


Standard Operating Procedures for Clinical Research at USF Morsani CRC			
	PROTOCOL COMPLIANCE		
SOP#: 312	Effective Date: 06/01/2016	Version # 1.0	Page 1 of 3

PURPOSE: The purpose of this SOP is to describe the procedures followed by the Investigator and study team engaged in clinical research at the CRC to ensure the rights and well-being of subjects and the quality and integrity of safety and efficacy data are carried out strictly according to the approved protocol.

SCOPE: This SOP applies to the investigator and all research site personnel involved in the implementation and coordination of clinical research.

RESPONSIBILITY: The Principal Investigator (PI) bears primary responsibility for complying with the provisions of the protocol. He/ She is also responsible for personally supervising all study staff to ensure their compliance with the protocol. The sponsor has responsibility to monitor the study and ensure that the investigator and site staff comply with the protocol

DEFINITIONS:

Compliance: Adherence to all the trial-related requirements, Good Clinical Practice (GCP) requirements, and the applicable regulatory requirements.

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.

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

Monitoring: The act of overseeing the progress of a clinical trial, and of ensuring that is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

Protocol: A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments.

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PROCEDURE:

1. Once IRB approval is obtained, the PI and study team will conduct the trial according to protocol in compliance with GCP.
2. The investigator and or study personnel will not implement any deviation from, or changes of, the protocol without agreement by the sponsor and prior review and documented approval from the IRB of an amendment, except where necessary to eliminate an immediate hazard(s).
3. The PI and study team will maintain protocol compliance while performing all of the study activities covered by the protocol in the exact manner specified in the approved protocol. This includes, but is not limited to, the following activities:
 - Identifying potential study subjects
 - Informing subjects fully of all study related procedures
 - Selecting subjects in accordance with inclusion/ exclusion criteria
 - Treating subjects with the investigational product (IP) as specified in the protocol
 - Observing and accurately recording key safety and efficacy endpoint data at specified time points
 - Reporting all adverse events (AEs) to the sponsor according to sponsor and regulatory authority guidelines.
 - Analyzing data, if applicable
4. Examples of noncompliance include, but are not limited to, the following:
 - Performing human subject research without first obtaining IRB approval or an IRB declaration of exemption.
 - Deviating from or violating the provisions of an IRB-approved protocol and/or procedures.
 - Permitting a protocol's IRB approval to expire without stopping all research-related activities and/or submitting a Final Report to the IRB. If there are overriding safety concern or ethical issues that necessities continuation of the study upon expiration, for example, it is in the subject's best interest to continue study participation, the investigator must arrange with the IRB to continue research activities.
 - Failure to obtain and document informed consent of research subjects unless appropriate waiver has been approved.
5. Investigators and research staff are required to report any observed, suspected, or apparent noncompliance to the IRB.

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REFERENCES:	21 CFR 312.50 General Responsibilities of Sponsors 21 CFR 312.60 General Responsibilities of Investigators May 1997 International Conference on Harmonization (ICH) Good Clinical Practices ICH GCP Consolidated Guideline—Part 4.5.2 Compliance with Protocol
RELATED POLICIES:	SOP 102: Training Clinical Research Staff SOP 103: Responsibilities of the Research Team SOP 104: Clinical Study Conduct
APPENDICES:	None
REVISION HISTORY: Keep a running history of all revision dates.	

Approval Date	Effective Date	Review/Revision Date
01/01/2015	01/01/2015	06/01/2016