



Quality Management Program QA-001

Effective date: 01/JAN/2019

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
 - 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

- 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
 - 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.





Quality Management Program QA-001

Effective date: 01/JAN/2019

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)

12/12/18

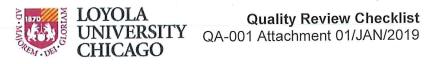
Director, LUMC Research Operation Office (or designee)

Date

Revision History

itevision mistory	
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.





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
	A		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
.0			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.



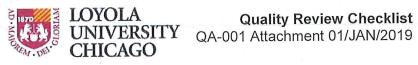


Quality Review Checklist QA-001 Attachment 01/JAN/2019

Study Documents/Records

IIIIOI	med Cor	Sell	ι.				
	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.	
	V		No		N/A	Inconsistencies in the informed consent process were	
	Yes		INO		IN/A	submitted to the IRB and documentation is on file in the	
						regulatory binder.	
Inve	stigator/S	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	
⊔	165		NO	"	IN//A	staff were submitted and approved by IRB and sponsor, and	
						documentation is on file in the regulatory binder.	
		L			11 1 1	Gocumentation is on the in the regulatory binder.	
						n 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.	
2	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	
-	100	_		_		central regulatory binder.	
DI	ace indi	rate	whathar t	he fo	llowing l	ab certifications are on file:	
	Yes	Jale	No		N/A	CLIA certification for all involved laboratories is filed in the	
	165		NO		IN//	study-specific or central regulatory binder.	
-	V		No		N/A	CAP certification for all involved laboratories is filed in the	
	Yes		NO .		IN/A	2010 M 12 C.S.	
						study-specific or central regulatory binder	





Gene	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
				77		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.



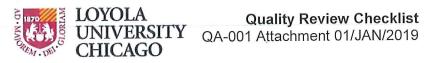


LOYOLA Quality Review Checklist UNIVERSITY QA-001 Attachment 01/JAN/2019 CHICAGO

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 sect	tion.			
П	Yes	□ No	□ N/A	The IDE application, all supporting documents, FDA			
				reports, and annual reports are filed in the IDE binder.			
IND	– Investig	ational New D	rug				
		9					
	N/A	If study does	not fall under tl	he purview of needing an IND application, please check N/A			
_		and proceed to the next section.					
П	Yes	□ No	□ N/A	The IND application, all supporting documents, FDA reports,			





IRE	Protocol #	<u>:</u>				w	
Abl	oreviated S	tudy	Title:		,		
Nu	mber of par	ticip	ants enrol	led:			
Da	te QA initia	ted:					
Da	te QA comp	olete	d:	1			
Na	me of indivi	dual	completin	ng ch	necklist:		4
	(t				< 4		
	tion 2						I de la constata de la constana
Plea	se refer to	the p	participant	bind	ders or onlir	ne medica	al record to complete this section.
	·				141		
	mber of par						
	mber of pa						
	the square			icipa	ints enrolled	a) .	
Ра	rticipant ID	num	per	2			<u> </u>
Dot	a Collectio	n of	Subjects				
Date	Conectio	11 01	<u>Jubjects</u>				
	Yes		No		N/A	Participa	ants met initial inclusion/exclusion criteria.
	Yes		No		N/A	There is	a completed eligibility checklist.
	Yes		No		N/A	Participa	ant eligibility was verified after screening and
					*	before a	ny study procedures were initiated.
	Yes		No		N/A		ibility checklist includes signature/initials and date
							erson obtaining the information.
	Yes		No		N/A		ons who did not meet eligibility, identifiable
				7			ion was destroyed or authorization was obtained
en 1		8		-			subject information.
	Yes		No		N/A		lection is complete and accurate for each subject,
							g appropriate signatures/initials and the date.
	Yes		No ,		N/A		documentation is available to support data entry.
	Yes		No		N/A	The cas	e report forms contain dated signatures or initials.
	Yes		No		N/A	In the ca	ase that any changes or cross-outs were made,
		27				the origi	nal data is still legible and contains a
20							e/initials and date of changes made.
	Yes		No		N/A	In the ca	ase that there is missing data, any additional
1		1				addad ir	oformation is noted by signature/initial and the

date.





LOYOLA Quality Review Checklist UNIVERSITY QA-001 Attachment 01/JAN/2019 CHICAGO

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 fol consent were		o indicate whet	her the following signature requirements for informed
□ 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.