CONTINUING REVIEW BY THE IRB

POLICY

The University of Cincinnati Institutional Review Board (IRB) shall conduct continuing review of human participant research at intervals appropriate to the degree of risk. Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn. All human participant research that is federally funded and/or more than minimal risk must be reviewed no less than once per year [45 CFR 46.109(e) and 21 CFR 56.109(f)]. Continuing review may occur earlier than the scheduled interval at the discretion of the IRB. Continuing review of minimal risk studies that are not federally funded may be occur at intervals up to 2 years at the discretion of the IRB.

Continuing review shall meet the same criteria for approval as initial review. Continuing review may use the expedited process or undergo full board review as described in the federal and institutional guidelines.

IRB approval may be withdrawn at any time if the IRB becomes aware that the conditions for approval are not being met. Federal regulations authorize the IRB to establish procedures for the monitoring of research activities involving human participants.

IRB approval for the conduct of a research project may be revoked if the risks to the participants are determined to be unreasonably high, for example, in cases in which there is more than an expected number of adverse events, unexpected serious adverse events, the Principal Investigator (PI) and/or research staff have not completed the educational requirements, or there is evidence that the research is not in compliance with IRB or Institutional guidelines.

Such findings may result in more frequent review of the research project to determine if approval should be withdrawn or enrollment stopped until corrective measures can be taken or the research project terminated.

Continuing review may include, but may not be limited to the following activities:

- Site visits and/or third party verification
- Review of serious and unexpected adverse events and unanticipated problems resulting in risks to participants or others
- Review of significant new findings
- Amendments
PROCESS

SUBMISSION BY THE PI
The PI shall submit all documentation required by the IRB in sufficient time to permit review and approval by the IRB before the expiration date.

ADMINISTRATIVE PRE-REVIEW

The Human Protections Administrator (HPA) shall prepare submitted documentation for review by the IRB and communicate the IRB's determination to the researcher in writing. The IRB members determine that the current consent document is still accurate and complete.

IRB CHAIR OR DESIGNEE REVIEW (EXPEDITED PROCESS)

If the continuing review qualifies for expedited review, the IRB Chair or designee shall thoroughly review all research documentation and reported activities since initial approval with particular attention to adverse or unanticipated events and recent findings that may impact participants' willingness to continue in the research to assure approval criteria are met. Under the expedited review procedure, the Chair or designee exercises all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in 45 CFR 46.108(b), 45 CFR 46.110(b), and 21 CFR 56.110(b).

FULL BOARD REVIEW AT A CONVENED MEETING

All IRB members (including alternate members) scheduled to attend a given IRB meeting are provided and review:

- The full protocol, application, or a protocol summary containing the relevant information necessary to determine whether the proposed research continues to fulfill the criteria for approval.
- The current consent document.
- Any newly proposed consent document.
- A status report on the progress of the research.

For continuing review of research, at least one IRB member is provided and reviews the complete protocol, including any protocol modifications previously approved by the IRB.
The continuing review submission will include a summary of the following since the last IRB review:

- Number of participants accrued.

- A summary since the last IRB review of:
  - Adverse events, untoward events, and adverse outcomes experienced by participants.
  - Unanticipated problems involving risks to participants or others.
  - Participant withdrawals.
  - The reasons for withdrawals.
  - Complaints about the research.
  - Amendments or modifications.
  - Any relevant recent literature.
  - Any interim findings, and
  - Any relevant multi-center trial reports.

- The researcher’s current risk-potential benefit assessment based on study results.

If the continuing review qualifies for review by the full IRB at a convened meeting, the IRB Chair or designee shall thoroughly review all research documentation and reported activities since initial approval with particular attention to adverse or unanticipated events and recent findings that may impact participants’ willingness to continue in the research and shall present the research study to the IRB members for their substantive review of the research study at a convened meeting to assure approval criteria are met.

**Site Visits, Audits and Third Party Verification**

The IRB has authority to observe or have a third party observe the consent process and the research to assure conditions for reapproval are being met [45 CFR 46.109(e) and 21 CFR 56.109(f)]. At its discretion, the IRB also may request a site visit or audit of the research or obtain information from non-UC sources. Sponsors may be asked to submit copies of monitoring reports. The IRB may conduct interviews with screened or enrolled participants as deemed necessary.

The IRB may request a site visit in any situation where they believe verification should be required. The following criteria will increase the likelihood that IRB require a site visit or third party verification:

- The research involves vulnerable populations or high risk procedures.
- The PI has a history of serious or continuing non-compliance. The IRB has reason to doubt the veracity of the information provided by the investigator.
Human Research Protection Program Policy

- The information provided by the investigator is inconsistent with other information known to the IRB and the inconsistency cannot be readily resolved through communication.

HRPP Procedure 314 Submission to and review of Amendments by the IRB describes review of protocol modifications and HRPP Policy II.02 Reporting to the IRB: Unanticipated Problems Involving Risks to Participants or Others, Adverse Events, and Other Problems describes reporting and review.

EXPIRATION OF IRB APPROVAL

If continuing review and reapproval does not occur before the expiration date of IRB approval, all research-related activity must cease unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. Enrollment of new subjects cannot occur after the expiration of IRB approval.

The expiration date is the first day the protocol is no longer considered an approved study by the IRB. If, after expiration of IRB approval, the IRB approves resumption of the study, the approval and expiration dates will be determined as for initial approvals.

VAMC RESEARCH

When research is conducted at Veterans Affairs Medical Centers (VAMC) the PI must submit the following for continuing review of research by a convened IRB:

- A brief summary of the research methodology;
- The gender and minority status of those entered into the protocol, when appropriate;
- The number of participants considered as members of specific vulnerable populations;
- Information that might influence the risk - potential benefit relationship; such as serious adverse events and complaints regarding the research;
- Summaries, recommendations, or minutes of the data monitoring committee meetings (if applicable) or findings based on information collected by the data and safety monitoring plan submitted in the initial proposal;
- An assurance that all identified unanticipated internal or local serious adverse events, whether related or unrelated to the research, have been reported as required to the IRB of record;
- A summary of all unanticipated problems involving risks to participants or others, and all internal or local serious adverse events;
- A statement signed by the researcher certifying that all participants entered onto the master list of participants for the study signed the consent document prior to undergoing
any study interactions or interventions, unless the IRB has granted a waiver of the consent process or a waiver of the requirement for a signed consent document.

For all VAMC research operating under UC IRB oversight if information required for continuing review is not submitted to the IRB and the IRB is unable to approve the protocol by the study expiration date, the following will occur:

- All research activities will stop, including, but not limited to, enrollment of new participants and continuation of research interventions or interactions with currently enrolled participants, and data analysis;
- The PI will immediately submit to the IRB Chair a list of research participants who could be harmed by stopping study procedures; and
- The IRB Chair, with appropriate consultation with the chief of staff, will determine whether participants on the list may continue participating in the research interventions or interactions.

Applicable Regulations and Documents:
45CFR46.109(e)  
21CFR56.109(f)  
45CFR46.110(b)  
21CFR56.110(b)  
45CFR46.113  
21CFR56.113  
OHRP Guidance on Continuing Review (January 15, 2007)  
HRPP Policy III.01 Review by the Institutional Review Board of Human Subjects Research  
HRPP Policy III.02 Review of new Human Subjects Research Submissions by the IRB  
HRPP Procedure 307 Institutional Review Board Review of Research at a Convened Meeting  
HRPP Procedure 314 Submission to and review of Amendments by the IRB  
HRPP Procedure 316 Review of Continuing Review Submissions by the Institutional Review Board
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Date Adopted: **March 2015**    Signature: **signed copy on file**