Participant Materials	☐ Recruitment Materials: Advertisements, Flyers, Scripts
☐ Department Approvals (i.e. PRMC, DMC, Radiation Safety, Psychiatry, etc)	☐ Other documents (i.e. FDA IND/IDE letters, Sponsor Letters
☐ PSF Appendices: D, F, G, and H (see below)	

If applicable the following Protocol Summary Form appendices must be uploaded and attached to the submission for the Protocol Information-Attachments section (appendices available on the IRB's 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)	

Responding to Revisions Requests

- Make the requested changes to the sections requested
- Comments are accessed via the Protocol Event Tab
- Respond to the revisions in Comments Section, indicating revisions have been made or responding to inquiries.

eProtocol Amendment Submission Reminders

- ☐ Use a supported web browser (Firefox 12, Safari 7)
- ☐ Make sure the Pop-Up Blocker is turned off
- ☐ Do not use the "Back button" in the system
- ☐ If adding Key personnel, key personnel must 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, Drugs & Devices, Attachments** 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
- Appendix N: Resumption of In-Person Clinical Research
- Coordinating Center Application

Please also HIGHLIGHT revisions made to the appendices if revising an appendix.