



Human Research Protection Program Policy

Policy Number: III.01
**Review of Human Subjects' Research by the
Institutional Review Board**
Adopted: 11/2005 **Revised: 03/2015**
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REVIEW OF HUMAN SUBJECTS' RESEARCH BY THE INSTITUTIONAL REVIEW BOARD

POLICY

The University of Cincinnati (UC) Institutional Review Board (IRB) is authorized by UC's Institutional Official (IO) to review human subjects' research projects and clinical investigations. All UC faculty, students, staff, or other representatives of the University must submit for UC IRB review any human subjects research project, regardless of funding source (or lack thereof) and/or location at which the research will be conducted. UC IRB approval or acknowledgement is required before a project may begin.

This policy shall apply to all human subjects research:

1. Conducted by or under the direction of any University employee or agent of the University in connection with his/her institutional responsibilities; or
2. Conducted by or under the direction of any University employee or agent of the University using any University property or facility; or
3. Involves the use of the University's non-public information to identify or contact human research subjects or prospective subjects.

Under no circumstance will the University take on the role as Sponsor, "a person or other entity that initiates but does not actually conduct the investigation" as defined by the regulations 21 CFR 312.3 (b) and 812.3(n).

CRITERIA FOR APPROVAL

The IRB's primary responsibility is to protect the rights and welfare of human research participants. These criteria are based on the principals of justice, beneficence, and autonomy as discussed in the Belmont Report. Except for research that is exempt or waived under 45 CFR 101(b) or 45 CFR 101(i), all human subjects research conducted by the Institution will be reviewed, prospectively approved, and subject to continuing oversight and review by the UC IRB. The IRB must determine that all of the following requirements listed in 45 CFR 46.111 and 21 CFR.56.111 are satisfied.

- (1) Risks to participants are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk; and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.



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- (2) Risks to participants are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits that participants would receive even if not participating in the research).
- (3) Selection of participants is equitable, taking into account the purposes of the research and the setting in which the research will be conducted, and the inclusion/exclusion criteria so that burden is fair and equitable and benefits are maximized. The IRB shall evaluate the recruitment and enrollment practices, in addition to the amount and timing of payments to participants. The IRB will be cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, and others, as designated by the IRB, the selection criteria, and the recruitment procedures.
- (4) Scientific or Scholarly Review by qualified individuals(s) has demonstrated that (a) the research uses procedures which are consistent with sound research design; (b) the research design is likely to answer the proposed scientific question, and (c) the importance of the knowledge expected to result justifies approval of the research. For Veterans Affairs Medical Center (VAMC) research, scientific review is conducted by the VAMC Research and Development Committee. Revisions to the study based on VAMC Research and Development Committee review is communicated as an amendment to the IRB.
- (5) In addition, the IRB should determine if the investigator has sufficient time to conduct and complete the research and that the investigator has adequate staff and other resources, including facilities, to conduct the research.
- (6) For VAMC research, non-veterans will only be allowed to enter VAMC-approved research studies when there are insufficient veterans available to complete the study.
- (7) Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116 and 21 CFR 50.20, the law of the state where the research is conducted, and as required by university policy.
- (8) Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117 and 21 CFR 50.20, with the law of the state where the research is conducted, and in accordance with and to the extent required by university policy.
- (9) When appropriate, the protocol makes adequate provision for monitoring the data collected to ensure the safety of participants.



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(10) When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

(11) When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as fetuses, pregnant women, and human in vitro fertilization (45 CFR 46 Subpart B), prisoners (45 CFR 46 Subpart C), and children (45 CFR Subpart D), mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

(12) For certain types of research, it may be appropriate to involve individuals from the community in which the research will take place. When reviewing such research, the IRB may consider the following, as pertinent to the type of research proposed:

- The appropriate community, and community representatives have been identified
 - The research plan involves collaboration and communication between researchers and community in research design, conduct, and dissemination of results as appropriate
 - It is recognized that the design and conduct of each phase of the research may be a somewhat iterative process, as researchers and community members gain knowledge and familiarity with the process
- Additional expertise will be called upon as needed to provide input on cultural or local context, or other special circumstances
- In addition to traditional research publication routes, results will be disseminated in ways that are accessible and intelligible to the community involved in the research
- Possible impacts of the research on the community beyond the life of the current project are addressed.

THE UNIVERSITY OF CINCINNATI IRB

The UC IRB reviews all human subjects research involving investigational drugs, biologics, devices, and other medical and surgical interventions as well as all non-medical research projects. The IRB Chair is responsible for ensuring that the IRB has appropriate expertise present at the meeting to review studies being considered. The IRB Chair is also responsible for ensuring that the appropriate vulnerable population advocate is present if a study being considered includes a vulnerable population. All research under this policy must be reviewed at a convened meeting, scheduled and timed according to submission volume and IRB member availability, of the UC IRB unless the IRB determines the research qualifies for expedited review or exempt status as described in 45 CFR 46.101 and 45 CFR 46.110. The IRB meetings are scheduled to occur once a week with the fifth week acting as a training period for continuing



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IRB member education. The schedule of meetings, although subject to change, is posted on the website.

REVIEW OF RESEARCH

The IRB shall have the authority to:

- Approve research, require modifications to secure approval of human subjects research, or disapprove all research activities subject to this policy;
- Suspend or terminate approval of human subjects research not being conducted in accordance with federal requirements or the university's policies and procedures governing human subjects research or that had been associated with unexpected serious harm to participants;
- Observe, or have a third party observe, the consent process and the conduct of the human subjects' research;
- With approval of the Institutional Official, suspend or terminate an investigator's privilege to conduct human subjects research in the face of serious or continuing non-compliance with applicable rules, policies, or law.

For research to be approved at a convened meeting it has to receive the approval of a majority of members present at the meeting and at least one unaffiliated member must be present. There must also be at least one member who represents the general perspective of participants is present for convened meetings. If the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, other than prisoners or children which are included in policy, one or more individuals who are knowledgeable about or experienced in working with such participants are present. For example, pregnant women or handicapped or disabled persons should be represented.

For VAMC research:

The IRB is required to determine whether the medical record must be flagged to protect the participant's safety by indicating participation in the study and the source of more information on the study. The IRB does not require medical records to be flagged if:

- Participation in the study involves only one encounter.
- Participation in the study involves the use of a questionnaire or previously collected biological specimens.
- Identification as a study participant places the participant at greater than minimal risk (in a minimal risk study).



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New protocols, modifications of approved research, and continuing review of approved research may be reviewed and approved under an expedited procedure or at a convened meeting.

The IRB will notify researchers in writing of its decision to approve or disapprove the proposed research or of modifications required to secure IRB approval. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

Research may only be disapproved at a convened meeting, as described in 45 CFR 46.109(d).

CONTINUING REVIEW

The IRB will conduct continuing review of research as described in HRPP Policy III.09 *Continuing Review of Research*. Intervals between review will be appropriate to the degree of risk, but not less than once per year for federally funded non-exempt studies. The IRB may, at its discretion, extend the interval between review up to 2 years for non-federally funded research. The IRB may require more frequent reviews based on the degree of risk, the inclusion of any vulnerable populations, occurrence of problems with the research, and any prior determination of noncompliance by the researcher(s).

CONSULTANTS

When the IRB or the IRB Chair determines that there is not at least one member with sufficient expertise among the membership to review a human subjects research protocol, the IRB Chair must obtain an individual or individuals with appropriate expertise review and comment on the human subjects research as described in Procedure 305 *Inviting Consultants to Review Institutional Review Board Protocol Documents*

CONTINGENT APPROVALS

When the convened IRB is able to stipulate specific revisions that require simple concurrence or changes to the study by the investigator, the IRB may determine that the IRB Chair or other IRB member may administratively review the revised research protocol on behalf of the IRB.

When the convened IRB requests non-directive or substantive modifications regarding the protocol or informed consent documents that are directly relevant to the determinations required by the IRB under HHS regulations at 45 CFR 46.111, IRB approval of the proposed research must be deferred, pending subsequent review by the convened IRB of responsive material.



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These approval processes are described in Procedure 307 *IRB Review of New Research Proposals at a Convened Meeting*

FURTHER APPROVALS

Human subjects research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the university. However, those officials may not approve the human subjects research if it has not been approved by an IRB.

DOCUMENTATION

For research to be approved at a convened meeting it has to receive the approval of a majority of members present at the meeting and at least one unaffiliated member must be present. There must also be at least one member who represents the general perspective of participants is present for convened meetings. If the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, other than prisoners or children which are included in policy, one or more individuals who are knowledgeable about or experienced in working with such participants are present. For example, pregnant women or handicapped or disabled persons should be represented.

The agenda will serve to inform the IRB members of research protocols approved using the expedited process. The expiration date on the approval letter is the first date that the protocol is no longer approved. The expiration date is calculated from the date of approval. The approval period may not exceed one year for federally funded non-exempt studies, or two years for non-federally funded non-exempt studies.

The minutes of the IRB meetings shall document quorum, separate deliberations, actions, and votes for each protocol under review. The IRB staff will make the minutes available to the IRB members for review. Minutes will be approved at a convened IRB meeting. The approved minutes will be made available to UC's IO and UC's Director of the Office of Research Integrity (ORI). Approved minutes are also made readily available to relying IRBs and institutions.

VAMC RESEARCH

When a study involves "usual care," in the protocol or a separate document in the IRB application the researcher must clearly designate the individual or entity (e.g., the appropriate research personnel versus the subject's health care provider) responsible for relevant aspects of both the research and the usual care.



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The patient medical record must be flagged if the participant's participation in the study involves:

- Any invasive research procedure;
- Interventions that will be used in the medical care of the participant, or that could interfere with other care the participant is receiving or might receive;
- Clinical services that will be used in the medical care of the participant, or that could interfere with other care the participant is receiving or might receive;
- The use of a survey or questionnaire that might provoke undue stress or anxiety unless that IRB determines that mandatory flagging is not in the best interest of the participant.

In other situations, the IRB determines whether flagging is necessary. The IRB might require the medical record to be flagged if:

- Participation in the study involves only one encounter.
- Participation in the study involves the use of a questionnaire or previously collected biological specimens.
- Identification as a participant in a particular study will place the participant at greater than minimal risk.

If the IRB determines and documents that the patient health record must be flagged in Computerized Patient Record System (CPRS) as participating in a research, then the health record must identify the researcher, as well as contact information for a member of the research team that would be available at all times, and contain information on the research study or identify where this information is available. The duration of flagging is determined by local policy.

Applicable Regulations and Document(s):

45 CFR 46.101, 46.107-112, 46.114-117

45 CFR 46 Subparts A, B, C and D.

21 CFR 50.20, 50.3(g),

21 CFR 56.102 (e), 56.103, 56.107-112, 56.115

21 CFR 312.3(b) and Part 812.3(p)

Cincinnati VAMC HRPP SOP (May 12, 2014), page 14, 24, 28

Policy III.09 *Continuing Review of Research*

HRPP Procedure 303 *Procedures Followed for Conducting Initial Full Board Protocol Review*

HRPP Procedure 305 *Inviting Consultants to Review IRB Protocol Documents*

HRPP Procedure 307 *IRB Review of New Research Proposals at a Convened Meeting*

HRPP Procedure 311 *Minutes of Convened Institutional Review Board Meeting*

HRPP Procedure 314 *Review of Modification Submissions by the Institutional Review Board*



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HRPP Procedure 316 *Review of Continuing Review Submissions by the Institutional Review Board*
 University Rule 10-17-10 *Ethical Conduct in Research Involving Human Subjects*

Adoption Date:	Created by:	Date of Revision:	Revised By:	Summary of Revision:
11/2005	L. Harpster	04/07	M. Linke	Clarify contingent approvals and follow-up required.
04/07	L. Harpster	07/08	J. Lindwall	Removal of policy applying to research sponsored by the University
		07/09	J. Gerlach	Revised text, removed web addresses, removed mention of department head or chair sign-off for scientific review.
		1-22-2014	C. Norman	Change reference to 3 IRBs into 1 IRB, clarify expertise at a meeting, change method for making minutes available for review, update title, corrections to regulations being referenced.
		5/2014	A.BraggsBrown	Revised to reflect organizational changes
		09/2014	A.Braggs-Brown	Revised to address AAHRPP recommendations
03/2015		03/2015	J. Strasser	Revisions for clarification

Date Adopted March 2015 Signature signed copy on file