1 PURPOSE

1.1 This guidance establishes the process used by Sharp HealthCare (SHC) to manage and communicate research activities among and within all Sharp sites, each a wholly owned subsidiary of Sharp HealthCare.

1.2 The guidance begins when an application for a human research study is submitted to the SHC Institutional Review Board (IRB).

1.3 The guidance ends when SHC IRB has acknowledged receipt of the Final Closure Report.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY STATEMENT

3.1 For a research study conducted at more than one Sharp site, SHC may use one of its facilities *(See Appendix 1)* as a primary site while the other Sharp site(s) serve as satellite site(s). The Principal Investigator (PI) is assigned to the primary research site and is responsible for overall conduct of the trial and operational oversight of all participating sites, specifically with regards to the following: a) a general communication plan and schedule, b) monitoring and collection of Case Report Form (CRF) data, c) test drug or device accountability, d) study document management, e) safety reporting, and f) staff training.

3.2 When satellite site(s) participate in a research study, each satellite site will have a sub-investigator designated with supervisor responsibilities for the site. The sub-investigator assigned to each satellite site will report directly to the principal investigator. The satellite site sub-investigator will utilize a qualified designee, such as the primary clinical research coordinator (CRC) as a liaison for updating the conduct of the study through various forms and procedures.

4 RESPONSIBILITIES

4.1 The PI is responsible for the overall conduct of the research study as referenced in 21 CFR 312. The sub-investigator is responsible for the coordination of the trial at the designated satellite site. The CRC or regulatory specialist is responsible for submitting all site-specific reports to the PI and SHC IRB.

5 PROCEDURE

5.1 Study Feasibility:

5.1.1 The Principal Investigator and/or qualified designee performs a feasibility assessment which includes a review of the protocol and a determination that the appropriate resources and infrastructure are available to conduct the trial at the primary SHC site and all prospective SHC satellite sites. The Principal Investigator and/or qualified designee will confirm that appropriately licensed, trained, and otherwise qualified personnel are in place at the primary SHC site and all prospective SHC satellite sites.

5.2 Site Qualification (aka: Pre-Trial Visit/Site Selection Visit):

5.2.1 The PI or qualified designee (e.g., primary CRC) prepares the primary SHC site and all prospective SHC satellite sites and personnel for the Site Qualification Visit.

5.2.2 The primary CRC notifies the primary SHC site and all prospective SHC satellite sites via email calendar invite and includes any relevant information available.

5.2.3 During the Site Qualification Visit, the sponsor assesses the abilities of the PI, Sub-Investigators, primary SHC site and all prospective SHC satellite site to meet the goals and objectives of the clinical trial.

5.3 IRB Submissions and Correspondence

5.3.1 The regulatory specialist or primary CRC is responsible for submitting all study submission materials and other correspondence to the SHC IRB.

5.3.2 All IRB submissions and approvals will be communicated to the PI, primary SHC site, and all satellite sites.

5.4 Dissemination of Study Information / Study Oversight for SHC enrolled subjects

5.4.1 Serious Adverse Events (SAE)

5.4.1.1 Each site is responsible for completing and submitting Serious Adverse Event (SAE) reports that occur at their site.

5.4.1.2 The completed SAE reports will be forwarded by the qualified designee to the PI for review and signature.

5.4.1.3 The signed SAE reports will be submitted by the primary CRC to the SHC IRB and sponsor.

5.4.1.4 Ongoing sponsor or IRB communication regarding SAEs is the responsibility of the site reporting the SAE and the PI.

5.4.1.5 The SAE occurrence will be communicated at staff meetings to the involved research personnel.

5.4.2 Investigational New Drug (IND) Safety Reports

5.4.2.1 All IND reports from the Sponsor will be saved in pdf format and stored electronically by the primary CRC or regulatory specialist.

5.4.2.2 All IND reports and/or cover letters will be forwarded to the PI for review and signature and will be filed in the primary site regulatory binder in the manner specified in the protocol. All satellite site sub-investigators will receive the electronic pdf version via email for their review.

5.4.2.3 The SHC IRB does not require the submission of IND Safety Reports.

5.5 Sponsor alert and updates, status changes

5.5.1 The primary CRC is responsible for communicating sponsor alerts, updates, and status changes regarding the conduct of the protocol.

5.5.2 All alerts, updates, and status changes will be processed for IRB acknowledgement and reviewed by the PI with required signature and date.

5.6 Site Staff Training-Protocol Training

5.6.1 Study specific training will be provided by the sponsor at the off-site Investigator Meeting (IM) and or the Site Initiation Visit (SIV).

5.6.2 For personnel involved in the conduct of the protocol but unable to attend the IM or SIV, the primary CRC and/or qualified designee is responsible for providing training using study materials provided by the sponsor (e.g. Investigator Brochure, slide decks, recruitment materials) and SHC guidance.

5.7 Site Binders

5.7.1 Each site is to maintain a study binder that includes but is not limited to the most current version of the protocol, Investigational Brochure (IB), Directions for Use Guides, Informed Consent Form (ICF), Protected Health Information (PHI), source documentation, protocol specific instructions and any form of ongoing communication that is necessary to conduct the trial.

5.8 Informed Consent Documentation

5.8.1 Each site is responsible for documenting the informed consent process in the subject's source document and in the Electronic Medical Record (EMR) (if applicable). The documentation should include all the elements listed in *GUIDANCE: Written Documentation of Consent (HRP-091).*

5.9 Study Drug

5.9.1 The primary CRC or regulatory specialist is to provide a description of facilities for study drug storage and handling at each individual site (primary and satellite sites). *See GUIDANCE: Investigational Drugs and Biologics (HRP-096).*

5.10 Source Documents

5.10.1 The primary CRC is responsible for creating the study specific source document template to be used at all sites.

5.10.2 All completed source documentation is maintained at the individual site.

5.10.3 Information captured from EMR may be printed out and kept in the subjects' source documents.

5.10.4 If any study related information is maintained in the hospital EMR, the monitor will be granted "read-only" "onsite only" access through *GUIDANCE: Third Party Access to Data for Non-Sharp Staff (HRP-092).*

5.11 Case Report Forms (CRFs)

5.11.1 All CRF's (paper or electronic) are completed using original source records and retained at the individual site.

5.12 Document Maintenance and Record Retention

5.12.1 The regulatory binder is to be located at the primary site. Drug Accountability Logs and Pharmacy documents will be stored at the designated site Investigational Pharmacy. Subject specific drug accountability will be stored in the subject specific source document.

6 MATERIALS

6.1 GUIDANCE: Written Documentation of Consent (HRP-091)

6.2 GUIDANCE: Investigational Drugs and Biologics (HRP-096)

6.3 GUIDANCE: Third Party Access to Data for Non-Sharp Staff (HRP-092)

7 REFERENCES

7.1 Guidance for Industry: Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects"

7.2 http://www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf

7.3 21 CFR 312.60 General responsibilities of investigators

7.4 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.60

This document is available on IRBANA, or by contacting research@sharp.com.

Appendix 1

Site Name	Address	IRB Name	Designated Pharmacist/Tech
Sharp Memorial Hospital	7901 Frost Street San Diego, CA 92123	Sharp HealthCare	X
Sharp Rehabilitation	2900 Health Center Drive San Diego, CA 92123	Sharp HealthCare	X
Sharp Grossmont Hospital	5555 Grossmont Center Drive La Mesa, CA 91942	Sharp HealthCare	X
Sharp Chula Vista	751 Medical Center Court Chula Vista, CA 91911	Sharp HealthCare	X
Sharp Coronado	250 Prospect Place Coronado, CA 92118	Sharp HealthCare	X
Sharp Mesa Vista	7850 Vista Hill Avenue San Diego, CA 92123	Sharp HealthCare	X
Sharp Mary Birch Hospital for Women and Infants	3003 Health Center Drive San Diego, CA 92123	Sharp HealthCare	X