Self-Assessment Tool

This purpose of this checklist is to allow investigators to conduct self-assessments of their IRB approved projects to ensure they are being conducted in compliance with IRB regulations and policies, as well as the protocol's approved procedures.

The UVA IRB-SBS encourages researchers to conduct self-assessments at least annually.

The IRB may also request that self-assessments be conducted and submitted to the UVA IRB by a specified date.

Please keep copies of completed assessments with your IRB related records.

Project Identification							
Principal Investigator (PI):		*Faculty Advisor (FA):*		*Assessment Completed by:*		*Date Conducted:*	
IRB Protocol #:		*Title:*					

Records Review				
1. Approval and Regulatory Documentation	*Yes*	*No*	*N/A*	*Notes*
Are all IRB related records being retained in an accessible location?	☐	☐		
Are grant application, progress reports and correspondence to/from the funding entity on file?	☐	☐	☐	
Are all versions of the IRB approved protocol on file?	☐	☐		
Are you tracking the versions and dates in an IRB Submission log?	☐	☐		
Are all versions of the IRB approved consent, parental permission, and assent documents on file?	☐	☐	☐	
Are all versions of IRB approved information provided to participants on file (handouts, brochures, survey tools)?	☐	☐	☐	
Are all IRB approval letters on file (initial approval, continuing review, modifications)?	☐	☐		
Are all external/local/ethical review approvals on file?	☐	☐	☐	
If international research, is there documentation on file that the protocol was reviewed and approved within the country's ethics review/approval infrastructure?	☐	☐	☐	
If research conducted at a location other than UVA, are permissions on file for study to be conducted at that location?	☐	☐	☐	
Are all project team members current (completed in last 3 years) in their human participants protections training (CITI)?	☐	☐		
Have all revisions to the project been approved by the IRB prior to implementation?	☐	☐	☐	

2. Participant Recruitment and Screening	Yes	*No*	*N/A*	*Notes*
Were all participants identified and recruited according to the procedures approved by the IRB?	☐	☐	☐	
Were the advertising and/or recruitment materials used approved by the IRB prior to use?	☐	☐	☐	
Were all inclusion and exclusion criteria followed as listed and approved by the IRB?	☐	☐	☐	
If not, were the deviations reported to the IRB?	☐	☐	☐	
For participants that did not meet eligibility requirements (failed screening), were IRB approved procedures followed?	☐	☐	☐	
How many participants have been enrolled to date?			☐	
Is the number of participants enrolled no greater than the IRB approved participant enrollment?	☐	☐	☐	
Date of Initial IRB Approval: Date first participant enrolled:			☐	
3. Informed Consent Process and Documentation				
Was the IRB approved version of the consent/assent used to enroll participants?	☐	☐	☐	
If using an oral or online consent, was the IRB approved script/text used to enroll participants?	☐	☐	☐	
Were any consent forms or language used which were not approved?	☐	☐	☐	
Did an appropriately trained study team member obtain consent from all participants?	☐	☐	☐	
Is there a signed and dated consent form on file for every participant enrolled in the project?	☐	☐	☐	
If changes were made to the consent form, were the changes submitted and approved by the IRB prior to use?	☐	☐	☐	
Did every participant receive a copy of the consent form?	☐	☐	☐	
If applicable, has every participant been fully debriefed after all research procedures?	☐	☐	☐	
Researcher's contact number listed in the consent document is correct and functional? Phone number listed:_____	☐	☐	☐	
4. Research Protocol				
Was the research conducted consistent with the description and procedures as approved by the IRB?	☐	☐		
Were all of the data collection tools which were used (surveys, interview questions, etc.) approved by the IRB prior to use?	☐	☐	☐	
For each participant, was consent obtained prior to performance of any protocol procedures?	☐	☐	☐	
Is participant payment consistent with the IRB approved protocol and consent, and are all participant compensation records being documented and stored appropriately?	☐	☐	☐	
If changes were made to the protocol, were the changes submitted and approved by the IRB prior to implementation?	☐	☐	☐	
Have all reportable events been addressed as required by the UVA IRB?	☐	☐	☐	
5. Privacy, Data Storage, and Confidentiality				
Were privacy standards and procedures implemented as approved by the IRB?	☐	☐	☐	
Are links to coded data stored separately from the data?	☐	☐	☐	
Are signed consent forms stored separately from the research data?	☐	☐	☐	Location:

	Yes	*No*	*N/A*	*Notes*
Are project data secured as approved by the IRB?	☐	☐	☐	Location:
If you are storing data on a computer and/or portable storage device, are these devices password protected and/or encrypted? Are these devices stored in a secure location?	☐	☐	☐	
Are electronic data secured (password protected, encrypted, etc.) as approved by the IRB?	☐	☐	☐	
Are your computing devices secured according to University standards?	☐	☐	☐	
Are you aware of the security and sharing policies for any software or servers utilized for data storage?	☐	☐	☐	
Is access to computer, electronic files, and physical files limited to appropriate project personnel?	☐	☐	☐	
Are identifiers stored/disposed of as approved by the IRB?	☐	☐	☐	
Are the research data (raw) stored as approved by the IRB?	☐	☐	☐	
Has data been shared only per the approved protocol and data sharing agreements?	☐	☐	☐	
6. Full Board Protocols Only: Continuing Review				
Are you aware of when the IRB approval for this project expires?	☐	☐	☐	Exp. Date:
Has IRB approval for this project ever expired?	☐	☐	☐	
If **Yes,** did you report any research activity that took place while IRB approval was expired?	☐	☐	☐	
Have there been any adverse events, unanticipated problems, or complaints while conducting this research?	☐	☐	☐	
If **Yes,** have all details been reported to the IRB as required?	☐	☐	☐	
Have you become aware of new information that changes the risk-benefit ratio of this project?	☐	☐	☐	
Has the number enrolled on the continuing reviews included individuals who consented but did not complete the project?	☐	☐	☐	
7. Project Completion				
Is data analysis complete for this project?	☐	☐	☐	
Have all identifiers been destroyed in accordance with IRB approved procedures?	☐	☐	☐	
If yes to both questions above, submit a Closure notice to the IRB. Note: research records should be retained for at least 5 years. For further information, see https://research.virginia.edu/irb-sbs/retention-research-records-and-destruction-data-0	☐	☐	☐	
8. Quality Improvement				
Have you any questions or concerns about your protocol?	☐	☐		
If yes, please describe:				
Overall, are you satisfied with the IRB review process?	☐	☐		
Overall, are you satisfied with IRB-SBS customer service?	☐	☐		
Have you any suggestions, recommendations or observations with regard to the protocol review process?	☐	☐		

If yes, please describe:	
Are there IRB-related topics for which you would like information or guidance?	

Certification			
I certify that all information provided in this document is accurate and that the IRB has been informed of any necessary issues.			
Principal Investigator Signature	Date	Faculty Advisor Signature	Date