University Hospitals
Clinical Research Center

Internal QA Checklist- Regulatory Study ID: _____ IRB#: _____ PI Name: _____

*NOTE: For chart review and/or discarded tissue studies, not all information contained within is applicable. Mark N/A accordingly.		INITIALS/DATE	COMMENTS
STUDY PERSONNEL			
Verify that a Delegation Log is present, accurate, and complete. • All study personnel are listed • Study roles and responsibilities are documented appropriately • Start and end dates are present and accurate • All study staff signatures are present	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No		
Verify that the Delegation Log matches the Personnel Table in the IRB application.	☐ Yes ☐ No		
Verify that all study staff training records are on file for all study personnel. • All study staff signatures are present • Documented protocol training is present • Ensure that protocol amendment and/or re-training is present	Yes No Yes No Yes No ☐ N/A		
Verify that all study staff have the following present: • Current CREC Certification • Current Research Credentialing • A current CV or resume or biosketch • Current licensure and or/ certification(s) • Disclosure of COI and a Conflict Management Plan in place, if applicable. (Refer to UH Policies R-43 and CE-08 for details) • Financial Disclosure Form(s) are on file, if applicable (Refer to Code of Federal Regulations Title 21 Part 54 for details) • Disclosure of ownership/interest in Intellectual Property, if applicable (Refer to UH Policy GM-21 – Intellectual Property for details)	Yes No Yes No ☐ N/A Yes No Yes No Yes No ☐ N/A Yes No ☐ N/A Yes No ☐ N/A		
Verify that appropriate personnel are listed on the 1572.	Yes No ☐ N/A		
REGULATORY BINDER			
Verify that all study related policies and procedures (manuals and/or documentation) are on file. • Ensure that a regulatory binder (paper-based or electronic) is present and available • Ensure that Notes to File are present for any missing documentation or documentation location • All Protocol Versions o Complete Protocol Signature Pages • All Consent Versions • A Monitoring Log • All IRB approvals and correspondence/submissions • All IRB or IEC Committee Rosters and Meeting Calendars	Yes No Yes No ☐ N/A Yes No ☐ N/A Yes No ☐ N/A Yes No ☐ N/A Yes No ☐ N/A Yes No ☐ N/A		

University Hospitals Clinical Research Center

Internal QA Checklist- Regulatory

Study ID: _____ IRB#: _____ PI Name: _____

		INITIALS/DATE	COMMENTS
REGULATORY BINDER			
• FDA correspondence and annual reports • FDA 1571, 1572, 3454, 3455 • Package Insert(s), Device Manual, or Investigator Brochure • Laboratory Ranges for UH and outside labs • CLIA or CAP Certificates for UH and outside labs • CV and Licenses for laboratory personnel at UH and outside labs • NIH Grant Application/protocol • NIH Correspondence	Yes No ☐ N/A Yes No ☐ N/A Yes No ☐ N/A Yes No ☐ N/A Yes No ☐ N/A Yes No ☐ N/A Yes No ☐ N/A Yes No ☐ N/A		
SAFETY REPORTING			
Verify that all (internal and external) study related information has been documented and reported to the IRB. • AEs • SAEs • Protocol deviations • Medically significant events • Unanticipated problems	Yes No ☐ N/A Yes No ☐ N/A Yes No ☐ N/A Yes No ☐ N/A Yes No ☐ N/A		
DATA SAFETY MONITORING BOARD (DSMB)			
Verify that all DSMB reports are on file.	Yes No ☐ N/A		
INTERNAL / EXTERNAL MONITORING			
Verify that all monitoring reports are received and are reconciled.	Yes No ☐ N/A		
CLINICALTRIALS.GOV			
Verify that clinicalTrials.gov is up-to-date.	Yes No ☐ N/A		

University Hospitals
Clinical Research Center

Internal QA Checklist- Regulatory

Study ID: _____ IRB#: _____ PI Name: _____

		INITIALS/DATE	COMMENTS
GRANT/CONTRACT AND FINANCIAL INFORMATION			
Verify that all study related costs and expenses have been charged/reconciled. • Clinical Procedures, Laboratory Tests and Imaging as applicable • Participant compensation / reimbursement • Administrative Costs - PI, RC, Data, IDS, IRB (CR, amendments, Safety Reporting, etc.)	Yes No ☐ N/A Yes No ☐ N/A Yes No ☐ N/A		
Verify that any study data shared with other organizations have contracts (e.g., Data Use Agreement (DUA), Confidentiality/Non-Disclosure Agreement (CDA/NDA), Material Transfer Agreement, etc.) in place.	Yes No ☐ N/A		
RESEARCH PROTOCOL			
Verify that all protocol information has been provided to the IRB and is disclosed in the approved consent form.	Yes No		
SCREENING AND ENROLLMENT			
• **Verify all screening and enrollment documents are up to date including all screen failures, and participant withdrawals** • **Verify that all demographic and contact information is accessible** • **For chart review studies and/or discarded tissue, verify there is a log of the participant records or specimens that were accessed/ collected.**	Yes No Yes No Yes No ☐ N/A		
TEST ARTICLE / DEVICE ACCOUNTABILITY			
Verify that all IND and IDE documentation is present.	Yes No ☐ N/A		
Verify that applicable IDS exemption forms are on file.	Yes No ☐ N/A		
Verify that all IDS temperature logs are on file.	Yes No ☐ N/A		

Additional Comments and Notes: