RESEARCH UNIT STANDARD OPERATING PROCURES IN CLINICAL HUMAN SUBJECTS RESEARCH

POLICY

Following regulations and guidance of Office of Human Research Protections (OHRP), Food and Drug Administration (FDA), and the International Conference on Harmonization (ICH), supported by institutional policies and Institutional Review Board (IRB) procedures, the University of Cincinnati (UC) ensures that the rights and welfare of the human subjects of such research will be overseen and protected in a uniform manner, regardless of changes in personnel. In order for the university to ensure compliance with this standard, template Standard Operating Procedures (SOPs) have been develop for use by each department, division, unit, or clinical practice (the “Research Unit”) that engages in clinical research.

DEFINITIONS

Clinical Research Unit – Department, division, unit or clinical practice affiliated with the University of Cincinnati. The Research Unit includes all personnel, including Sponsor-Investigators, involved in the implementation and coordination of investigations involving human subjects by all departments.

Sponsor-Investigator - A Sponsor-Investigator is an individual who both initiates and conducts an investigation, under whose immediate direction of investigational drug(s) or investigational device(s) are administered or dispensed. The term does not include any person other than the individual. The Sponsor/Investigator complies with all the obligations of both a Sponsor and an investigator under (21 CFR §312 Subpart D; 21 CFR §812 Subparts C & E) when there is no corporation, agency, academic institution, or other organization serving as the Sponsor. UC is never the Sponsor as described in 21 CFR §312 Subpart D; 21 CFR §812 Subparts C &E.

Clinical Research: research that

APPLICABILITY

All “Research Units” that engage in clinical research will develop Standard Operating Procedures (SOPs) similar to the template SOPs provided by the Human Research Protection Program. SOPs address how the Clinical Research Unit conducts research ethically, in accordance with good clinical practice, and in keeping with federal, state, and local law and regulations Research Units must review and revise as needed at least annually and . Clinical research SOPs can be found at http://ahc-sharepoint.uc.edu/hrp_policies/Clinical%20Site%20SOP%20Templates/Forms/AllItems.aspx

Any researcher who acts as a Sponsor-Investigator of an IND/IDE will follow the Sponsor Investigator template SOPs for all aspects of the clinical trial(s) as indicated in 21 CFR §312 & 21 CFR §812. These SOP templates can be found at http://ahc-sharepoint.uc.edu/hrp_policies/SponsorInvestigator%20SOPs/Forms/AllItems.aspx
PROCEDURES

1. SOPs will be used in the day-to-day functioning of the researchers/clinical research units to assure subject safety, protocol/regulatory compliance, and to ensure data integrity.

2. The SOPs will be the basis for educating new research staff about the conduct of human subjects’ research.

3. Each clinical research unit shall maintain records demonstrating that all persons engaged in human subjects’ research are appropriately trained in those SOPs.

4. Each approved SOP will include the name of the clinical research unit, an adoption date, and bear the signature of a person within the organization, designated by the department and/or practice corporation, with responsibility for compliance in the area of human subjects’ research.

5. SOPs will be used to guide regulatory agency inspectors, sponsor company monitors or auditors, and HRPP staff as they examine and evaluate the conduct of human subjects’ research.

6. SOPs will be reviewed annually to assure they accurately reflect research processes within UC. Designated topic experts will be asked to assist in the reviews.

7. A record (official) copy of the SOPs will be maintained in at the Research Unit Administration office or designated area.

Applicable Regulations, Documents:

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<th>Adoption Date:</th>
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<th>Date of Revision:</th>
<th>Revised By:</th>
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<tr>
<td>11/05</td>
<td>C. Fabby</td>
<td>7/08</td>
<td>J. Lindwall</td>
<td>Addition of requirement for Sponsor Investigators to adopt IND/IDE Assistance Program SOPs</td>
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<tr>
<td>04/2014</td>
<td></td>
<td>06/2014</td>
<td>A. Braggs-Brown</td>
<td>Update to reflect organizational and website changes</td>
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Date Adopted: June 2014
Signature on signed copy on file