

<b>Continuing Review</b>	Effective:	7.12.2012
	Revised:	1.21.2019

**1.0 Purpose:** This standard operating practice (SOP) 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 and provided with an expiration date.

**3.0 SOP:** Research studies that have been reviewed by the IRB (or the IRB Chair/designee) and approved for a limited period (i.e. has been assigned an expiration date) may not continue past the expiration date. Enrollment and study related procedures may not occur in any research study outside of the approval dates. For a study to continue past the expiration date, it must be reviewed by the IRB (or the IRB Chair/designee) and approved for continuation.

**4.0 Definitions:**

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

(1) Information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens, or

(2) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

4.2 **Research** is 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.

4.3 **Continuing Review** is the process by which research studies get renewed. Also an activity within the electronic IRB submission system that allows the PI (or other study team member) to renew their study.

**5.0 Responsibilities:**

5.1 Principal Investigator (PI) will ensure research studies maintain current UMCIRB approval. Notices for an upcoming study expiration will be generated from the electronic IRB submission system 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 the electronic IRB submission system. Study team members will receive a notification,

generated by this system, of the study expiration via email. This information is also available to the relevant institutional leadership, human protections administrators, signatory officials and UMCIRB committee.

- 5.2 UMCIRB Office staff will provide assistance and guidance in training research team members about when continuing review is required and how to submit a Continuing Review, and IRB members in the proper method of conducting continuing review.
  - 5.2.1 The electronic IRB submission system 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 UMCIRB office staff will review continuing review applications for completeness prior to IRB review.
- 5.3 UMCIRB 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 Research initially reviewed by the convened IRB will continue to receive review by the convened committee unless the IRB determines that the study meets the criteria for expedited review. Research approved previously by expedited review that has an expiration date 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.
  - 6.1.1 Expedited categories of research with no expiration date will only require a Final Report to be submitted once the study can be closed (see Study Completion and Closure SOP).
- 6.2 The approval periods for studies renewed at the convened UMCIRB meeting will appear on the approval letters and 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 UMCIRB Chair (or designee).
  - 6.2.1 It is the goal of the UMCIRB 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 date stamped for research studies no longer enrolling participants.
- 6.4 Expedited continuing reviews are reported to UMCIRB members and other appropriate officials within UMCIRB minutes.
- 6.5 If some element of the research study must continue after it has expired and before it will be renewed, 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 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, staff 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

#### Revision History:

Date	Change	Reference Section(s)
1.21.2019	Updated to reflect revised regulations removing requirements for continuing review of Expedited categories of research; added revised definitions.	Sections 2.0-6.0

#### References

FDA. Code of Federal Regulations:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=56.109>

DHHS, OHRP. Code of Federal Regulations:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.109>