REVIEW BY THE INSTITUTIONAL REVIEW BOARD
WHEN A UNIVERSITY OF CINCINNATI RESEARCHER IS THE LEAD PRINCIPAL INVESTIGATOR OF A MULTI-SITE RESEARCH STUDY

DESCRIPTION

When a University of Cincinnati (UC) researcher serves as the lead Principal Investigator (PI) for a multi-site study, the PI is responsible for ensuring that the research is appropriately approved and conducted at all UC and non-UC sites. This extra responsibility requires additional effort and documentation from the PI.

A multi-site study has one lead site or lead PI, with other site(s) having their own local PI and research team that are not supervised directly by the lead PI. Sites may rely upon their own Institutional Review Board (IRB) for study oversight or may rely upon a central IRB. The UC IRB may serve as the central IRB for participating sites.

RESPONSIBILITY

The UC IRB must ensure that appropriate oversight and documentation requirements for multi-site research are incorporated into the research proposal prior to IRB approval. The UC IRB must also evaluate the progress of the study as indicated by reportable events, amendments and continuing reviews to ensure continued protection of research participants.

PROCESS

INITIAL REVIEW

The UC researcher must submit a standard research proposal to the UC IRB as described in the applicable Human Research Protection Program (HRPP) policies and procedures. The researcher must also include the following information about the non-UC sites.

1. Site-specific information
   a. The name and description of the site, including the address of the physical facility.
   b. The name of a contact person at the site with a phone number and email address where the contact may be reached.
   c. Whether or not the other site has an IRB.
   d. If the site has an IRB, explanation whether it will review the study itself or rely on UC’s IRB using an Institutional Authorization Agreement (IAA) form.
   e. If the research is federally funded, documentation that the site has an FWA.
f. If new sites are added after approval by the UC IRB, research at those sites cannot begin until a modification to add the sites is submitted to the UC IRB and has been approved.

2. Data Safety Monitoring Plan
   If the research involves greater than minimal risk to participants, the lead PI must provide a data safety monitoring plan that includes provision for review of all adverse events and unanticipated problems from all sites where the research is conducted as described in HRPP policies. Results of the data safety monitoring must be provided to the UC IRB at intervals established by the IRB.

The UC IRB shall review the submission in accordance with HRPP policies and procedures. The UC researcher must obtain approval from the UC IRB before sites identified in the protocol may begin study-related activities. The UC researcher is expected to conform to applicable federal regulations, as applicable to the research study.

For a multi-site study involving a Veterans Affairs Medical Center (VAMC), all local site researchers must obtain written approvals from the relevant local VAMC facilities’ IRBs of record and all other local committees, subcommittees, and other approvals according to the respective applicable local, VAMC and other federal requirements. Research cannot be initiated at any given site until the local researcher has obtained written notification that the research can be initiated from the local associate chief of staff for research and development.

CONTINUING OVERSIGHT

1. Amendments (modifications)
   Changes to the approved protocol, attachments, informed consent document, study sites, and any other aspects of the research must be approved by the UC IRB before they may be implemented, as described in HRPP policies and procedures. It is the responsibility of the UC researcher to ensure that appropriate IRB review and approval has been granted before changes are implemented at any non-UC site.

2. Continuing Review (progress reports)
   At the time of continuing review by the UC IRB, the lead PI must provide a summary of research activities at all sites in addition to the usual summary of research activities from the UC site. The UC IRB will review the study in accordance with HRPP policies and procedures. The research study should be closed at all non-UC sites before the lead PI submits the final continuing review to the UC IRB.
Human Research Protection
Program Procedure

3. Reportable Events and Unanticipated Problems
Copies of all adverse events and unanticipated problems from non-UC sites that require changes to the research must be provided to the UC IRB, in accordance with HRPP policies and procedures.

4. The UC researcher will need to retain copies of the following documents in the research file:
   a. Documentation that facilities and equipment at the non-UC site are adequate to conduct the research, including a plan to provide emergency care to participants, if applicable.
   b. If the non-UC site's IRB conducts its own reviews and approvals, a copy of all approval letters from that IRB for initial review and for each amendment and continuing review.
   c. Copies of all continuing review reports submitted by the external IRB to the UC researcher serving as lead PI.
   d. Copies of all adverse events and unanticipated problems submitted by the external IRB to the UC lead PI.
   e. All regulatory documents and correspondence.

Applicable Regulations and Documents:
21 CFR 56.114
45 CFR 46.114
International Conference on Harmonisation, *E6 Good Clinical Practice* guidance
HRPP Policy II.02 *Reporting to the IRB: Unanticipated Problems Involving Risks to Participants or Others, Adverse Events, and Other Problems*
HRPP Policy III.04 *Safety Monitoring in Human Subjects Research.*
HRPP Procedure 303 *Procedures Followed for Conducting Initial Full Board Protocol Review*
HRPP Policy 314 *Modification Submissions and Review by the Institutional Review Board*
HRPP HRP Procedure 316 *Review of Continuing Review (Progress Report) Submissions by the Institutional Review Board*
HRPP Procedure 320 *Review of Reportable Events*

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<tr>
<th>Adoption Date:</th>
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<th>Summary of Revision</th>
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<tbody>
<tr>
<td>11/1005</td>
<td>M. Belskis</td>
<td>07/2009</td>
<td>J. Gerlach</td>
<td>Defined Multi-site study. Revised the information needed from multisite studies.</td>
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<td>12/2013</td>
<td>C. Norman</td>
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<td></td>
<td>Change title from &quot;Review of Multi-Site Research by the IRB&quot; to &quot;Review by the IRB when a UC Researcher is the Lead PI of a Multi-Site Research Study&quot;. Add references to UC policies and procedures and ICH GCP guidance. Revise format and wording for</td>
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Human Research Protection Program Procedure

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<tr>
<th>Date</th>
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<tr>
<td>9/2014</td>
<td>A. Braggs-Brown</td>
<td>Revised to include AAHRPP recommendations</td>
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<td>3/2015</td>
<td>J. Strasser</td>
<td>Revisions for clarification</td>
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Signature: signed copy on file