Investigator Self-Assessment Checklist for Human Subjects Research

TEXAS A&M UNIVERSITY

DIVISON OF RESEARCH

This self-assessment checklist is designed for Investigators to assess their compliance with federal and institutional requirements regarding research with human subjects. The use of this checklist is entirely voluntary and does not need to be sent to, or reviewed by, the Institutional Review Board (IRB) or the Human Subjects Protection Program (HSPP).

More information about the HSPP is available at http://rcb.tamu.edu/humansubjects and about the IRB at http://irb.tamu.edu. Investigators are encouraged to contact the HSPP (irb@tamu.edu or 979.458.4067) with any questions.

Please Note:

- Use of this checklist is entirely voluntary. It is not an IRB or HSPP requirement to complete this form.
- Not all sections of the checklist may apply to all studies.
- If revisions to the project or corrective action may be necessary, please contact the HSPP for assistance.
- If you are unsure if corrective action is necessary or if a deviation has occurred, please contact the HSPP to discuss the findings.
- After the self-assessment has been completed, consider sharing the findings with the study team.
- If you would like assistance with reviewing the study files, please contact the HSPP to schedule a meeting with a Post Approval Monitor.

INVESTIGATOR SELF-ASSESSMENT CHECKLIST

Investigator: _____ IRB#:_____ Date:_____

Project Title: _____

APPROVAL AND RECORD KEEPING	YES	NO	N/A	NOTES / ACTION NEEDED
Does the project have current IRB approval?	☐	☐	☐	
Have all IRB-related records—e.g., approval letter, application, signed consent forms, continuing review activities, and correspondence—been retained in an accessible location? (Note: All records must be kept for at least three years after completion of the study.)	☐	☐	☐	
Are all investigators associated with this project current in their CITI training?	☐	☐	☐	
Have all revisions to the project been reviewed and approved by the IRB prior to implementation?	☐	☐	☐	
CONSENT	**YES**	**NO**	**N/A**	**NOTES / ACTION NEEDED**
Was the IRB approved (i.e., stamped) version of the consent(s)/assent(s) used to enroll subjects?	☐	☐	☐	
Were all approved consent forms signed by subjects prior to enrollment?	☐	☐	☐	
Do you have a signed and dated consent form on file for every subject enrolled in the study?	☐	☐	☐	
Are all consent forms kept in a single location on the Texas A&M campus, as stated on the IRB application?	☐	☐	☐	
If changes were made to the consent form, were the changes submitted and approved by the IRB?	☐	☐	☐	

RECRUITMENT	YES	NO	N/A	NOTES / ACTION NEEDED
Were subjects identified and recruited according to the methods approved by the IRB?	☐	☐	☐	
Were all advertising or promotional materials used to recruit subjects approved by the IRB?	☐	☐	☐	
Were all inclusion and exclusion requirements as listed and approved by the IRB followed? Were any deviations reported to the IRB?	☐	☐	☐	
If subjects received any compensation, is there documentation?	☐	☐	☐	
Are the number of subject enrolled in the study less than or equal to the number approved?	☐	☐	☐	
RESEARCH PROTOCOL	**YES**	**NO**	**N/A**	**NOTES / ACTION NEEDED**
Does the research conducted comply with the project description and procedures as approved by the IRB?	☐	☐	☐	
Were all data collection instruments used during the project submitted to and approved by the IRB?	☐	☐	☐	
PRIVACY, DATA STORAGE, AND CONFIDENTIALITY	**YES**	**NO**	**N/A**	**NOTES / ACTION NEEDED**
Are the subjects' privacy protections and safeguards 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 the computer(s) and server(s) used for this study?	☐	☐	☐	

PRIVACY, DATA STORAGE, AND CONFIDENTIALITY - CONTINUED	YES	NO	N/A	NOTES / ACTION NEEDED
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**	**N/A**	**NOTES / ACTION NEEDED**
Are you aware of when the approval period for the study expires? Have you placed a reminder on your schedule to submit a continuing review form four 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, unanticipated problems, complaints, or subject withdrawals while conducting this research? If yes, have all details been reported to the IRB?	☐	☐	☐	
Has the number enrolled on the continuing reviews included individuals who consented but did not complete the study?	☐	☐	☐	
Has the number enrolled as listed on the continuing review accurately reflected the number enrolled in the last year (since the last continuing review)?	☐	☐	☐	
COMPLETION	**YES**	**NO**	**N/A**	**NOTES / ACTION NEEDED**
If the project is complete and data analysis is no longer performed, can the study be closed?	☐	☐	☐	

General Resources

IRB – Standard Operating Procedures http://vpr.tamu.edu/compliance/rcc/irb/sops
TAMU – Standard Administrative Procedures - http://rules-saps.tamu.edu/TAMURulesAndSAPs.aspx

- See Section B Sub-section 15 and Section C Sub-section 21

Topic-Specific Resources

Consent

- Consent Information Resource Page http://rcb.tamu.edu/humansubjects/resources/consentinfo
- SOP IRB 124 Informed Consent Process and Documentation http://vpr.tamu.edu/compliance/rcc/irb/sops/124
- SOP IRB 125 Waivers or Alterations to Consent Process or Documentation Requirements http://vpr.tamu.edu/compliance/rcc/irb/sops/125

Recruitment

- Recruitment/Advertising Guidelines http://rcb.tamu.edu/humansubjects/resources/recradvguidelines

Privacy, Data Storage and Confidentiality

- SOP IRB 122 Privacy of Human Subjects http://vpr.tamu.edu/compliance/rcc/irb/sops/122
- SOP IRB 123 Confidentiality of Identifiable Data http://vpr.tamu.edu/compliance/rcc/irb/sops/123
- FAQ General Resource Page http://rcb.tamu.edu/humansubjects/faqhumansubjects
- University SAP 15.99.03.M1.03 Guidelines for Gathering, Storage, and Retention of Data and Results http://rules-saps.tamu.edu/PDFs/15.99.03.M1.03.pdf

Compensation

- SOP IRB 139 Compensation for Research Participation http://vpr.tamu.edu/compliance/rcc/irb/sops/139
- University SAP 21.01.99.M0.03 http://rules-saps.tamu.edu/PDFs/21.01.99.M0.03.pdf

Continuing Review

- SOP IRB 108 Continuing Review of Research http://vpr.tamu.edu/compliance/rcc/irb/sops/108
- Conduct Research Resource Page http://rcb.tamu.edu/humansubjects/approvals/conductresearch

Completion

- Conduct Research Resource Page http://rcb.tamu.edu/humansubjects/approvals/conductresearch
- Study Completion/Not Initiated Form located in iRIS https://imedris.tamu.edu