INVESTIGATOR SELF-ASSESSMENT CHECKLIST FOR IRB PROTOCOL POST-APPROVAL MONITORING

For Expedited and Full Board IRB Protocols

Responsible Project Investigator: _____ IRB#:_____ Date: _____

Project title: _____

Approval and Record Keeping	Yes	No	NA	Corrective actions
The project has current IRB approval.				
All IRB related records (approval letter, application, signed consent forms, continuing review activities & correspondence) has been retained in an accessible location. All records must be kept for at least 3 years after completion of the research.				
All investigators listed on this project are currently certified in the human subjects protection training.				
Were there any changes to the approved project since the last continuing review? If yes, was a revision submitted to the IRB?				
Consents	**Yes**	**No**	**NA**	**Corrective actions**
Was the IRB approved (with footer or stamp) version of the consent(s)/assent(s) used to enroll subjects?				
Were all consent forms (with footer or stamp) signed by subjects prior to enrollment?				
If using an oral consent, the IRB approved script was used to enroll subjects.				
Do you have a signed and dated consent form on file for every subject enrolled in the study?				
If changes were made to the consent form, were the changes submitted and approved by the IRB?				

Recruitment	Yes	No	NA	Corrective actions
Subjects were identified and recruited according to the methods approved by the IRB.				
Any advertising or recruitment materials used to recruit subjects were approved by the IRB.				
All eligibility and ineligibility requirements as listed and approved by the IRB were followed. Any deviations were reported to the IRB.				
If subjects received any compensation is there documentation?				
Research Protocol	**Yes**	**No**	**NA**	**Corrective actions**
Research conducted complies with the project description and procedures as approved by the IRB.				
All data collection instruments used was those approved by the IRB.				
Privacy, Data Storage and Confidentiality	**Yes**	**No**	**NA**	**Corrective actions**
The subject's privacy is protected and safeguards are in place as approved by the IRB.				
If you proposed to collect the data anonymously, has anonymity been maintained in the physical or electronic records?				
Are hard copies (consent forms and data forms) stored in a secure, locked location?				
Is electronic data on a secure and protected computer? Are you aware of the security on your computer and server?				

Privacy, Data Storage and Confidentiality - Continued	Yes	No	NA	Corrective actions
Are electronic data files password protected?				
Is access to computer, electronic files, and physical files limited to appropriate study personnel?				
Was the research data (raw) stored/disposed of as described and approved by the IRB?				
Continuing Review	**Yes**	**No**	**NA**	**Corrective actions**
Are you aware of when your project expires? Have you placed a reminder on your schedule to submit a renewal form 4 weeks prior to the expiration?				
Have there been any lapses in IRB approval? If yes, did you report any research activity that was done during the lapse?				
Have there been any adverse events (AE) or unanticipated problems, complaints or subject withdrawals while conducting this research? If yes, have all details been reported to the IRB?				
Have there been any new findings to change the risk benefit ratio?				
Closure	**Yes**	**No**	**NA**	**Corrective actions**
If your project is complete, or you are performing data analysis only on anonymous or de-identified data, can you close the protocol?				

If you would like to discuss any aspects of your self-assessment contact the: IRB Staff or HRPP at 765-494-5942 or irb@purdue.edu
Or RQAU staff at 765-494-4590 or horton1@purdue.edu