



## Human Research Protection Program Procedure

**Procedure Number: 303**

**Institutional Review Board Review of New  
Human Subjects' Research Studies**

**Adopted: 3/2005**

**Revised: 10/2016**

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### **INSTITUTIONAL REVIEW BOARD REVIEW OF NEW HUMAN SUBJECTS' RESEARCH STUDIES**

#### **DESCRIPTION**

All human subjects' research being conducted at the University of Cincinnati (UC) must be reviewed and approved by the Institutional Review Board (IRB) as described in Human Research Protection Program (HRPP) Policy III.01 *Review of Human Subjects' Research by the Institutional Review Board*.

#### **RESPONSIBILITY**

The IRB Chair is responsible for ensuring adequate review and IRB oversight of all human subjects' research at UC as described in HRPP Policy III.01 *Review of Human Subjects' Research by the Institutional Review Board*.

HRPP staffs are responsible for managing and facilitating the review process through the electronic Protocol Administration System (ePAS), the IRB's internet-based research management system. HRPP staff shall attend convened IRB meetings as needed.

The Principal Investigator (PI) is responsible for obtaining IRB approval before starting a human subjects' research study.

#### **PROCESS**

HRPP staff shall pre-review submissions for completeness, make the initial determination of review type, and assign IRB member(s) to do the review as described in HRPP Procedure 301 *Administrative Pre-Review of Research Submissions, Initial Determination of Review Type and Assignment of Reviewers*.

The IRB member(s) doing the review shall make the final determination of documents needed, the appropriate type of review. If the IRB member thinks the study needs review by a consultant with specific expertise, expert consultation shall be obtained as described in HRPP Procedure 305 *Inviting Consultants to Review Institutional Review Board Protocol Documents*.

All review processes shall be documented in ePAS. All documentation and correspondence in ePAS shall be visible to all IRB members and HPAA staff.



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Regardless of the type of research or the type of review, approval criteria listed in 45 CFR 46.111 and 21 CFR 56.111 must be satisfied, as described in HRPP Policy III.01 *Review of Human Subjects' Research by the Institutional Review Board*.

### REVIEW METHODS USED BY THE UC IRB

#### **Primary Reviewer System**

The UC IRB uses a primary reviewer system for research reviewed at a convened meeting. The HRPP staff shall assign a Primary Presenter and, if needed, a Secondary Presenter from among the IRB members based on their expertise and availability to present the study at a designated IRB meeting. The Presenter(s) are responsible for explaining the research study at the convened meeting to facilitate review by the IRB. Protocols, informed consent documents, and all other study related materials are provided to non-presenting IRB members through ePAS. Non-presenting IRB members are expected to be familiar enough with the study to participate in discussion at the IRB meeting.

If a Presenter is a member of the study's research team, has a financial conflict of interest with the study's sponsor, or any other conflict of interest, he/she may still present the study but must disclose the conflict and leave the meeting for final discussion and voting as described in HRPP Procedure 102 *Managing Conflicts of Interest of IRB Members and Consultants*.

A Presenter is expected to complete his/her review within 10 business days unless other arrangements are made with the IRB Chair or HRPP staff. Documentation of review by Primary and Secondary Presenters shall be kept in ePAS. All documents and correspondence relating to review of the study shall be visible in ePAS to all IRB members and HRPP staff. Non-presenter IRB members may also add comments to the study's record in ePAS.

#### **Designated Reviewer System**

The UC IRB uses a designated reviewer system for Exempt and Expedited research types, which are reviewed by expedited procedures rather than at a convened meeting. The HRPP staff shall assign a designated reviewer from among the IRB members based on their expertise and availability. The designated reviewer has all the authority of the convened IRB except that he/she may not disapprove a study. A study must be referred to the convened IRB for review before it may be disapproved.



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If a designated reviewer is a member of the study's research team or has a financial conflict of interest with the study's sponsor, or any other conflict of interest, he/she must disclose the conflict and may not be the designated reviewer as described in HRPP Procedure 102 *Managing Conflicts of Interest of IRB Members and Consultants*. He/she may be a secondary reviewer but may not approve the study.

A designated reviewer is expected to complete his/her review within 10 business days unless other arrangements are made with the IRB Chair or HPAA staff. Documentation of review by the designated reviewer shall be kept in ePAS. All documents and correspondence relating to review of the study shall be visible in ePAS to all IRB members and HRPP staff. If a second designated reviewer is assigned or other IRB member wants to add comments, those comments shall be added to the study's record in ePAS.

### ELEMENTS BEING REVIEWED

The IRB member(s) assigned to review a study shall evaluate all aspects of the proposed research study including participant enrollment procedures, selection of participants, consent procedures, provisions to protect the privacy interests of participants, provisions to maintain the confidentiality of data, and additional safeguards to protect the rights and welfare of participants who are likely to be vulnerable to coercion or undue influence to participate in the study. The reviewer(s) shall review all attached documentation that is appropriate for the study including, but not limited to, the protocol, recruitment materials, informed consent document(s), data collection documents, PI's and research team's CV or résumé, conflict of interest disclosure, CITI training, FDA form 1572, IND or IDE documentation, IB, federal grant application, translated materials, and any other correspondence.

### INITIAL REVIEW OF A NEW STUDY

All required determinations listed in 45 CFR 46.111 and 21 CFR 56.111 must be met before a new study may be approved, as described in HRPP Policy III.01 *Review of Human Subjects' Research by the Institutional Review Board*.

1. The protocol must accurately and completely describe the research's purpose, activities, inclusion and exclusion criteria and data analysis. If the protocol is written by the researcher, it must use the protocol template posted on the IRB's website. If the protocol is written by the sponsor or the lead investigator in a multi-site study, it does not need to be re-written to follow UC's protocol template. However, UC-specific information needs to be provided in ePAS, such as the number of participants to be enrolled at UC, recruitment methods to be used at UC, etc.



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Research activities must present the lowest possible risk and the highest possible benefit to participants. Even if the research presents only minimal risk, the PI must make sure the risk is the lowest possible level.

Special consideration must be given to protections for vulnerable participants, including children, pregnant women/fetuses/neonates, prisoners, cognitively impaired subjects or economically or educationally disadvantaged persons.

2. All recruitment materials and data collection materials must be provided. The IRB must review and approve everything the subject will see or hear. If materials are commonly used, such as the Mini Mental Exam, it may be mentioned but not attached.
3. Informed consent document(s) must be consistent with information presented in the protocol and must use the informed consent template posted on the IRB's website, as described in HRPP Procedure 201 *Writing An Informed Consent Document for Human Subject Research*.
4. The UC IRB does not review or approve HIPAA Authorization forms, but does review and approve HIPAA Authorization Waiver requests. Required information is collected in ePAS. If a PI wants a separate HIPAA Waiver form, it may be attached in ePAS.
5. Research involving an investigational drug must have supporting documentation including an Investigational New Drug number (IND), Investigator Brochure (IB), FDA Form 1572 or explanation why they are not available. Research involving an investigational medical device must also have supporting documentation including an Investigational Device Exemption (IDE) number, recommended Significant or Non-Significant Risk determination or explanation why they are not available.
6. If the research will be conducted at a non-UC location, such as a public school classroom or a physician's office, documentation from the site giving the PI permission to do the research at the site is required. This "site support letter" may be a formal letter, informal note or email but the name and title of the person giving permission must be clearly provided.
7. If recruitment, consent or data collection will be conducted in a language other than English, the initial submission should only include the English version of all



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documents. After the English version has been approved, translation of the appropriate documents should be done.

For medical studies, a professional translation service must be used because of the technical terminology that may be used. A certification of translation from the service must be provided to the IRB.

For non-medical studies, a professional translation service is not required; however, translations should be performed by translators who have an adequate understanding of the purpose of the document and the technical points to be covered in the documents. The consent form must be translated into the non-English version by one translator and then translated back into the English version by another translator. The person translating the non-English version back into English must not be a member of the research team or one of their family members. The person doing the back-to-English translation must provide their name and contact information in case the IRB has questions.

8. The PI and research team must have sufficient experience and resources to conduct the research as described. If the PI is a student, a UC faculty advisor must be listed as part of the research team.
9. The HRPP staff will schedule a Full-Board study to an IRB meeting date. All IRB members who will be attending that meeting are expected to review study documentation posted in ePAS so they will be able to participate in review at the meeting but only the Primary and Secondary Presenters are expected to post their reviews in ePAS. After the meeting, the HRPP staff assigned to the study will manage correspondence with the PI in ePAS until all IRB requirements for approval have been met and the approval notification has been posted in ePAS.

The HRPP staff will not schedule an Exempt or Expedited study to an IRB meeting. Instead, the designated IRB reviewer is expected to post his/her review in ePAS. If there is a second IRB reviewer, his/her comments may be posted in ePAS but does not require a formal review form. The HRPP staff assigned to the study will manage correspondence with the PI in ePAS until all IRB requirements for approval have been met and the approval notification has been posted in ePAS.

If an advocate for a vulnerable population such as children or prisoners needs to provide review, documentation of the review shall be posted in ePAS.



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HPAA staff shall keep track of the number of new studies to be reviewed at a convened IRB meeting. Every effort shall be made to allow sufficient time for thorough discussion of each study by the IRB. HPAA staff may notify the PI of the meeting date when the study will be discussed so the PI can be available by phone to answer questions from the Board, if necessary. A PI may request a date that suits his/her schedule.

### **Applicable Regulations and Document(s):**

21 CFR 56.111

45 CFR 46.111

Policy III.01 *Review of Human Subjects' Research by the Institutional Review Board*

Procedure 102 *Managing Conflicts of Interest of IRB Members and Consultants*

Procedure 301 *Administrative Pre-Review of Research Submissions, Initial Determination of  
Review Type and Assignment of Reviewers*

Procedure 305 *Inviting Consultants to Review Institutional Review Board Protocol Documents*

Procedure 307 *IRB Review of Research at a Convened Meeting*

