

Standard Operating Procedures for Clinical Research at USF Health Morsani CRC

	RESPONSIBILITIES OF THE RESEARCH TEAM		
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PURPOSE: The purpose of this standard operating procedure (SOP) is to identify all members of the research team, to define their roles and responsibilities as well as to record written procedures for the delegation of tasks and responsibilities within the framework of the principles inherent in Good Clinical Practice (GCP) of the International Conference on Harmonization (ICH).

SCOPE: This SOP applies to all clinical research personnel and research support staff involved in supervising, managing, conducting or supporting study related activities at the CRC.

RESPONSIBILITY: The Principal Investigator (PI) and all members of the research team are responsible for having a clear working knowledge about their specific duties. The PI may delegate authority to trained and/or licensed members of the research team; however, the PI is ultimately responsible for the conduct of the study.

DEFINITIONS:

Conflict of Interest (COI): A COI exists in research when an investigator's or other study team member's self-interests have the potential to compromise his/ her professional judgment and objectivity in the design, conduct or reporting of research.

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

International Conference on Harmonization (ICH): A joint initiative by the European Union (EU), Japan and the United States that established the ICH GCP Guideline to provide a unified standard to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

PROCEDURE:

- 1. Principal Investigator (PI):** The PI is responsible for assuming overall authority and accountability for the ethical conduct of a clinical study in accordance with all applicable federal and state laws and regulations and with institutional policy. The PI promotes GCP in the conduct of clinical studies by assuming the following essential roles and responsibilities:
 - 1.1. Is qualified by education, training and experience
 - 1.2. Protects the rights and welfare of subjects
 - 1.3. Protects the private health information (PHI) of subjects
 - 1.4. Discloses applicable COIs as required by the Institutional Review Board (IRB)
 - 1.5. Conducts study activities in compliance with IRB requirements after IRB approval and in accordance with the approved protocol, except where necessary to eliminate apparent immediate hazards to participants

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PROCEDURE (cont.):

- 1.6. Accurate and prompt reporting of all adverse events as required by the IRB and the sponsor
 - 1.7. Obtains informed consent from each subject
 - 1.8. Assures the validity of the data reported to the sponsor
 - 1.9. Assures documentation of study-related procedures, processes and events
 - 1.10. Assures the proper use and storage of investigational products
 - 1.11. Ensure privacy and security of research data
 - 1.12. Maintains adequate and accurate records and make records available for inspection to external and internal monitors. Meet with auditors (FDA, sponsor and internal) at the conclusion of their audits to review findings and to implement changes to correct weaknesses or deficiencies.
 - 1.13. Assures delegation of responsibilities is appropriate and documented and that individuals recruited as members of the research team are appropriately licensed and/or trained. Delegating the work, however, does not relieve investigators of their responsibility. They ultimately bear the responsibility for all work conducted in the trial.
- 2. Co-Investigator (Co-I)/ Sub-investigator (Sub-I):** The Co-I/ Sub-I (e.g., associate, resident, research fellow) has the following roles and responsibilities:
- 2.1. Designated and supervised by the investigator to perform all or some of the functions of the PI, however, the PI has ultimate responsibility for the conduct of a research project.
 - 2.2. Plays a key role in study scientific development and conduct in collaboration with the PI.
 - 2.3. Obliged to ensure that study design and conduct is compliant with applicable laws, regulations and institutional policies governing human subjects research.
- 3. Clinical Research Coordinator /Research Nurse:** Responsible for managing all aspects of the conduct of the clinical trial with in-depth knowledge of the protocol and GCP per federal regulations. Responsibilities include, but are not limited to, the following:
- 3.1. Manages the business aspects of studies, including collaborative development and negotiation of study budgets with the Project Liaison. Acts in conjunction with the Office of Clinical Research (OCR), facilitating the contract review process as needed.
 - 3.2. Assures protocol compliance through a thorough understanding of the protocol.
 - 3.3. Assists with study start up.
 - 3.4. Develops organizational aids and checklists to facilitate patient recruitment and the collection of complete and accurate study data.

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PROCEDURE (cont.):

- 3.5. Designs appropriate recruitment strategies and tracks study enrollment.
 - 3.6. Maintains the regulatory and study files for each research project.
 - 3.7. Prepares regulatory documents as needed for the FDA (e.g., Form 1571, 1572) and IRB (e.g. Description of Study, Informed Consent Form).
 - 3.8. Communicates with the IRB as appropriate.
 - 3.9. Screens and enrolls study participants.
 - 3.10. Schedules and maintains study visits with patients.
 - 3.11. Obtains informed consent and personal health information (PHI) Authorization/HIPAA from trial subjects before performing any study related procedures.
 - 3.12. Assures proper handling of the investigational product (IP).
 - 3.13. Assures proper handling and accurate processing of samples (e.g. blood and tissue).
 - 3.14. Tracks participant compliance with the research drug, device or procedure.
 - 3.15. Completes source documents and case report forms (CRFs) in an accurate and timely manner.
 - 3.16. Tracks, reports and monitors adverse events and deviations as appropriate.
 - 3.17. Participates in quality assurance activities of the sponsor, the FDA, other regulatory agencies.
 - 3.18. Trains and supervises other clinical research personnel as appropriate.
 - 3.19. Protects all research data in accordance with USF privacy and security requirements.
 - 3.20. Assists with study close out.
 - 3.21. Oversees study closure and reporting of results.
 - 3.22. Meets with the representatives of the sponsor to discuss planned and ongoing studies.
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4. **Investigational Pharmacists:** The Clinical Investigational Research Pharmacy (CIRP) is responsible for providing the following services in compliance with local, state and federal laws and sponsor requirements.
 - 4.1. Consultation for investigator-initiated studies
 - 4.2. Study design/protocol development
 - 4.3. Randomization
 - 4.4. Investigational product procurement, storage, preparation and distribution
 - 4.5. Maintenance of product accountability and study-related records
 - 4.6. Product/placebo compounding
 - 4.7. Maintenance and control of investigational product inventories
 - 4.8. Return of used/unused product to sponsors or destruction of product for pharmacy-managed protocols
 - Development of educational materials
 - 4.9. Participation in study initiation and close-out visits

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- 4.10. Assistance with data analysis (e.g. pharmacokinetics), manuscript preparation and peer review
- 4.11. Participation in audit processes
- 4.12. Descriptive reports of pharmacy services

5. Other members of the research team (such as Data Manager, Research Assistant, Regulatory Coordinator, etc.) will:

- 5.1. Conduct clinical studies according to federal and local regulations and guidelines, Good Clinical Practices, IRB policies, and departmental/division SOPs.
- 5.2. Assure the safety and welfare of study subjects by being knowledgeable about ongoing study protocols and investigational articles.
- 5.3. Comply with federal regulations governing disclosure of personal, professional or financial interests in a research study that may impact upon its conduct, evaluation or outcome.
- 5.4. Maintain confidentiality of all clinical trial related information (including patient records).
- 5.5. Fulfill job responsibilities specific to each job title according to federal regulations and guidelines as well as the appropriate job descriptions maintained at the site.
- 5.6. Assure that the PI and Clinical Research Coordinator are informed in a timely manner of all study-related activities.
- 5.7. Maintains the regulatory and study files for each research project.
- 5.8. Prepares regulatory documents as needed for the FDA (e.g., Form 1571, 1572) and IRB (e.g. Description of Study, Informed Consent Form).
- 5.9. Communicates with the IRB as appropriate.

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REFERENCES:	21 CFR 312.53 Selecting investigators and monitors 21 CFR 312.60 General responsibilities of investigators 21 CFR 312.61 Control of the investigational drug 21 CFR 312.62 Investigator recordkeeping and record 21 CFR 312.64 Investigator reports 21 CFR 312.66 Assurance of IRB review 21 CFR 312.68 Inspection of investigator's records and reports 21 CFR 312.69 Handling of controlled substances 21 CFR 54 Financial Disclosure by clinical investigators January 1988 Guidelines for the monitoring of clinical investigations FDA Information Sheets October 1998 - Frequently Asked Questions, Continuing Review After Study Approval, Recruiting Study Subjects, Payment to Research Subjects, Screening Tests Prior to Study Enrollment, A Guide to Informed Consent, Sponsor-Investigator- IRB Interrelationship May 1997 - International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline	
RELATED POLICIES:	USF HRPP Policies and Procedures USF CIRP Policies & Procedures	
APPENDICES:	Appendix D: Delegation of Responsibility Log	
REVISION HISTORY: A running history of all revision dates will be kept in a log		
Approval Date	Effective Date	Review/Revision Date
01/01/2015	01/01/2015	06/15/2016