



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

SECTION 1

Study Protocol

<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	No study procedures began prior to IRB approval.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	The current original signed protocol is on file in the regulatory binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Past versions of the protocol are on file in the regulatory binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Amendments to the protocol were submitted to the IRB and approval was received prior to implementation of any changes.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	In the case of premature un-blinding, the appropriate documentation was provided to the IRB and sponsor.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> 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.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Noncompliance with study protocols and procedures, and rules and regulations concerning research were reported to the IRB.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	SAEs that meet reporting criteria and significant protocol deviations were reported to the IRB and FDA within 10 business day of the site becoming aware, and the sponsor was notified as well.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Documentation of the IRBs response and/or recommendation for either significant protocol deviations or SAEs are on file in regulatory binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Follow up for SAEs (that meet reporting criteria) and significant protocol deviations are documented on file in the regulatory binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Follow up for SAEs and significant protocol deviations was reported to the IRB, FDA and sponsor, as appropriate.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Non-significant deviations were reported to the IRB, if required by sponsor.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Documentation that external adverse safety reports were submitted to the IRB, if applicable.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	In the case of emergency use of an investigational drug or device, the IRB was notified within 5 working days.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	In the case that the study was suspended, the suspension was reported to the IRB.



Study Documents/Records

Informed Consent:

<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	All versions of the informed consent document were approved by the IRB.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Current and all previous versions of the IRB approved informed consent are in the regulatory binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> 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:

<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Form 1572 was completed and submitted to the FDA/sponsor prior to the start of the study.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Original copy of Form 1572 remains on file in the regulatory binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> 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:			
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Completed Financial Disclosure Form is on file in the regulatory binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	An original copy of the most recent signed and dated CV is on file on in the regulatory binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	An original copy of the most recent medical license issued in Illinois is on file in the regulatory binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	An original copy of CITI training and any other specialty training is on file in the regulatory binder.

Lab Records:

<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Normal lab values are in the regulatory binder or a hard copy is on file for the duration of the study.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Current license of the lab director is in the regulatory binder or a hard copy is on file.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Current CV of lab director is in the regulatory binder or a hard copy is on file.
Please indicate whether the following lab certifications are on file:			
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	CLIA certification is in the regulatory binder or a hard copy is on file for all involved laboratories.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	CAP certification is in the regulatory binder or a hard copy is on file for all involved laboratories.



General Records:

<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Investigative Brochure is signed and dated by the PI.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> 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.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	The delegation log is on file in the regulatory binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Advertisements used for recruitment were approved by the IRB and documentation is on file in the regulatory binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Each continuing review was submitted and approved by the IRB; documentation is on file in the regulatory binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> 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.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Closure to enrollment was submitted to the IRB as applicable, and is on file in the regulatory binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Permanent Closure report was submitted to the IRB after all study activity is completed and is on file in the regulatory binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	DSMB reports, if applicable, are on file in the regulatory binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> 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)

<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> 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.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> 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.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> 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

<input type="checkbox"/> 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.
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<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	The IDE application, all supporting documents, FDA reports, and annual reports are filed in the IDE binder.
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IND – Investigational New Drug

<input type="checkbox"/> 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.
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<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	The IND application, all supporting documents, FDA reports, and annual reports are filed in the IND binder.
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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

<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Participants met initial inclusion/exclusion criteria.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	There is a completed eligibility checklist.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Participant eligibility was verified after screening and before any study procedures were initiated.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	The eligibility checklist includes signature/initials and date of the person obtaining the information.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	For persons who did not meet eligibility, identifiable information was destroyed or authorization was obtained to keep subject information.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Data collection is complete and accurate for each subject, including appropriate signatures/initials and the date.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Source documentation is available to support data entry.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	The case report forms contain dated signatures or initials.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> 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.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> 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

<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Informed consent was obtained prior to any study procedures.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	The consent forms on file are the original signed and dated version.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Study participants received and signed the most current IRB approved informed consent document.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	The subject received a copy of the signed and dated consent form.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> 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).
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	All yes/no or similar options on the consent form are completed/initialed.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Consent forms are free of any handwritten changes/corrections.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> 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.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	For persons who cannot read, a witness signed the informed consent document and the documentation is on file in participant binder.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> 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:			
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Research participant signature.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Signature of individual conducting the informed consent discussion.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Witness signature.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A	Signature of parent/legal guardian/LARs.