STUDY START UP CHECKLIST

REGULATORY BINDER

☐Label binder with protocol name, number and name of Pi
☐Table of Contents

IRB and Regulatory Approvals

☐IRB/CPHS/MHHS/Sponsor approval letter
☐Protocol (all versions with newest version on top)
☐Informed consent document (all versions with newest version on top)
☐Continuing Review Approval letters
☐Form 1572 if applicable
☐Investigational New Drug (IND) or Investigational Device Exemption (IDE) approval (if applicable)
☐Register study in ClinicalTrials.gov (if applicable)
☐Financial Disclosure Form (if applicable)
☐DSMB charter (if applicable)

Study-Specific Materials and Tools

☐Sample Case Report Forms (CRF)
☐Sample assessment Tools
☐Sample patient diaries/surveys
☐Investigators Brochure
☐Lab Manual

Lab and Specimen Storage Documentation

☐Lab certifications and normal value ranges collected (if applicable)
☐Specimen Log
☐Temperature Logs/Freezer Logs

Study Team Training and Delegation

☐Good Clinical practice (GCP) and Human Subjects Research training
☐Orientation for Clinical Research Staff
☐ Informed Consent Training
☐ Site Initiation visit documents and Study Training log
☐Delegation of Authority Log

Study Personnel and Certifications

☐CVs for all PIs and Co-Is (must be signed and dated and updated every 2 years)

STUDY START UP CHECKLIST

☐Medical Licenses for all PIs and Co-Is
☐Contact list for all study team members (email and phone numbers)

Logs and Monitoring

☐Screening and Enrollment log
☐Deviation log
☐Adverse Event log
☐Drug Accountability Log
☐Device Accountability Log
☐Monitoring log

Standard Operating Procedures (SOPs) and Miscellaneous Documents

☐SOPs
☐Note to files
☐Sponsor correspondence
☐IRB Roster

PATIENT STUDY CHART

☐Checklist
☐Informed Consent
☐Documentation of informed Consent
☐Form showing randomization arm if applicable
☐Source Documents (high light pertinent information)
☐Patient diaries/surveys/assessment tools {person (maybe patient) completing forms should sign and date them}
☐Case Report Forms (CRFs)
☐Patient specific correspondence

For more templates and guidance visit https://www.uth.edu/ctrc/gcp-policies

More information on the UTH **Committee for the Protection of Human Subjects**