

## Deadline & Submission Information Sheet

**Deadlines:** More than minimal risk research proposals that require full committee review must be in the UMCIRB office by specific dates to be placed on the agenda. The deadlines for both the Biomedical Review Board and the Behavioral/Social Sciences Review Board are located at: <http://www.ecu.edu/irb/BioBSS.html> Exempt or expedited research proposals may be received in the UMCIRB office **any** time. To determine whether a research study may be exempt or expedited, visit these categories on our website under Tips & Tools or go to the following link:  
<http://www.ecu.edu/irb/docs/exempt%20and%20expedited%20categories%2002-05-04.doc>

**Revisions:** Any changes to the protocol, consent form or research process must have UMCIRB approval. Requests for changes (amendments) to approved studies may be promptly submitted at any time during the approval period and, before the change is implemented, it must receive UMCIRB approval. The need for protocol changes to be submitted as revisions includes one-time protocol exceptions issued by the sponsor. The only exception to this order of approval is when a protocol change is required to protect subjects from an immediate hazard. If a change is required to prevent an immediate hazard, then this revision must be submitted to the UMCIRB office as soon as possible after the change is implemented in the single participant, so that it may be approved for future participants. A rationale must be supplied by the investigator for any delays in submitting revisions to a research study. The approval date for a revision does **not** extend the approval period for the research study. When revisions require full board review and approval and, in this case, must follow the same submission deadline policy as with new study submissions: <http://www.ecu.edu/irb/BioBSS.html>. Instructions for completing revision forms are located at: <http://www.ecu.edu/irb/docs/Revision%20form%20instructions%202-21-07.doc>

**Continuing Review:** Research studies, excluding those studies with an exempt status, are given an approval period that can extend for **no longer** than 365 days. [21 CFR 56.108 and 56.109](#). Enrollment may **not** occur in any research study outside of the approval dates. If some element of the research study must continue in order to maintain the safety and well being of human subjects, the UMCIRB must be notified to determine the appropriate action and required reporting. Restrictions may be placed on data collected outside of the IRB approval period. The UMCIRB will **not** provide retrospective approval for a lapse in study approval. The UMCIRB committee or 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. The principal investigator is responsible for ensuring research studies maintain current UMCIRB approval. A notice for an upcoming continuing review interval will be mailed prior to the research study expiration date; however, it is highly recommended for the principal investigator to establish a reliable system within their office to track upcoming expiration dates. The UMCIRB office will assist the investigator by communicating study expiration. Notice for an upcoming continuing review interval will be mailed at approximately 90 and 60 days prior to the research study expiration date with an email sent to the PI at 30 days prior to expiration. The continuing review form must be submitted even if there has been no activity, no participant's enrolled, or the PI does not wish to continue the activity any longer. It is the goal of the UMCIRB office for studies to undergo review during the month prior to their expiration. This is in efforts 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 committee review prior to the expiration date, the UMCIRB will reset the approval date and period. Those continuing reviews that do require full board review and approval must follow the same submission deadline policy as with new study submissions: <http://www.ecu.edu/irb/BioBSS.html>. Those continuing reviews that may be approved under expedited review should also be submitted at least 2 weeks prior to their expiration in case the chair or their designee has any questions or requests any necessary modification to be made before approving the study. To determine whether a study must go to full committee or whether it may be expedited at continuing review, see the following continuing review instructions: Biomedical research:  
[http://www.ecu.edu/irb/docs/Cont\\_Review\\_Biomedical\\_Instructions%202-21-07.doc](http://www.ecu.edu/irb/docs/Cont_Review_Biomedical_Instructions%202-21-07.doc)  
Behavioral/Social Sciences research:  
[http://www.ecu.edu/irb/docs/Cont\\_Review\\_Behavioral\\_Instructions%202-21-07.doc](http://www.ecu.edu/irb/docs/Cont_Review_Behavioral_Instructions%202-21-07.doc)