University Hospitals
Clinical Research Center

Internal QA Checklist- Participant Subject ID: _____

*NOTE: For chart review and/or discarded tissue studies, not all information contained w ithin is applicable. Mark N/A accordingly.		INITIALS / DATE	COMMENTS
INFORMED CONSENT DOCUMENT/ HIPAA AUTHORIZATION			
Ensure all originals of the informed consent and assent document are present and fully executed for participant • Participant signature and date present • Parent or legal guardian signature and date • Person obtaining consent signature and date • No missing content or incomplete fields or unmarked checkboxes • Contact person information included • No pre-populated fields or written notes • No redacted information	Yes No N/A		
Verify the informed consent process has been documented via a checklist or narrative note.	Yes No N/A		
Ensure all participants signed the proper consent and assent documents. • No expired forms • No unstamped forms	Yes No N/A		
Ensure all study procedures were performed only after informed consent and assent was obtained.	Yes No N/A		
Ensure all participants receive a copy of the consent and assent form.	Yes No N/A		
Ensure all participants were re-consented appropriately. (prior to the execution of study procedures)	Yes No N/A		
Verify that there is a copy of the ICF in the subjects' medical records for treatment studies.	Yes No N/A		
Ensure that all staff obtaining consent are listed on the Personnel Table and Delegation Log.	Yes No N/A		
Ensure that all staff obtaining consent have accurate credentials. (CREC, Research Credentialing)	Yes No N/A		
If Informed Consent was waived, ensure a copy of the IRB waiver is present in Regulatory Binder.	Yes No N/A		

PHI			
All PHI removed from documents when sent externally.	Yes No N/A		

PI Name: _____ IRB#: _____ Study ID/Short Title: _____

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		INITIALS/DATE	COMMENTS
ELIGIBILITY			
Verify documentation regarding participant meeting all inclusion and exclusion criteria is present.	Yes No N/A		
Verify an IRB approved Investigator has signed off on eligibility documentation before the participant started research procedures.	Yes No N/A		

SAFETY REPORTING			
Verify that all (internal and external) study related information has been documented and reported to the sponsor and/or regulatory specialist. • AEs • SAEs • Protocol deviations • Medically significant events • Unanticipated problems	Yes No N/A		

TEST ARTICLE / DEVICE ACCOUNTABILITY			
Verify that all investigational product and devices were administered, implanted, utilized per protocol.	Yes No N/A		
Verify that all investigational product was administered per protocol and is documented; including start and stop times as applicable.	Yes No N/A		
Verify that all randomization procedures were followed per protocol, as applicable.	Yes No N/A		
Verify that a subject specific drug or device accountability log is maintained and all used and unused medication is accounted for.	Yes No N/A		
Verify that all returned medication bottles from participants are taken to the IDS.	Yes No N/A		

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SPECIMENS			
Verify that all specimens were collected per protocol and are documented.	Yes No N/A		
Verify specimen, including discarded tissues, were collected, transported, and stored per protocol. This includes temperature monitoring, as applicable.	Yes No N/A		
Verify that there are provisions in place for potential sample storage failure.	Yes No N/A		
Verify that all specimen reports with abnormal or out-of-normal range values are evaluated by a medically qualified study personnel for clinical significance; and initialed, dated, and reported as AEs if required per protocol.	Yes No N/A		
Verify that all original specimen shipping records are present.	Yes No N/A		
Verify that samples being sent to third parties are anonymized.	Yes No N/A		

DATA COLLECTION AND SOURCE DOCUMENTATION			
Verify that study visits are completed within window and dates correspond per protocol.	Yes No N/A		
Verify out of window or missed visits are listed on a protocol deviation log and reported as applicable.	Yes No N/A		

DATA COLLECTION AND SOURCE DOCUMENTATION			
Verify that study specific procedures are reviewed, signed and dated by medically qualified study personnel (i.e. EKGs, Imaging, diagnostic tests, etc. - These include those with normal results.)	Yes No N/A		
Verify that SAEs are reported per protocol, Sponsor requirements and IRB policy.	Yes No N/A		
Verify that study materials storage and archive procedures are in place.	Yes No N/A		
Verify that required signatures are present with the correct dates and formatting.	Yes No N/A		
Verify that study participant identification number or code is documented on each page of the source document.	Yes No N/A		

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		INITIALS/DATE	COMMENTS
Ensure that correction of errors are marked with a single line, a date, and initials (i.e., no white out, not blacked out).	Yes No N/A		
Verify that all study data has been entered onto the CRFs, EDC, RDC, or REDCap (i.e., no blank or empty fields).	Yes No N/A		
Verify that CRF and source document boxes are marked as applicable.	Yes No N/A		
Verify that diary cards, memory aids, worksheets or questionnaires are reconciled, complete and have been returned.	Yes No N/A		
Verify that screening procedures were followed per protocol and are documented.	Yes No N/A		
Verify that the study participant's medical history is documented with start and stop dates as applicable.	Yes No N/A		
Verify that concomitant medications are documented with the medical indication and start and stop dates as applicable.	Yes No N/A		
Verify that vital signs are captured per protocol and are documented.	Yes No N/A		
Verify that a physical assessment is on record as applicable by appropriately qualified and delegated staff.	Yes No N/A		
Verify that the eligibility checklist is consistent with the IRB application and IRB approved protocol.	Yes No N/A		

DATA COLLECTION AND SOURCE DOCUMENTATION			
Verify that inclusion and exclusion criteria are documented per protocol and supporting documentation is available for review.	Yes No N/A		
Verify that the appropriate study staff has accurately assessed the eligibility criteria (PI).	Yes No N/A		
For chart review and/or discarded tissue studies, verify that your study records reflect that you have ensured adequate provisions to protect the privacy of the participants and maintained the confidentiality of data that were accessed/collected. • Password Protected • Limited Access (IRB-approved staff only) • The number of charts accessed did not exceed the IRB approved number/goal reported.	Yes No N/A		

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For chart review studies, verify that your study records, if transferred or downloaded, were saved to encrypted devices.	Yes No N/A		
For chart review studies and/or discarded tissue, verify whether there is a Linking Sheet/Data Table.	Yes No N/A		

FINANCIAL INFORMATION			
Verify that study related costs and expenses have been charged and reconciled. • Study participant compensation has been submitted and completed (i.e., Clincards, parking tickets, meal tickets, gift cards, FoxPro, etc.). • A Voucher Log is present and complete and copies made and filed per subject. • Study related visits are entered into the coverage analysis.	Yes No N/A Yes No N/A Yes No N/A		

Additional Comments and Notes: