IRB Post Approval Monitoring

Section 1. Protocol Pre-Assessment by Monitor

Study Details

IRB Protocol Reference Number:	
Principal Investigator (PI):	
Title:	
Sponsor(s) on file:	
Project End Date (If known)	
Original Review Type	☐ Exempt (Cat_____) ☐Expedited ☐Full
Original Approval Date	
Expiration/Admin. Check-In Date	

Amendments/Modifications

Has the protocol been amended/modified since the beginning of the study? ☐ Yes ☐ No
If yes, summarize all approved amendments below (attach separate form if needed).

Amend. Number	Approval Date	Brief Description
		Example

Personnel

Please include any current personnel listed in the study record prior to the monitoring visit.

1. Are any external investigators currently included in the research?
   - ☐ Yes, other institutional affiliations (Authorization Agreements/reliance)
   - ☐ Yes, with other IRB or Ethics Committee approvals
   - ☐ Yes, Independent Investigators (Independent Investigator Agreements)
   - ☐ No, all personnel are affiliated with Purdue University

2. If external investigators are included, are all agreements in the IRB record?
   - ☐ Yes ☐ No ☐ N/A

Name (Include PI and Key Personnel) **List any external affiliations**	**CITI Training Status**
	☐ Current ☐ Expired
	☐ Current ☐ Expired
	☐ Current ☐ Expired
	☐ Current ☐ Expired
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	☐ Current ☐ Expired

Pre-Visit Summary

Provide a brief description of the research study prior to conducting the monitoring visit.

Recruitment and Consent/Assent

1. What form(s) are used for participant consent/assent in the study? Check all that apply.

   ☐ Informed Consent (Signed)
   ☐ Informed Consent (Signature Waived)
   ☐ Child Assent (signed)
   ☐ Study Information Sheet
   ☐ HIPAA Release Authorization
   ☐ Participant Debriefing Form
   ☐ None (exempt study or waiver of consent authorized)
   ☐ Other(s)-Describe _____

2. Are multiple versions of consent approved for use in the study? If yes, please summarize the versions. ☐ Yes ☐ No ☐ N/A
   Summary:

3. Which data collection methods are used for the study?
   ☐ Questionnaires or Surveys (Non-electronic)
   ☐ Questionnaires or Surveys (Electronic [e.g. Qualtrics, RedCap, etc.])
   ☐ Physical or Biometric measurements
   ☐ Blood draw/Venipuncture/Finger Stick
   ☐ MRI, EEG, ECG
   ☐ Other(s)-Describe _____

4. Does the study population include vulnerable populations?
   ☐ No vulnerable populations
   ☐ Children
   ☐ Prisoners
   ☐ Pregnant women/fetuses
   ☐ Other(s)-Describe _____

5. Have any adverse events been reported to the IRB prior to the monitoring visit?
   ☐ Yes ☐ No

6. Does the IRB electronic file have current copies of all documents?
   ☐ Yes ☐ No

7. If any protocol-specific questions exist after reviewing the record, IRB requests, and any responses from the PI. Include any additional questions below (if any) that will be addressed during the visit.

Section 2. Details of Monitoring Visit

Date of Monitoring Visit:_____

Monitoring Visit Conducted By:_____

Visit Type: ☐ Directed ☐ Random

1. What is the status of the enrollment for the protocol?
   ☐ Currently Enrolling ☐ Data Analysis Only ☐ Not Started/Paused ☐ Closed or Complete

2. Are the materials and methods used to recruit participants approved in the protocol?
   ☐ Yes ☐ No

3. Are all personnel correct and current in the protocol record?
   ☐ Yes ☐ No

4. Do the recruitment materials and methods match the IRB approved documents?
   ☐ Yes ☐ No ☐ N/A

5. As of the date of the monitoring visit, how many participants were enrolled/consented for the study?

   _____

6. Where the use of signed consent form is required, what is the number of signed consent forms signed by unique study participants?

   _____ ☐ N/A

7. Do/es the current consent form(s) match the HRPP/IRB-approved version(s)?
   ☐ Yes ☐ No ☐ N/A

8. Are all assent documents, HIPAA release forms, and/or participant debriefing forms signed and retained when applicable for consented participants or their legally authorized representatives?
   ☐ Yes ☐ No ☐ N/A

9. Do all data collection instruments match the IRB approved documents?
   ☐ Yes ☐ No ☐ N/A

10. Did the Monitor observe any consent or data collection processes with participants?
    ☐ Yes ☐ No

11. Does the PI have access controls in place for any hard copy or electronic study records?
    ☐ Yes ☐ No ☐ N/A

12. Summarize the data and study record storage processes.

13. Are documents and data stored in the method approved in the IRB protocol?
    ☐ Yes ☐ No

14. Do any special IT or other security parameters apply for protected data (e.g. PHI or FERPA)?
    ☐ Yes ☐ No

15. Is/are the funding source(s) current and accurate for the study record?
    ☐ Yes ☐ No ☐ N/A

16. Does the study involve the use compensation for the participant enrollment, eligibility, participation and/or completion?
    ☐ Yes ☐ No

17. If compensation is permitted, are accurate records kept to document payment practices and IRB approved amounts?
    ☐ Yes ☐ No ☐ N/A (no compensation)

18. Are there any changes or deviations from the approved compensation amount (or practice of no compensation)?
    ☐ Yes ☐ No

19. Are there any other items not otherwise addressed here that may require clarification, guidance or reporting to the IRB? If yes, document in Notes below.
    ☐ Yes ☐ No

Monitoring Visit Dialogue and Best Practice Refresher

1. Did the Monitor provide information on reporting adverse events?
   ☐ Yes ☐ No

2. Did the Monitor review guidance provided on the IRB website related to general SOPs, guidance documents, forms, metrics, and contacts with the PI?
   ☐ Yes ☐ No

3. Did the Monitor generate and review a list of all active protocols to review with the PI?
   ☐ Yes ☐ No ☐ N/A

4. Were any protocols found to be ready for closure or renewal due to expiration or inactivity?
   ☐ Yes ☐ No ☐ N/A

5. Did the monitor review document retention guidelines with the PI during the visit?
   ☐ Yes ☐ No

6. Does the PI have any further questions about Purdue HRPP/IRB processes or procedures?
   ☐ Yes ☐ No

Monitoring Visit Notes:

Example