1. PURPOSE
   1.1. This policy establishes the process for continuing reviews. Beginning July 19, 2018, unless otherwise determined by the IRB, annual Continuing Review will no longer be required by default for ongoing research originally approved through Expedited Review.

2. REVISIONS FROM PREVIOUS VERSION
   2.1. None

3. POLICY
   3.1. Unless the IRB determines otherwise, continuing review of research is not required for research subject to the revised Common Rule in the following circumstances:

      3.1.1. Research eligible for expedited review in accordance with §__.110;

      3.1.2. Research reviewed by the IRB in accordance with limited IRB review as described in IRB-130 Exempt Determinations and Limited IRB Review;

      3.1.3. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

         a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, **or**
         b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

   3.2. The IRB may determine that continuing review is required for any research protocol that falls within 3.1 if the research protocol is:

      3.2.1. Required by other applicable regulations (e.g., FDA);

      3.2.2. The research involves topics, procedures, or data that may be considered sensitive or controversial;

      3.2.3. The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability;

      3.2.4. An investigator has minimal experience in research or the research type, topic, or procedures; and/or

      3.2.5. An investigator has a history of noncompliance

3.3. If the IRB determines that continuing review is required for such research, it will document the rationale in the IRB record and communicate the requirement to the investigator.

3.4. Research protocols requiring continuing review

3.4.1. The IRB will generate a continuing review reminder notice and sends to PI and if the student is the PI, the faculty advisor approximately 4-6 weeks prior to the study's expiration date, with a due date approximately 2 weeks prior to current study approval expiration.

3.4.2. IRB staff will enter the submission data into the data management system and conduct an administrative review on the submission to determine accuracy and completeness. Investigators may be contacted and required to provide missing documentation, revisions, and/or clarifications.

3.4.3. The continuing review submission is reviewed by the convened IRB or an Expedited Reviewer (if necessary for an Expedited Review). The criteria for approval of research with continuing review are the same as for initial review (see IRB-100: Initial Review). The review will be documented in the IRB record.

3.5. The Principal Investigator is ultimately responsible for completing the appropriate continuation request and submitting it to the IRB for processing by the due date.

3.5.1. If a request for continuation is not submitted by the return due date, the IRB may follow up with additional notices and a new due date.

3.5.2. If a completed continuing review fails to be submitted to the IRB, or the IRB has not reviewed and approved a research study by 11:59 p.m. on the expiration date set by the IRB, the current approval expires automatically and research activities including (but not limited to) recruitment, enrollment, data collection, and data analyses must stop, unless the IRB finds that there is an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating in the research interventions or interactions.

3.5.3. Expiration of IRB approval does not need to be reported to federal regulators at the Office of Human Research Protections (OHRP) under DHHS regulations.

3.6. In order for an expired protocol to regain approved status, the IRB must conduct a review and approve the protocol.

3.7. Research protocols not requiring continuing review may be still be required to submit information as requested by the IRB. For example, the IRB may conduct status inquiries to determine whether the IRB record may be closed or remain open.