I. SCOPE

The purpose of a Quality Review Plan is to enhance the reliability and validity of clinical research data and ensure that IRB approved protocols are conducted in compliance with state, federal and local laws. Quality Review reviews provide educational support and guidance for the development of best practices related to clinical research conduct.

The Quality Review checklist may be used to review externally and internally funded studies involving human subject research.

II. PROCEDURES

A. Criteria for Quality Review

1. The Quality Review process may be initiated based on the following criteria or time points:
   a. An investigator's first clinical research study
   b. A CRC or Research Nurse's first clinical research study
   c. Greater than minimal risk, as deemed by the IRB
   d. Involving a Loyola sponsored Investigational New Drug (IND) or Investigational Device Exemption IDE
   e. In preparation for an internal or external audit
   f. Repeated evidence of non-compliance
   g. After first study participant
   h. Prior to a continuing review
   i. At study closure
   j. At the discretion of the Regulatory Manager, the Senior Director of the Clinical Research Office (CRO), the Division Administrator or the Principal Investigator.

B. Procedure

1. Department personnel and/or CRO staff (upon request by the department) will complete the Quality Review
2. The recommended number of participant records to review to adequately assess trends is the square root plus one of the total number of participants enrolled
3. The assigned department or CRO staff will follow the steps below to complete the Quality Review:
   a. Complete the checklist by verifying the necessary documents in the regulatory binder, medical record, or participant binder as appropriate
   b. Complete the checklist in its entirety; marking N/A for any areas that are not applicable
   c. Submit the completed checklist to the Regulatory Manager, the Senior Director of the Clinical Research Office (CRO), the Division Administrator or the Principal Investigator

C. Procedure Review

1. Any follow up measures will be determined by the Regulatory Manager, the Senior Director of the Clinical Research Office (CRO), the Division Administrator or the Principal Investigator as applicable.
2. A Corrective and Preventive Action (CAPA), also called corrective action / preventive action, or simply corrective action) should be developed including follow up surveillance and reporting.

III. REFERENCES

A. www.fda.gov
B. www.hhs.gov
C. 21 CFR 50 – Protection of Human Subjects
D. 21 CFR 54 – Financial Disclosure by Clinical Investigators
E. 21 CFR 312.32 – IND Safety Reporting
F. 21 CFR 812 – Investigation Device Exemptions

IV. ASSOCIATED DOCUMENTS AND FORMS

A. Quality Review Checklist

V. APPROVALS

Senior Director, LUC Clinical Research Office (or designee) Date 12/14/18

Director, LUMC Research Operation Office (or designee) Date 12/17/18

Revision History

Effective Date	Summary of Changes
01/OCT/2016	Initial
01/DEC/2018	Addition of electronic copies as alternative to hard copies and addition of time points for review.

LOYOLA UNIVERSITY HEALTH SYSTEM

LOYOLA UNIVERSITY CHICAGO

Quality Review Checklist
QA-001 Attachment 01/JAN/2019

IRB Protocol #:	
Abbreviated Study Title:	
Number of participants enrolled:	
Date QA initiated:	
Date QA completed:	
Name of individual completing checklist:	

SECTION 1

Study Protocol

☐ Yes	☐ No	☐ N/A	No study procedures began prior to IRB approval.
☐ Yes	☐ No	☐ N/A	The current signed protocol is on file in the regulatory binder.
☐ Yes	☐ No	☐ N/A	Past versions of the protocol signature pages are on file in the regulatory binder (full past protocol versions can be stored by electronic copy or hard copy filed in the regulatory binder).
☐ Yes	☐ No	☐ N/A	Amendments to the protocol were submitted to the IRB and approval was received prior to implementation of any changes.
☐ Yes	☐ No	☐ N/A	In the case of premature un-blinding, the appropriate documentation was provided to the IRB, sponsor, and DSMB if Loyola sponsored IND/IDE.
☐ Yes	☐ No	☐ N/A	In the case that either the study participant decides to withdraw or is asked to withdraw by the PI, there is documentation in the regulatory binder and it was reported to the IRB and sponsor.
☐ Yes	☐ No	☐ N/A	Noncompliance with study protocols and procedures, and rules and regulations concerning research were reported to the IRB.
☐ Yes	☐ No	☐ N/A	SAEs and significant protocol deviations that meet reporting criteria were reported to the IRB and FDA within 10 business day of the site becoming aware, and the sponsor was notified as well.
☐ Yes	☐ No	☐ N/A	Documentation of the IRBs response and/or recommendation for either significant protocol deviations or SAEs are on file in regulatory binder.
☐ Yes	☐ No	☐ N/A	Follow up for SAEs (that meet reporting criteria) and significant protocol deviations are documented on file in the regulatory binder.
☐ Yes	☐ No	☐ N/A	Follow up for SAEs and significant protocol deviations was reported to the IRB, FDA and sponsor, as appropriate.
☐ Yes	☐ No	☐ N/A	Non-significant deviations were reported to the IRB, if required by sponsor.
☐ Yes	☐ No	☐ N/A	Documentation that external adverse safety reports were submitted to the IRB, if applicable.
☐ Yes	☐ No	☐ N/A	In the case of emergency use of an investigational drug or device, the IRB was notified within 5 working days.
☐ Yes	☐ No	☐ N/A	In the case that the study was suspended, the suspension was reported to the IRB.

Study Documents/Records

Informed Consent:

☐ Yes	☐ No	☐ N/A	All versions of the informed consent document were approved by the IRB.
☐ Yes	☐ No	☐ N/A	Current and all previous versions of the IRB approved informed consent are in the regulatory binder.
☐ Yes	☐ No	☐ N/A	Inconsistencies in the informed consent process were submitted to the IRB and documentation is on file in the regulatory binder.

Investigator/Staff Records:

☐ Yes	☐ No	☐ N/A	Form 1572 was completed and submitted to the FDA/sponsor prior to the start of the study.
☐ Yes	☐ No	☐ N/A	Original copy of Form 1572 remains on file in the regulatory binder.
☐ Yes	☐ No	☐ N/A	Any changes in principal investigator/sub investigator/study staff were submitted and approved by IRB and sponsor, and documentation is on file in the regulatory binder.
Please indicate for the persons listed on Form FDA 1572, whether the following forms are on file:			
☐ Yes	☐ No	☐ N/A	Completed Financial Disclosure Form is on file in the regulatory binder.
☐ Yes	☐ No	☐ N/A	The most recent signed and dated CV is filed in the study-specific or central regulatory binder.
☐ Yes	☐ No	☐ N/A	A copy of the most recent medical license issued in Illinois is filed in the study-specific or central regulatory binder.
☐ Yes	☐ No	☐ N/A	A copy of CITI training and any other specialty training is on file in the regulatory binder.

Lab Records:

☐ Yes	☐ No	☐ N/A	Normal lab values are filed in the study-specific or central regulatory binder for the duration of the study.
☐ Yes	☐ No	☐ N/A	Current license of the lab director is filed in the study-specific or central regulatory binder.
☐ Yes	☐ No	☐ N/A	Current CV of lab director is filed in the study-specific or central regulatory binder.
Please indicate whether the following lab certifications are on file:			
☐ Yes	☐ No	☐ N/A	CLIA certification for all involved laboratories is filed in the study-specific or central regulatory binder.
☐ Yes	☐ No	☐ N/A	CAP certification for all involved laboratories is filed in the study-specific or central regulatory binder

General Records:

☐ Yes	☐ No	☐ N/A	Investigative Brochure is signed and dated by the PI.
☐ Yes	☐ No	☐ N/A	The original copy of the Investigative Brochure signature page remains on file in the regulatory binder, along with a note to file stating that the full Investigative Brochure is stored electronically.
☐ Yes	☐ No	☐ N/A	Accurate delegation log is on file in the regulatory binder.
☐ Yes	☐ No	☐ N/A	Advertisements used for recruitment were approved by the IRB and documentation is on file in the regulatory binder.
☐ Yes	☐ No	☐ N/A	Each continuing review was submitted and approved by the IRB; documentation is on file in the regulatory binder.
☐ Yes	☐ No	☐ N/A	Documentation of correspondence relative to the conduct of the protocol and/or important decisions regarding study conduct (such as notes to file) is on file in the regulatory binder.
☐ Yes	☐ No	☐ N/A	Closure to enrollment was submitted to the IRB as applicable, and is on file in the regulatory binder.
☐ Yes	☐ No	☐ N/A	Permanent Closure report was submitted to the IRB after all study activity is completed and is on file in the regulatory binder.
☐ Yes	☐ No	☐ N/A	DSMB reports, if applicable, are on file in the regulatory binder.
☐ Yes	☐ No	☐ N/A	DSMB reports were received from sponsor, submitted to the IRB and correspondence of the IRB's receipt of the DSMB report is on file in the regulatory binder.

Document Retention (at study closure)

☐ Yes	☐ No	☐ N/A	Investigator retains records for 2 years following the date the marketing application is approved, 2 years after investigation is permanently closed, or as directed by the study sponsor.
☐ Yes	☐ No	☐ N/A	For IND studies, investigator retains records for 2 years following the date the marketing application is approved, 2 years after the investigation is permanently closed, or as directed by the study sponsor.
☐ Yes	☐ No	☐ N/A	For IDE studies, investigator retains records for 2 years following the date of permanent closure, the date that the records are no longer required for a premarket approval application, completion of a product development protocol, or as directed by the study sponsor.

IDE – Investigational Device Exemption

☐ N/A	If study does not fall under the purview of needing an IDE application, please check N/A and proceed to the next section.

☐ Yes	☐ No	☐ N/A	The IDE application, all supporting documents, FDA reports, and annual reports are filed in the IDE binder.

IND – Investigational New Drug

☐ N/A	If study does not fall under the purview of needing an IND application, please check N/A and proceed to the next section.

☐ Yes	☐ No	☐ N/A	The IND application, all supporting documents, FDA reports, and annual reports are filed in the IND binder.

IRB Protocol #:	
Abbreviated Study Title:	
Number of participants enrolled:	
Date QA initiated:	
Date QA completed:	
Name of individual completing checklist:	

Section 2

Please refer to the participant binders or online medical record to complete this section.

Number of participants enrolled:	
Number of participant charts to be reviewed: (= the square root +1 of participants enrolled)	
Participant ID number	

Data Collection of Subjects

☐ Yes	☐ No	☐ N/A	Participants met initial inclusion/exclusion criteria.
☐ Yes	☐ No	☐ N/A	There is a completed eligibility checklist.
☐ Yes	☐ No	☐ N/A	Participant eligibility was verified after screening and before any study procedures were initiated.
☐ Yes	☐ No	☐ N/A	The eligibility checklist includes signature/initials and date of the person obtaining the information.
☐ Yes	☐ No	☐ N/A	For persons who did not meet eligibility, identifiable information was destroyed or authorization was obtained to keep subject information.
☐ Yes	☐ No	☐ N/A	Data collection is complete and accurate for each subject, including appropriate signatures/initials and the date.
☐ Yes	☐ No	☐ N/A	Source documentation is available to support data entry.
☐ Yes	☐ No	☐ N/A	The case report forms contain dated signatures or initials.
☐ Yes	☐ No	☐ N/A	In the case that any changes or cross-outs were made, the original data is still legible and contains a signature/initials and date of changes made.
☐ Yes	☐ No	☐ N/A	In the case that there is missing data, any additional added information is noted by signature/initial and the date.

Informed Consent of Subjects

☐ Yes	☐ No	☐ N/A	Informed consent was obtained prior to any study procedures.
☐ Yes	☐ No	☐ N/A	The consent forms on file are the original signed and dated version.
☐ Yes	☐ No	☐ N/A	Study participants received and signed the most current IRB approved informed consent document.
☐ Yes	☐ No	☐ N/A	The subject received a copy of the signed and dated consent form.
☐ Yes	☐ No	☐ N/A	Documentation that participants had opportunity to ask questions, withdraw, decline participation, and sufficient time to make a decision; (proof of documentation could be the note in EPIC).
☐ Yes	☐ No	☐ N/A	All yes/no or similar options on the consent form are completed/initialed.
☐ Yes	☐ No	☐ N/A	Consent forms are free of any handwritten changes/corrections.
☐ Yes	☐ No	☐ N/A	In the case that the IRB required subjects to be re-consented, subjects were accurately re-consented with the most up-to-date consent document or consent addendum.
☐ Yes	☐ No	☐ N/A	For persons who cannot read, a witness signed the informed consent document and the documentation is on file in participant binder.
☐ Yes	☐ No	☐ N/A	If applicable, minors who gave assent also signed and dated written informed consent/assent document and documentation is on file in participant binder.
Check the following boxes to indicate whether the following signature requirements for informed consent were met:			
☐ Yes	☐ No	☐ N/A	Research participant signature.
☐ Yes	☐ No	☐ N/A	Signature of individual conducting the informed consent discussion.
☐ Yes	☐ No	☐ N/A	Witness signature.
☐ Yes	☐ No	☐ N/A	Signature of parent/legal guardian/LARs.