IRB PROCESS FOR FACULTY SPONSORED IND/IDE APPLICATIONS

DESCRIPTION

All research protocols submitted to the University of Cincinnati IRB involving a faculty sponsored IND or IDE application will be reviewed for appropriate documentation prior to review by the IRB and subsequent release of IRB approved documents.

RESPONSIBILITY

The designated HRPP staffs are responsible for ensuring that all appropriate documentation is provided by the faculty sponsor once the IND or IDE study has been identified. IRB approved documents will be held until all appropriate documentation has been received and the Research Compliance Officer or designee has signed the appropriate form indicating that IRB approved documents may be released.

The IRB is responsible for ensuring that the faculty sponsor is knowledgeable about his/her responsibilities, has adequate policies and procedures in place to comply with the FDA regulatory requirements and adequate resources are available to conduct the study.

PROCESS

The procedure for assuring all faculty sponsored IND/IDE studies that are submitted to the IRB for review is as follows:

- The HRPP HPA (Human Protections Administrator) will review the electronic protocol submission to determine if the study involves a faculty sponsored IND/IDE application.
- The HRPP HPA will notify the HRPP Director or designee of all research submissions involving a faculty sponsored IND/IDE application is pending or active.
- The HPA will process the protocol according to IRB procedures. A notation will be made in the HRPP database indicating that the release of the IRB approved documents will not be completed until the appropriate sign-off has been received.
- Written notification indicating all required documents have been received for the faculty sponsored IND/IDE application will be provided to the HPA by the HRPP Director or designee. This notification will be filed in the HRPP database for the applicable study.
The IRB will review the protocol to verify that the investigator is qualified and has proper procedures in place to assume the responsibilities of a sponsor as well as an investigator (if applicable). The IRB will review the submission documents to verify that conflicts of interest (e.g., faculty acting as manufacturers and/or sponsors as well as investigators) is also managed.

Applicable Regulations, Document(s):
Policy # III.08
IRB Procedure # 301
IRB Procedure # 303

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<tr>
<td>07/2008</td>
<td>J. Lindwall</td>
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<td>Changes in department to handle IND/IDE documents</td>
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<td>07/2009</td>
<td>A. Braggs-Brown</td>
<td>Changes to clarify responsibilities and titles of groups responsible</td>
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<td>06/2014</td>
<td>A. Braggs-Brown</td>
<td>Revisions to reflect organizational changes.</td>
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Date Adopted June 2014

Signature signed copy on file