University Hospitals
Case Medical Center

STANDARD OPERATING PROCEDURE (SOP) FOR CLINICAL RESEARCH Title: Development and Maintenance of Standard Operating Procedures (SOPs)	Last Revised: 12/2014 Prior Version: 03/2012
SOP NUMBER: GA-101	Page 1 of 5

1. PURPOSE:

This Standard Operating Procedure (SOP) describes the standard format and method the Center for Clinical Research and Technology (CCRT) will use in writing and maintaining the Clinical Research SOPs for University Hospitals of Cleveland (UHC). This SOP also describes how the research community may use these SOPs as guidelines and examples in developing their own SOPs.

2. SCOPE:

This SOP will provide instruction and promote consistency among all departments within University Hospitals of Cleveland involved with the conduct of research and the development of research SOPs.

3. RESPONSIBLE INDIVIDUALS:

The Clinical Research SOP Committee is responsible for:

- Preparing, revising and implementing the SOPs to serve as a reference or guidance for the research community on appropriate research practices at this site; and
- Obtaining input and discussion by investigators.

The Center for Clinical Research and Technology (CCRT) is responsible for:

- Monitoring compliance with Clinical Research SOPs at UHC;
- Posting these SOPs on the UHCMC website as reference material;
- Ensuring timely review of the SOP; and
- Provide training to the research team members on implementing Clinical Research SOPs in their particular research area.

The Investigator is responsible for:

- Developing specific SOPs, as necessary but not conflicting with institutional policies, local, state, and federal laws and regulations;
- Monitoring compliance with site specific SOPs; and
- Training research team members on implementing site-specific SOPs in their particular research area.

4. DEFINITIONS:

Please reference the Glossary for complete definitions of the following terms and additional terms not listed.

- Clinical Research SOP Committee
- Standard Operating Procedures (SOPs)

5. POLICY STATEMENT:

This SOP must be used as a guide to write, format, implement, and maintain the Research SOPs for University Hospitals of Cleveland (UHC). SOPs are not intended to supersede existing institutional policies, and local, state, and federal laws and regulations.

6. PROCEDURES:

6.1 Identifying the Need for SOPs

Institutional Level

The Clinical Research SOP Committee will determine the priority of the SOPs to be completed and formally implemented at UH. The priorities will be based on the input from each of the Committee members who will be representing their department and/or investigators.

Department/Investigator Level

Priorities should be based on the need of the Department and/or Investigator.

6.2 Writing the SOP

Institutional Level

After designating an activity, the Clinical Research SOP Committee determines the level of detail for the SOP. The SOP Committee prepares a step-by-step listing of the activities including the necessary qualifications and certifications of staff assigned to completing these activities. After the first draft of the SOP is completed, each SOP is reviewed for accuracy and clarity. Tools are designed to be used with the SOP such as forms, templates, checklists, etc.

Department/Investigator Level

Depending on the nature of the SOP, the appropriate individuals should determine the level of detail for the SOP. Those individuals should prepare a step-by-step listing of the activities including the necessary qualifications and certifications of staff assigned to completing these activities. After the first draft of the SOP is completed, each SOP must be reviewed for accuracy and clarity. Tools are designed to be used with the SOP such as forms, templates, checklists, etc.

Each research area ensures that the site procedures, and activities detailed in the SOP accurately reflect how the tasks are performed within their research area. If revisions are required to reflect how the tasks are performed within each research area, the Department Chair, Principal Investigator, or other designee must ensure these revisions are made to the SOP and implemented within the research area. These changes should be documented in a site-specific or protocol specific SOP, as needed.

6.3 Format

TITLE of SOP: Descriptive statement that represents document's purpose. The wording should be descriptive but not too long.

1. PURPOSE of SOP: Qualifies and describes the intent of the document.

2. SCOPE: Statement that describes who the SOP applies to.

3. RESPONSIBLE INDIVIDUALS: Documents the parties involved and specific performance standards/requirements for the procedure.

4. DEFINITIONS: A brief, precise statement of the meaning of a word or phrase.

5. POLICY STATEMENT: The governing statement of standards for a specific activity

6. PROCEDURES: A description of the tasks or step-by-step procedures necessary for completion of the activity. Include definitions as necessary.

7. REFERENCES: A list of regulations, policies and guidelines applicable to and/or referenced in the SOP. The citation in the SOP will also identify documents to review for additional information regarding a specific activity.

8. FORMS OR ATTACHMENTS: A list of reference materials such as forms, checklists, or other additional information that may be utilized in the implementation of the SOP.

6.4 Implementation

Signature
Institutional Level
The Draft SOP will undergo formal review and approval by the VP for Research and Technology Management and other designee, as appropriate (Chief Medical Officer, Legal Counsel, IRB, Grants and Contracts, Office of Research Compliance and Education, Technology Management).

Department/Investigator Level
The Draft SOP will undergo formal review and approval by the Department Chair or other designee, as appropriate.

Formal Notice and Training
Institutional Level
After the SOP is final, the SOP will be posted on the Research SOP website and notification will be distributed throughout the organization. The Office of Research Compliance and Education will

organize live education sessions for the research community on the SOPs on a quarterly basis to ensure an understanding of the requirements of the Clinical Research SOPs, and the activities necessary for adherence to the SOPs. Announcements will also be disseminated in the research newsletter.

The SOP will be effective 60 days after the formal announcement. During that 60-day period, appropriate individuals (including investigators and research staff) must participate in training (live and on-line online opportunities will be available) pertaining to the announced SOP. The online training will be available in the Learning Management System (LMS).

If an SOP is related to an individual's scope of practice or research assignment, including investigators, coordinators, research administrators, they must complete the training. Training can be completed via LMS, department facilitated education session, or training provided by or approved by the Research SOP committee. Individuals should consult with their manager or Department Chair to determine the applicability of the SOP. Investigators or managers will be responsible for registering themselves and their direct reports.

Documentation of this training will be maintained in LMS if completed online, in the department if the education was provided at the department level, or by the CCRT if the education was provided at the community level.

Department/Investigator Level

After the SOP is final, the Department Chair or other designee, as appropriate, should ensure that all appropriate individuals are trained. Documentation of this training must be maintained.

6.5 SOP revisions and retention

Institutional Level

Each SOP is reviewed every three years for possible revisions needed due to updates or changes in regulations, local policies or procedures, and maintain compliance with applicable regulations, policies, and/or laws. Each revision is labeled as a new version. A copy of the revised SOP will be posted on the website. The SOP will be effective 60 days after the formal announcement of the revision. The research community will be instructed to destroy any copies (paper or electronic) of the previous version of the SOP. The Office of Research Compliance and Education must maintain all old versions of the institutional SOPs for monitoring/audit purposes. In the event of a regulatory audit, the regulatory agency may audit a study against the SOP that was in effect at the time of study conduct, and thus appropriate documentation must be maintained.

Retraining will occur as described above in Formal Notice and Training

Department/Investigator Level

Each research area ensures that the site procedures, and activities detailed in the SOP accurately reflect how the tasks are performed within their research area. If revisions are required, the Department Chair, Principal Investigator, or other designee must ensure these revisions are made to the SOP and implemented within the research area. Each revision must be labeled as a new version with an effective date listed. The department and/or research team should be instructed to destroy any copies (paper or electronic) of the previous version of the SOP. Documentation of retraining must be maintained. For monitoring/audit purposes, all versions of the SOP must be maintained and is the responsibility of the Department Chair, Principal Investigator, or other designee. In the event of a regulatory audit, the regulatory agency may audit a study against the SOP that was in effect at the time of study conduct, and thus appropriate documentation must be maintained.

7. REFERENCES

- Food and Drug Administration (FDA) Federal Regulations (21 CFR 50, 54, 56, 312, 314, 600, 601, 812 and 814) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
- Department of Health and Human Services (DHHS) Regulations (45 CFR 46 Subparts A, B, C, and D) http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
- International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073122.pdf)
- University Hospitals Case Medical Center (UHCMC) Clinical Policies, Center for Clinical Research and Technology Policies (IRB, Grants & Contracts, Office of Research Compliance), http://www.uhhospitals.org/Research.aspx and UH Compliance and Ethics guidelines. http://www.uhhospitals.org/aboutuh/missionvision/tabid/1806/codeofconduct.aspx

8. FORMS OR ATTACHMENTS

None

APPROVALS

Approved by Carol Fedor, Director, HRPP– December 10, 2014
Approved by Philip Cola –VP, Research and Technology – December 10, 2014