Study Start-Up Checklist for Minimal Risk Research

Researchers conducting minimal risk research are required to maintain records of human-subject research activities to demonstrate the quality of study data and compliance with federal regulations, institutional policies and good clinical practices (GCP). The QI Minimal Risk Checklist assists researchers in achieving and maintaining compliance with the core requirements for human subject research as indicated in the QI Regulatory Binder.

I. Regulatory Binder

Protocol	☐ Current IRB approved protocol summary
CVs	☐ Signed and dated CVs for all IRB approved study staff
Licensures	☐ Valid medical licenses and/or certifications that confirm staff eligibility to conduct study/perform delegated tasks
Logs	☐ Staff Signature and Delegation of Responsibility Log ☐ Pre-screening Log *(if pre-screening subjects to determine initial eligibility)* ☐ Enrollment Log *(if enrolling and consenting subjects)* ☐ Tissue Log *(if collecting, sharing and/or transferring tissue samples)* ☐ Protocol Deviation/Exception/Violation Tracking Log ☐ Adverse Event Log ☐ Monitoring Log
IRB Documents	☐ Original and approved IRB submissions filed in the order of review ☐ IRB notifications and investigator responses to the IRB
Consent Forms	☐ Current IRB approved consent form(s)
Data Collection Sheets	☐ Template forms used to collect study data (ex. demographic sheet)
Lab *(if performing Lab procedures/tests)*	☐ Laboratory certification ☐ Lab Director's CV ☐ Normal lab/reference values
Sponsor *(if funded by an External source)*	☐ Copies of significant correspondences with Sponsor

II. Subject Files

Source Documents	Examples of source documents include but are not limited to: ☐ Eligibility Checklist *(if enrollment is based on inclusion/exclusion criteria)* ☐ Signed and dated informed consent ☐ Documentation of informed consent process ☐ Completed data collection sheets and/or case report forms ☐ Progress notes/Lab reports/Notes to file/Logs/Checklists

Records of human-subject research activities should be kept for at least 7 years upon study closure. If records are stored electronically, a note should be added to the Regulatory binder indicating their location. Please contact the QI program if you have questions or would like to schedule a Regulatory Binder consultation.