


Standard Operating Procedures for Clinical Research at USF Health CRC		
	QUALITY CONTROL	
	Effective Date: 01/01/2015	Revision Date:
SOP#: 601	Version: 1	Page 1 of 3

PURPOSE: This Standard Operating Procedure (SOP) describes the methods of Quality Control (QC) for clinical studies conducted at the CRC.

SCOPE: This SOP applies to the all clinical studies conducted at the CRC.

RESPONSIBILITY:

Investigator: The PI is responsible for maintaining and enforcing a quality system for all research studies conducted at the CRC. He/ She delegates the implementation and supervision of QM activities to designated research personnel who are trained and qualified to perform these delegated tasks.

Clinical Research Coordinator and Key Personnel: The study coordinator and other key research personnel are responsible for the development of quality measures and activities specific to their area and need that include adherence to written SOPs, training, and ongoing assessment of use, need and validity.

DEFINITIONS:

Corrective and Preventive Actions (CAPA): A system for implementing corrective actions and preventive actions resulting from the investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings, and trends from process performance and product quality monitoring.


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.

Quality Assurance (QA): All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s).

Quality Control: Continuous operational checks within each functional department to verify that clinical data are generated, collected, handled, analyzed, and reported according to protocol, SOPs, and Good Clinical Practices (GCPs).


PROCEDURE:

1. Research staff will ensure compliance with the established SOPs, FDA requirements, sponsor's protocol and local regulatory authorities.
2. Staff training of Human Subjects Research Protection, GCP, SOPs and federal/local regulatory requirements will be performed and documented.

Standard Operating Procedures for Clinical Research at USF Health CRC		
	QUALITY CONTROL	
	Effective Date: 01/01/2015	Revision Date:
SOP#: 601	Version: 1	Page 2 of 3

PROCEDURE (cont.):

3. Research personnel will utilize the Quality Improvement (QI) Program within the USF Division of Research Integrity and Compliance (DRIC) as a resource to ensure the highest ethical standard and data integrity for human subjects research at the CRC.
4. Research personnel will utilize standardized forms and checklists to ensure documentation is accurate and complete.
5. Study personnel will conduct periodic internal QAs/ reviews to ensure compliance with CRC SOPs, GCPs, regulatory, protocol requirements and data accuracy. Refer to *Appendix HH: Study Documentation Self-Assessment Tool*
 - QA checks can be done by any research staff member.
 - Internal quality control forms will be completed randomly.
 - Deficiencies found through internal QA or sponsor monitoring visits will be corrected.
 - QA checks will be performed annually at a minimum.
 - An internal QC binder will be maintained by the research staff.
6. Documentation for each study will be reviewed periodically throughout the study using FDA audit criteria to ensure that is adequate and accurate. This includes:
 - Who performed each task
 - Degree of delegation of authority by PI
 - How and where data were recorded
 - Verification of protocol adherence
 - How study test article accountability and dispensation are/were maintained
 - Communications between sponsor and PI
 - IRB documentation, communications and approvals
 - Signed, IRB stamped consent forms for each subject with correct version
 - Accurate and complete report of adverse events followed to resolution or satisfactory endpoint
 - CRF form verification with source documentation and other records
 - Record retention consistent with GCPs and sponsor requirements
7. The PI and study coordinator will review sponsor monitoring reports and correspondence to assess errors and develop a CAPA plan to prevent further errors
8. Documentation of periodic quality reviews that contain confidential information for continued QA should be maintained separately from official study records.
9. Research management will review quality QA checks to ensure continued research quality and training needs of all research personnel are met.

Standard Operating Procedures for Clinical Research at USF Health CRC		
	QUALITY CONTROL	
	Effective Date: 01/01/2015	Revision Date:
SOP#: 601	Version: 1	Page 3 of 3

PROCEDURE (cont.):

10. Research management will review quality QA checks to ensure continued research quality and training needs of all research personnel are met.
11. After QA checks and internal audits, the PI and study coordinator will specify a timeline within which any corrective actions should be made. This should not take longer than 2 weeks but may vary depending on the nature of the particular findings.
12. Study staff will not make documentation of such internal quality reviews available during Sponsor audits. The FDA may have access to these records by a court ordered subpoena.

REFERENCES:	21 CFR 312.60 General Responsibilities of Investigators 21 CFR 312.62 Investigator recordkeeping and record retention 21 CFR 312.64 Investigator reports 21 CFR 312.66 Assurance of HRRC review, September 1993, FDA Clinical Investigator Inspections: October 1998 International Conference on Harmonization; Good Clinical Practice: sections 1.46-1.47, 1.6 USF Division of Research Integrity and Compliance (DRIC) Quality Improvement (QI) Program
RELATED POLICIES:	
APPENDICES:	Appendix HH: Study Documentation Self-Assessment Tool
REVISION HISTORY: Keep a running history of all revision dates.	

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