
Post-Approval Monitoring

Routine review is a necessary component of an IRB protocol and contributes toward the shared goal of human subjects research protections. This process is conducted in accordance with Purdue University HRPP Standard Operating Procedure 306, "Post Approval Monitoring". Your protocol has been selected for post approval monitoring. Please complete this questionnaire prior to the post approval monitoring visit.

Please provide the name of the Principal Investigator.

Please provide the protocol title and protocol number.

Please provide the name of the individual completing this questionnaire.

Has the scope or purpose of the original project changed since IRB approval?

Yes

No

Please describe how the project has changed since the IRB approval.

Were there any changes to the methods of recruitment approved in the original or approved amendments?

- Yes
- No

What are the new methods of recruitment being used?

What are the current sources of funding for this protocol? Please list all confirmed sponsors and grant titles.

Has your research team encountered any adverse events?

- Yes
- No

Please list any adverse events that have occurred.

Is recruitment of study participants occurring at a markedly faster or slower rate than originally anticipated?

- Above average
- Average
- Below average

Will you need to add any new personnel or co-PIs to your IRB protocol? Note: New personnel must not participate in collection and analysis of identifiable data until all training is completed and study personnel amendments are approved.

Yes

No

Are there any personnel who have been removed from the project, or will be leaving the project soon?

Yes

No

Are you familiar with the proper procedures to add or remove personnel?

Yes

No

Please contact the IRB Office for assistance with adding/removing personnel.

Does your study have an approved consent form or information sheet?

Yes

No

Do you have possession of all signed consent forms for participants enrolled in your study? (For studies where the IRB has waived the need for a participant's signature, note this in your response).

Are study files kept in a safe location, locked, password protected, and inaccessible to personnel not on the study?


Yes

No

Where are they kept?

Do you have other questions to address with Human Research Protection Program or IRB regarding your protocol or the review?

Please verify before you submit this questionnaire. Thank you!

I'm not a robot 
reCAPTCHA
Privacy - Terms
