PROTOCOL TITLE:		**PROTOCOL IRB #:**	
Principal Investigator:		**Date of Review:**	

Institutional Review Board
Schwitalla Hall, Suite M238
1402 S Grand Blvd
St. Louis, MO 63104
Phone 314-977-7744
irb@slu.edu

Investigator Self-Assessment Checklist

INTRODUCTION

The IRB Quality Assurance Review (QAR) Program aims to promote high ethical and quality standards in the conduct of human subjects' research. To support that aim, the QAR Program has issued this "Investigator Self-Assessment Checklist" to empower investigators to assess whether their research is being conducted in accordance with regulations and best practices.

Elements on this checklist derive from federal regulations (DHHS, NIH, and FDA), SLU IRB policies, and ICH Good Clinical Practice, the latter of which is most relevant to interventional studies and clinical trials. Thoroughly complete the tool's header information. Even if you complete the checklist manually, we recommend that you fill out the heading/header information electronically so that it will be carried across all document pages.

Mark the appropriate box for each criterion listed. Any issues noted should be summarized within the "Comments" section.

When doing the assessment, if a red box is checked, the issue needs to be reported to the IRB Office as soon as possible via a Report Form as a "Protocol Violation" (see SLU IRB Reporting Guidelines). While this may seem intimidating, the IRB realizes that errors in the conduct of research occur and does not aim to be punitive when such items are reported. It is always better to self-report than have a finding emerge during an audit. The IRB does not otherwise need to be informed about the results of your assessment.

For non-exempt studies, it is Good Clinical Practice to complete this tool prior to the start of the study. It provides guidance for a complete research Regulatory Binder. File the completed tool in the study files with other Quality Assurance materials.

If there are any questions about the checklist, if you need assistance customizing or implementing it, or if you are interested in requesting a QAR team visit to assess your research operation, please contact the IRB Office at 314-977-7744 or irb@slu.edu.

PROTOCOL TITLE:		PROTOCOL IRB #:	
Principal Investigator:		Date of Review:	

SECTION 1: GENERAL INFORMATION

Principal Investigator			
Department			
Co-Investigator(s)	*Please provide a copy of the most recently IRB-approved study team (e.g., eIRB Personnel Information or Submission Authorization Form).*		
Study Coordinator(s)			
Study Category (Select All That Apply)	☐ Drug ☐ Device ☐ Observational ☐ Other:	**Funding**	☐ Not Funded ☐ Sponsor ( ) ☐ FDA Regulated ☐ NIH Funded ☐ Other:
Study Title			
IRB of Record	☐ SLU ☐ Advarra ☐ WCG ☐ NCI-CIRB ☐ Other:		
Date of Initial IRB Approval			
Total # Enrollment	# Approved:	# Enrolled to Date:	
Study Status (Check one)	☐ Open for enrollment or active data collection ☐ Study is closed for enrollment, but participants are in active follow up ☐ Study is closed to participants and participation is complete ☐ Other, please explain:		
Individual Completing Review of Self-Assessment Form		**Date of Review:**	

PROTOCOL TITLE:		PROTOCOL IRB #:	
Principal Investigator:		Date of Review:	

SECTION 2: REGULATORY DOCUMENTATION

Document	Criteria	YES ✓	NO ✓	N/A ✓	Comments
Study Identification	Identification of the site, including name of PI, study location(s), Protocol Number, and Study Title, etc. is present and correct on the study file.	☐	☐	☐	
Protocol	A current and IRB-approved copy of the Protocol is on file.	☐	☐	☐	
	All previous versions of the Protocol are on file.	☐	☐	☐	
	Signed versions of the protocol signature page are available for each version of the Protocol.	☐	☐	☐	
	Any lapses have been documented properly.	☐	☐	☐	
Consent Document(s)	A current and IRB-approved copy of the Consent Document is on file.	☐	☐	☐	
	All previous versions of the Consent Document are on file.	☐	☐	☐	
	Any lapses have been documented properly.	☐	☐	☐	
Local Regulatory Approvals	All local, state, and/or special authorizations related to the protocol are maintained and up to date.	☐	☐	☐	

PROTOCOL TITLE:		PROTOCOL IRB #:	
Principal Investigator:		Date of Review:	

Document	Criteria	YES ✓	NO ✓	N/A ✓	Comments
Federal Wide Assurances (FWA)	Current Federal Wide Assurance and IRB Registration documents for governing regulatory bodies (e.g., IRB), issued from OHRP, are present and include expiration dates. *SLU's Federal Wide Assurance Documentation can be located here.*	☐	☐	☐	
IRB Membership	The IRB Roster or Membership composition is on file and has been updated annually. If the IRB does not provide a roster, official IRB documentation is present stating that names are not released. *SLU's IRB Membership Documentation can be located here.*	☐	☐	☐	
IRB Approvals	The initial IRB Approval for the Protocol and the Consent Document(s) is present.	☐	☐	☐	
	Continuing Review Approval(s) are present (annually).	☐	☐	☐	
	IRB Approvals for information given to study subjects are on file (advertisements, recruitment scripts, subject information materials).	☐	☐	☐	
	Periodic reports are present (if applicable).	☐	☐	☐	
	Approvals for any protocol/consent/assent amendments are present.	☐	☐	☐	

PROTOCOL TITLE:		PROTOCOL IRB #:	
Principal Investigator:		Date of Review:	

Document	Criteria	YES ✓	NO ✓	N/A ✓	Comments
Curricula Vitae (CVs)	Current CVs are present for the Principal Investigator, sub-investigators, and all relevant research staff. *Basic requirements of the CV include current work address, professional title, degrees, current relevant licensure, and clarification of site affiliation.* ***CVs should be updated every 2 years.***	☐	☐	☐	
Licenses	Appropriate licenses (medical, nursing, pharmacy) are present and current for Principal Investigator, all sub-investigators, and medical research staff.	☐	☐	☐	
Investigator Brochures/ Package Inserts	Investigator brochures are present, current, and available for investigational products. Documentation of IRB submission is present (if applicable).	☐	☐	☐	
	Package inserts are present, current, and available for approved drugs. Documentation of IRB submission is present (if applicable).	☐	☐	☐	
FDA 1572	All copies/versions of the FDA 1572 form are present and complete.	☐	☐	☐	
	The agreement is current, accurate, and signed by the PI.	☐	☐	☐	
Financial Disclosure Forms (IND/IDE)	Financial disclosure forms for all key personnel listed on the FDA 1572 are present (if applicable).	☐	☐	☐	

PROTOCOL TITLE:		PROTOCOL IRB #:	
Principal Investigator:		Date of Review:	

Document	Criteria	YES ✓	NO ✓	N/A ✓	Comments
Sponsor Correspondence	Documentation of correspondence between the site and sponsor is present and current (If applicable).	☐	☐	☐	
	Copies of all sponsor issued "Dear Doctor", or Dear Health Care Provider Letters (DHCP) letters are present and have been submitted to the IRB. (if applicable)	☐	☐	☐	
Internal Correspondence	Documentation of internal correspondence is present and current.	☐	☐	☐	
Telephone Contact Reports	Subject Telephone Contact Reports are present and current. (If applicable)	☐	☐	☐	
Final Reports	The Final Report to the IRB is present (if applicable).	☐	☐	☐	
	The Final Report to the sponsor is present (if applicable).	☐	☐	☐	
Notes to File	Relevant study-specific notes to file/numbered memos are present.	☐	☐	☐	
Delegation of Responsibilities Log	The Delegation of Responsibilities Log is present and current for all individuals authorized to make entries in study records or participate in protocol execution. *Any site staff making medical decisions, performing study-related procedures, collecting data, or determining regulatory compliance would be appropriate to include in the delegation form* ○ *PI has signed/dated the form in the appropriate places with start/end dates*	☐	☐	☐	

PROTOCOL TITLE:		PROTOCOL IRB #:	
Principal Investigator:		Date of Review:	

Document	Criteria	YES ✓	NO ✓	N/A ✓	Comments
Training: Clinical Research and Study-Specific	Documentation of Human Subjects Protection Training (CITI) for all relevant personnel is present and complete.	☐	☐	☐	
	Documentation of all study-specific training for all relevant personnel is present and complete (including GCP, EDC, IATA, etc., if applicable).	☐	☐	☐	
Subject Code List	The Subject Code List is present. This is a list that links patient names to subject IDs, if applicable. *(It often exists in a secured location separate from the remainder of the study file.)*	☐	☐	☐	
Site Screening and Enrollment Log	The Site Screening and Enrollment Log is present and up to date.	☐	☐	☐	
Investigational Product **(This section is only applicable if IP is open label, otherwise if study has Unblinded Personnel please file this section in Unblinded Pharmacy Binder)**	Investigational Product Accountability Records are present, accurate, and current. Records reconcile with current IP inventory. (Records must be able to link batch numbers to subjects.)	☐	☐	☐	
	Instructions (protocol-specific MOP) for the storage, mixing, and handling of Investigational Product are present, or their location is specified and easily accessible.	☐	☐	☐	
	Shipping records for Investigational Product documenting the receipt date, quantity, and lot numbers of all test articles are present and current.	☐	☐	☐	

PROTOCOL TITLE:		PROTOCOL IRB #:	
Principal Investigator:		Date of Review:	

Document	Criteria	YES ✓	NO ✓	N/A ✓	Comments
	Randomization list and decoding procedures for Blinded Investigational Product are present.	☐	☐	☐	
	Investigational Product Temperature Logs are present, or their location is specified in a note to file and easily accessible.	☐	☐	☐	
Laboratory Normal and Accreditations	Laboratory certifications and accreditations are present for U.S. labs (e.g., CAP and CLIA Accreditation, JCAHO, CLIA Compliance, CLIA exempt, etc.).	☐	☐	☐	
	If not a U.S. lab, appropriate certificates of qualification for the lab are present. If not present, a statement is present explaining the reason and a description of the standard being used.	☐	☐	☐	
	Approvals from collaborating research laboratories are present.	☐	☐	☐	
	Current and historical Normal Ranges for all protocol-required tests are documented. This must include all clinical laboratory tests required by the protocol, the unit of measure, the laboratory name, and the date of the document. Documentation via individual lab reports is acceptable.	☐	☐	☐	

PROTOCOL TITLE:		PROTOCOL IRB #:	
Principal Investigator:		Date of Review:	

Document	Criteria	YES ✓	NO ✓	N/A ✓	Comments
Specimen Tracking Logs	Specimen Tracking Logs or Retention Records are present, or their location is specified in a note to file and easily accessible.	☐	☐	☐	
Monitoring Visit Logs and Associated Visit Documents	Monitoring Visit Logs and associated visit documentation are present (site initiation, interim monitoring, close-out). *For more information, please see SLU's Post Approval Submission Requirements for Local IRB Review and SLU's Post Approval Submission Requirements for External/Central IRBs.*	☐	☐	☐	
	Monitoring Reports have been submitted to the IRB per guidelines (If applicable).	☐	☐	☐	
Study-specific Procedures / Manual of Procedures	Current and historical study-specific procedures or the Manual of Procedures (MOP) are present and clearly identifiable as current or historical.	☐	☐	☐	
Sample Case Report Forms (CRF)/eCRF(s)	If data are captured on paper CRFs, a blank copy of each approved version is present and easily identifiable as current or historical.	☐	☐	☐	

SECTION 3: RESEARCH TEAM

	Criteria	YES ✓	NO ✓	N/A ✓	Comments
3.1	All personnel working on the research project are IRB approved.	☐	☐	☐	

PROTOCOL TITLE:		PROTOCOL IRB #:	
Principal Investigator:		Date of Review:	

3.2	Delegation Log is up to date, signed, and qualified research staff are trained to perform study tasks.	☐	☐	☐	
3.3	Staff is doing **only** the tasks that have been delegated to them according to the **Approved** IRB protocol.	☐	☐	☐	

SECTION 4: IRB PROTOCOL ADHERENCE, AMENDMENTS, CONTINUING REVIEW

	IRB PROTCOL ADHERENCE	YES ✓	NO ✓	N/A ✓	Comments
4.1	Study procedures were conducted according to the **approved current** protocol.	☐	☐	☐	
4.2	Did any research activities occur prior to IRB approval?	☐	☐	☐	
4.3	Were there any lapses in IRB approval (failure to submit continuing reviews prior to expiration dates)?	☐	☐	☐	
4.4	Were any study related activities conducted during the lapse period without IRB permission to do so?	☐	☐	☐	
4.5	Were any subjects enrolled during this lapsed period?	☐	☐	☐	
	CONTINUING REVIEW				
4.6	Number of Continuing Reviews:				
	AMENDMENTS				
4.7	Number of Amendments:				

PROTOCOL TITLE:		PROTOCOL IRB #:	
Principal Investigator:		Date of Review:	

4.8a	Have there been any changes in procedures (amendments) to the approved protocol? *If yes, proceed to 4.8b.*	☐	☐	☐	
4.8b	Have all amendments been submitted to and approved by the IRB prior to implementation? *For more information, please see SLU's Post Approval Submission Requirements for Local IRB Review and SLU's Post Approval Submission Requirements for External/Central IRBs.*	☐	☐	☐	

SECTION 5: SUBJECT ELIGIBILITY/RECRUITMENT PROCEDURES

	Subject Selection	YES ✓	NO ✓	N/A ✓	Comments
5.1	Source documentation to verify inclusion/exclusion criteria prior to study enrollment is filed, signed, and dated by research staff verifying eligibility and confirmed via PI or qualified personnel with signature/date.	☐	☐	☐	
5.2	Were any participants enrolled that did not meet **all** inclusion/exclusion criteria?	☐	☐	☐	
	RECRUITMENT PROCEDURES				
5.3	All recruitment methods (ads, phone scripts, email scripts, or anything that is seen by the subject for recruitment purposes) being used are described in the **approved** IRB application.	☐	☐	☐	

PROTOCOL TITLE:		PROTOCOL IRB #:	
Principal Investigator:		Date of Review:	

SECTION 6: INFROMED CONSENT, ASSENT, and HIPAA AUTHORIZATION FORMS

	Criteria	YES ✓	NO ✓	N/A ✓	Comments
6.1	Current, approved, and valid (stamped/watermarked) IRB-approved consent forms have been used throughout the study. *For more information, please see SLU's Consent Process: Do's and Don'ts and SLU's Common Consent Process Errors and Corrective Actions.*	☐	☐	☐	
6.2	Consent form was signed by the participant prior to the initiation of any study procedures, including screen-failures and any participant who has been withdrawn.	☐	☐	☐	
6.3	Original copies (not photocopied) of all consent forms signed and dated by participants are kept in the research file that includes measures to maintain confidentiality.	☐	☐	☐	
6.4	The research team member who obtained consent is approved to do so according to the approved IRB Application and the Delegation Log.	☐	☐	☐	
6.5	In the event someone other than an MD/DO signed the consent form for a biomedical study, is there documentation that an MD/DO was present during the consent discussion to answer any questions?	☐	☐	☐	
6.6	Source documentation of the participant/participant's legal authorized representative receipt of a copy of the consent form is on file.	☐	☐	☐	
6.7	Consenting PI/research team member entered the same date as the participant on the consent form.	☐	☐	☐	
6.8	All the pages of the consent form are on file for each subject.	☐	☐	☐	

6.9	All participants who have reached the age of majority while still active in the research study have signed a new consent form (or have been withdrawn from the study) at the earliest opportunity.	☐	☐	☐	
6.10	All yes/no boxes or additional signature lines in the consent form are completed appropriately for all subjects.	☐	☐	☐	
6.11	Current, approved, and valid (stamped/watermarked) IRB-approved assent forms have been used throughout the study.	☐	☐	☐	
6.12	Source documentation of the participant/participant's legal authorized representative receipt of a copy of the assent form is on file.	☐	☐	☐	
6.13	All the pages of the assent form are on file for each subject.	☐	☐	☐	
6.14	Current, approved, and valid (stamped/watermarked) IRB-approved HIPAA Authorization forms have been used throughout the study.	☐	☐	☐	
6.15	HIPAA Authorization form was signed by the participant prior to the initiation of any study procedures, including screen-failures and any participant who has been withdrawn.	☐	☐	☐	
6.16	Original copies (not photocopied) of all HIPAA Authorization forms signed and dated by participants are kept in the research file that includes measures to maintain confidentiality.	☐	☐	☐	
6.17	The research team member who obtained HIPAA Authorization is approved to do so according to the approved IRB Application and the Delegation Log.	☐	☐	☐	

6.18	Source documentation of the participant/participant's legal authorized representative receipt of a copy of the HIPAA Authorization form and Notice of Privacy Practices is on file.	☐	☐	☐	
6.19	Consenting PI/research team member entered the same date as the participant on the HIPAA Authorization form.	☐	☐	☐	
6.20	All the pages of the HIPAA Authorization form are on file for each subject.	☐	☐	☐	
6.21	Internal auditing of consent process documentation accuracy has been completed on an on-going basis.	☐	☐	☐	

SECTION 7: SAFETY MONITORING/ADVERSE EVENT REPORTING

When completing this portion of the assessment, please refer to the SLU definitions for reportable events in the SLU IRB Reporting Guidelines

	Adverse Events/SAEs	YES ✓	NO ✓	N/A ✓	Comments
7.1	All Adverse Events have been documented and classified by approved study personnel.	☐	☐	☐	
7.2	AE's classified as related Serious Adverse Event (SAE) were identified and reported according to protocol and IRB requirements. *For more information, please see SLU's Guidelines for Reporting Events Relating to Subjects/Subject Safety, SLU's Post Approval Submission Requirements for Local IRB Review, and SLU's Post Approval Submission Requirements for External/Central IRBs.*	☐	☐	☐	
7.3	Copies of all sponsor study issued "Dear Doctor" or Dear Health Care Provider Letters (DHCP) letters are present.	☐	☐	☐	
7.4	Sponsors and/or Federal agencies (such as the FDA if the investigator is the IND or IDE holder) were notified of AEs according to their requirements (if applicable).	☐	☐	☐	

7.5	AE's were reported/provided to monitors/data safety boards as required by the protocol.	☐	☐	☐	
7.6	Any potentially study-related SAEs were identified and reported according to protocol and IRB requirements. *For more information, please see please see SLU's Guidelines for Reporting Events Relating to Subjects/Subject Safety and SLU's Serious Adverse Event Decision Tree.*	☐	☐	☐	
7.7	Any SAE was assessed as potential unanticipated problem (UP). *For more information, please see please see SLU's Guidelines for Reporting Events Relating to Subjects/Subject Safety, SLU's Serious Adverse Event Decision Tree, and SLU's Unanticipated Problem (UP) Decision Tree.*	☐	☐	☐	
7.8	Any UPs were identified and reported according to protocol and IRB requirements. *For more information, please see SLU's Unanticipated Problem (UP) Decision Tree.*	☐	☐	☐	
7.9	Any reportable Protocol Violations were identified and reported according to protocol and IRB requirements. *For more information, please see SLU's Guidelines for Reporting Events Relating to Subjects/Subject Safety, SLU's Post Approval Submission Requirements for Local IRB Review, and SLU's Post Approval Submission Requirements for External/Central IRBs.*	☐	☐	☐	

PROTOCOL TITLE:		PROTOCOL IRB #:	
Principal Investigator:		Date of Review:	

SECTION 8: PRIVACY, DATA STORAGE & CONFIDENTIALITY

	Criteria	YES ✓	NO ✓	N/A ✓	Comments
8.1	If you proposed to collect the data anonymously, has anonymity been maintained in the physical and electronic records? (Are identifiers tied to subject data?)	☐	☐	☐	
8.2	Hard copies (consent forms and source docs) are stored in a secure, locked location.	☐	☐	☐	
8.3	Access to computer, electronic files, and physical files is limited to only appropriate study personnel.	☐	☐	☐	
8.4	Electronic data files are password protected or encrypted.	☐	☐	☐	
8.5	Research data stored/disposed of as approved by the IRB in the IRB application.	☐	☐	☐	

SECTION 9: DATA SAFETY & MONITORING

	Criteria	YES ✓	NO ✓	N/A ✓	Comments
9.1	The Data Safety Monitoring Plan (DSMP) is implemented as described in the **approved** protocol.	☐	☐	☐	
9.2	Is there a Data Safety Monitoring Board for this study? *If yes, proceed to 9.3a and 9.3b.*	☐	☐	☐	
9.3a	The DSMB operated in accordance with the IRB **approved** DSMB charter.	☐	☐	☐	
9.3b	All DSMB reports or indication of DSMB review and recommendations are on file and have been submitted to the IRB within reporting requirements. *For more information, please see SLU's Guidelines for Data Safety Monitoring on Human Subjects Research.*	☐	☐	☐	

PROTOCOL TITLE:		**PROTOCOL IRB #:**	
Principal Investigator:		**Date of Review:**	

SECTION 10: MISCELLANEOUS

Insert any additional findings.

SECTION 11: PRINCIPAL INVESTIGATOR (PI) ASSURANCE

By signing below, I certify:

1) that the information submitted within this assessment is true, complete, and accurate to the best of my knowledge;
2) that any false, fictitious, or fraudulent statements or claims may subject me to further investigation and could result in potential serious or continuing noncompliance;
3) that the I agree to accept responsibility for the scientific conduct and the ethical performance of the study and that any identified reportable events will be reported to the IRB Office in accordance with SLU's Reporting Guidelines.

Principal Investigator (PI) Signature **Date**

Principal Investigator (PI) Printed Name