

Standard Operating Procedures for Clinical Research at USF Health Morsani CRC			
	CLINICAL STUDY CONDUCT		
SOP#: 104	Effective Date: 06/01/2016	Version #: 1.0	Page: Page 1 of 5

PURPOSE: This Standard Operating Procedure (SOP) describes the clinical study conduct standards expected of all clinical research personnel at the CRC.

SCOPE: This SOP is applicable to all study site staff involved in all studies conducted at the CRC. This SOP specifically covers the period from first patient consent until study close out.

RESPONSIBILITY: The overall responsibility for study conduct at the CRC rests with the Principal Investigator (PI), however all staff delegated with study responsibilities by the PI, and in accordance with the study protocol, are legally and ethically bound to fulfill those responsibilities in compliance with GCP and this SOP.

DEFINITIONS:

Case Report Form (CRF): A paper or electronic questionnaire specifically used in clinical trial research. The CRF is the tool used by the sponsor of the clinical trial to collect data from each participating site. All data on each patient participating in a clinical trial are held and/or documented in the CRF, including adverse events.

Food and Drug Administration (FDA): The FDA is a federal agency responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, food supply, cosmetics, and products that emit radiation; and that these products are honestly, accurately and informatively represented to the public.

Good Clinical Practice (GCP): An internationally recognized 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.

Human Research Protections Program (HRPP): A program managed by the USF Division of Research Integrity & Compliance (DRIC) that promotes the rights and welfare of all human subjects who participate in research at USF regardless of funding.

Institutional Review Board (IRB): An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

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

Standard Operating Procedures for Clinical Research at USF Health Morsani CRC			
	CLINICAL STUDY CONDUCT		
SOP#: 104	Effective Date: 06/01/2016	Version #: 1.0	Page: Page 2 of 5

DEFINITIONS (cont.):

Investigational Product (IP): A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial.

Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial.

Standard Operating Procedure (SOP): The International Conference on Harmonization (ICH) defines a SOP as "detailed written instructions to achieve uniformity of the performance of a specific function." (ICH GCP 1.55). A SOP is a written process for a clinical site to perform a task the same way each time it is completed.

Test Article: Any drug (including a biological product) or medical device for human use, human food or color additive, electronic product, or any other article subject to regulation by the FDA.

PROCEDURES:

1. Standards:

- 1.1. The Investigator and clinical research staff will follow the complete set of SOPs for the CRC which meet or exceed FDA regulations and GCP guidelines.
- 1.2. Study activities are completed using standardized methods and forms to ensure compliance and consistency.

2. Training:

- 2.1. The Investigator and clinical research personnel will be trained in in compliance with FDA and ICH/GCP requirements and responsibilities.
- 2.2. All USF faculty, staff, and students engaged in clinical research studies must complete the USF HRPP mandatory education requirements for human subject protection.
- 2.3. Study specific training and tasks will be provided to research staff.
- 2.4. Training requirements for all key research personnel are detailed *in SOP # 102: Training Clinical Research Staff*.
- 2.5. Documentation of all training will be kept in an employee file in each department and on file in the OCR.

Standard Operating Procedures for Clinical Research at USF Health Morsani CRC



CLINICAL STUDY CONDUCT

SOP#: 104

Effective Date: 06/01/2016

Version #: 1.0

Page: Page 3 of 5

PROCEDURES (cont.):

3. Data Collection:

- 3.1. The procedure for collection of study data will be detailed in the study protocol, and all data will be handled and stored in compliance with federal and USF IRB requirements.
- 3.2. Please refer to *SOP #501 Case Report Form (CRF) Completion*, *SOP# 504 Archiving Study Records*, and *SOP #505 Printing and Certifying Medical Records*.

4. Study Procedures:

- 4.1. All activities related to a clinical study must be reviewed and approved by the USF IRB or a USF relied upon IRB ((Western, Shulman and Quorum), All Children's Hospital (ACH), Florida Department of Health (DOH)) prior to the initiation of any study activities.
- 4.2. Research staff will submit timely progress/final reports and amendments in accordance to USF IRB or USF relied upon IRB requirements.
- 4.3. Study specific procedures will be detailed in the study protocol and only performed by staff delegated with this responsibility in the site file authorized delegation log.
- 4.4. Training in these procedures will be the responsibility of the sponsor and research team.
- 4.5. Standard procedures, not detailed in the protocol, will be performed according to the CRC SOPs.
- 4.6. No study specific procedures will be performed prior to signed and witnessed informed consent being obtained.
- 4.7. All procedures will be recorded in the specified source document as soon as possible after completion.
- 4.8. If further written instructions for study procedures are produced, these should be reviewed by a second person, and should be dated and version controlled.

5. Documentation:

- 5.1. Study staff will support the sponsor's requirement for maintaining essential source documents in a confidential, complete and timely manner.
- 5.2. Regulatory documents will be filed in a regulatory binder.

6. Test Article/IP Storage and Management:

- 6.1. All test articles/IP are received and inventoried upon receipt.
- 6.2. Whenever possible, all study drugs are stored in the CRC Investigational Pharmacy.
- 6.3. When the test article is needed for a subject, the Investigational Pharmacist or Research Nurse/Coordinator takes the supplies for that subject and logs them out of central inventory.

Standard Operating Procedures for Clinical Research at USF Health Morsani CRC



CLINICAL STUDY CONDUCT

SOP#: 104

Effective Date: 06/01/2016

Version #: 1.0

Page: Page 4 of 5

PROCEDURES (cont.):

- 6.4. When the subject returns the test article/IP, it is returned to inventory and logged into the test article/IP log.
- 6.5. Depending on where the test article is stored, the Investigational Pharmacist/Research Nurse/Coordinator is responsible for maintaining complete accountability logs and storage of the test article supplies.

7. Clinic Records:

- 7.1. Only those individuals with legitimate access to participant's records should be able to view clinic records.
- 7.2. A participant's enrolment in a research study should be noted in their clinical record, recording study title and date. It is best practice to scan the informed consent form into the participant's clinical records if appropriate.
- 7.3. A participant's clinic record may contain source data in which case must be retained for the archive period, as specified in the protocol.

8. Safety Reporting:

- 8.1. Study staff will familiarize themselves with safety reporting guidelines provided in the study protocol and documentation presented at study initiation visit.
- 8.2. Research personnel will report adverse events and unanticipated problems in compliance with *USF HRPP Policy and other commercial IRBs policies and procedures*

9. Study Monitoring:

- 9.1. The sponsor is responsible for determining the nature and extent of monitoring for any study.
- 9.2. Refer to SOP *section III Study Management* for details regarding monitoring visits.

10. Study Samples:

- 10.1. All study samples must be handled, stored and transported as specified in the protocol.
- 10.2. Research personnel can refer to SOP section III Study Management for process regarding specimen collection and management.

11. Audit and Inspection

- 11.1. An audit may be performed by a sponsor or sponsor representative, the local USF IRB and/or an inspection by a regulatory authority such as the Food and Drug Administration (FDA).

Standard Operating Procedures for Clinical Research at USF Health Morsani CRC



CLINICAL STUDY CONDUCT

SOP#: 104

Effective Date: 06/01/2016

Version #: 1.0

Page: Page 5 of 5

- 11.2. All staff is required to respond to requests for information/access from inspectors or auditors. See *SOP#602 FDA Audits*.

PROCEDURES (cont.):

12. Study Close Out

- 12.1. Designated research personnel will facilitate study close out initiated by the sponsor to formally end study activity at the CRC site.
- 12.2. Please refer to *SOP #311 Study Close- Out Visit*.

REFERENCES:	21 CFR 50, 54, 56, 312, 314, 45 CFR 46 ICH GCP 1.55;	
RELATED POLICIES:	USF HRPP Policies and Procedures	
APPENDICES:	None	
REVISION HISTORY: Keep a running history of all revision dates.		
Approval Date	Effective Date	Review/Revision Date
01/01/2015	06/01/2016	06/15/2016