1.0 **Purpose:** This rule establishes guidelines and mechanisms for continuing review of human research activities. This rule is to ensure that investigators and their study staff along with UMCIRB members know what is expected when continuing review is due for human subject research.

2.0 **Research Protocols Affected:**

2.1 Human research activities reviewed and approved by the UMCIRB (does not include Exempt categories of research).

3.0 **Rule:** Research studies, excluding those studies with an exempt status, are given an approval period appropriate to their degree of risk and extend for no longer than 365 days. Enrollment and study related procedures may not occur in any research study outside of the approval dates. Continuing review may stop only when the research is permanently closed to the enrollment of new subjects, all participants have completed all research-related intervention or activities, and collection and active analysis of private identifiable information has been completed. Once this occurs, a final report is required.

4.0 **Definitions:**

4.1 **Human participant:** a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

4.2 **Research:** a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

5.0 **Responsibilities:**

5.1 **Principal Investigator (PI)** will ensure research studies maintain current UMCIRB approval. Notices for an upcoming continuing review will be generated within ePirate and sent to the study team prior to the research study expiration date. Although the UMCIRB office will assist the investigator by communicating the need for continuing review, it is primarily the responsibility of the Principal Investigation and, therefore, recommended for the principal investigator to establish a reliable system within their office to track upcoming expiration dates.

5.1.1 Complete and submit the continuing review application at least 30 days prior to the date of expiration to allow time for appropriate IRB review before the study approval expires.

5.1.2 Research studies that are allowed to expire will be designated as Expired in ePirate. Study team members will receive a notification, generated by ePirate, of the study expiration via email. This information is available to the relevant institutional leadership, relevant human protections administrator, ECU signatory official and relevant UMCIRB committee.

5.2 **Office for Human Research Integrity (OHRI)** will provide assistance and guidance in training research team members and IRB members in the proper method of conducting continuing
Continuing Review

5.2.1 ePirate will generate reminders of pending study expiration at the approximate time points prior to the date of study expiration: 75, 50, 30, 15 days. A study expiration notice will be generated should the study approval expire. These notices will be sent to study team members listed on the IRB application.

5.2.2 OHRI staff will review continuing review application for completeness prior to IRB review.

5.3 **OHRI Administrative Director or designee** will ensure compliance with this policy.

5.3.1 The Administrative Director or designee will inform study team members and IRB members about any new regulation or guidance necessary to conduct a successful continuing review.

5.4 **UMCIRB Chairperson or designee** will review and approve research studies that are eligible for expedited continuing review.

5.4.1 Any research study requiring medical judgment must have a reviewer with an appropriate health care training or background. A "no more than minimal risk" research study eligible for expedited review that involves an FDA regulated test item must receive continuing review by a biomedical UMCIRB Chair or designee.

5.5 **UMCIRB Committee** will review and approve research studies requiring review by a convened IRB.

5.5.1 A primary reviewer will be assigned to present the continuing review to the committee with emphasis on the number of subjects enrolled, any problems that occurred during the prior approval period, and any changes being requested as a part of the current renewal.

6.0 **Procedures:**

6.1 Projects that were initially reviewed by the convened IRB continue to receive the same type of review unless the IRB determines that the study meets the criteria for expedited review. Research approved previously by expedited review is considered eligible for expedited review at the time of its regular continuing review if, during the course of the study, the risks of the study have not increased.

6.2 The approval periods for studies renewed at the convened UMCIRB meeting will start on the date approved by the convened UMCIRB committee (even if minor modifications eligible for review by the UMCIRB Chairperson or designee are requested by the UMCIRB committee). The approval period for studies renewed by expedited procedures will start from the date of final approval by the reviewer.

6.2.1 It is the goal of the UMCIRB/OHRI for studies to undergo review during the month prior to their expiration. This is an effort to minimize studies missing an opportunity for full review if a meeting should be cancelled or other extenuating circumstances should arise. In the case of continuing review prior to the expiration date, the UMCIRB will reset the approval date and period. The UMCIRB is aware that this will disrupt the original date of approval. Should a sponsor request justification, this Rule can be provided.

6.3 The investigator will receive an approval letter routinely within 5 to 7 business days for expedited continuing review approvals. Investigators whose continuing review must be approved by the convene UMCIRB will receive a letter within 2 days of the IRB meeting. Final approval is not granted until all required changes have been made and submitted for review and approval. Approved informed consent documents will include the approval dates on each page. Informed consent documents will not be stamped for research studies no longer enrolling participants.

6.4 Expedited reviews are reported to UMCIRB members and other appropriate officials within
UMCIRB minutes.

6.5 If some element of the research study must continue in order to protect the safety and well-being of human participants, the UMCIRB must be notified in writing as soon as possible to determine the appropriate course of action. The UMCIRB chair or his/her designee may permit continued research intervention in already enrolled participants, but may prohibit enrolling any new participants into the research until the study has been reapproved. Restrictions may be placed on data collected outside of the UMCIRB approval period. The UMCIRB will not provide retrospective approval for a lapse in study approval. It is not the intention of the UMCIRB to create any situation that would endanger the safety and well being of human participants or cause harm, but it is vital to the protection of all participants that research fully comply with federal and institutional policies.

6.6 The UMCIRB committee, OHRI or other institutional officials may request an interim report or simple update on the study progress for any active study for reasons such as breaking news items.

6.7 The following are examples of factors the UMCIRB committee considers when setting the approval period:

- Studies with significant risk medical devices
- Early phase studies such as Phase I and II
- Investigator experience or mentor oversight
- Evidence of previous or current noncompliance
- Studies with vulnerable populations
- Interim data analysis and data monitoring plans
- Non-externally sponsored research studies
- Rate of proposed enrollment or proposed sample size
- Proposed study location

In specifying an approval period of less than one year, the IRB may define the period with either a time interval or a research milestone, e.g., number of participants enrolled. The minutes should clearly reflect any determination requiring a review more frequently than annually.

6.8 UMCIRB has the authority to request verification from sources other than the investigator or research staff that no material changes have occurred since the previous IRB review. This request will be copied to the Principal Investigator and will occur when there is sufficient evidence to warrant third party verification. Examples of when the UMCIRB may seek such verification include, but are not limited to:

- There is a complex project involving unusual risks or the high probability and magnitude of anticipated risks to participants;
- The proposed participants have a medical condition that is potentially terminal or life threatening;
- The likely emotional condition of the proposed participants;
- The probable nature and frequency of changes that may ordinarily be expected in the type of research proposed;
- Prior experience with the principal investigator and research team; or
- Any other factors that the IRB deems relevant

6.8.1 The IRB has the authority to obtain this verification by reasonable methods which include, but are not limited to:

- Conducting audits or inquiries to collect information about the conduct of the research;
• Observing or having third parties observe the consent process and/or the conduct of the research; or
• Any other method the IRB deems appropriate

7.0 Revision History:

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<tr>
<th>Date</th>
<th>Revision #</th>
<th>Change</th>
<th>Reference Section(s)</th>
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References

FDA. Code of Federal Regulations:

DHHS, OHRP. Code of Federal Regulations:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.109