



March 31, 2021

IRB Policy RE: Expired research or research received close to day of expiration

To Whom It May Concern:

OHRP and FDA regulation both state that the timely and complete submission of research for continuing review is the **responsibility of the Investigator conducting the research.**

For research that is greater than minimal risk:

- Convened board review will be required if enrollment is open and participants have been enrolled, or if enrollment is closed but participants are still actively participating (NOTE: Reviews can only be scheduled for the next available and appropriate agenda. There are 7 biomedical board meetings per month, for FDA regulated research, and 1 social/behavioral board meeting per month, for research not involving an investigational product or invasive biomedical procedures)
- If any study activity has to continue to occur during the lapse in approval, the Investigator conducting the research will be responsible for submitting an exception request outlining the research that needs to occur during the lapse and the rationale for why this is appropriate from a human participant protections perspective
- The Investigator will be responsible for reporting that the research is expired (or expiring) and addressing the following:
 1. Rationale for the delay in submission, and
 2. A corrective action plan to avoid delayed submissions in the future.

For research that is minimal risk and requires continuing review:

- Expedited review under the original expedited category (or categories) will be required
- Reviews will occur in alignment with other submissions already in process or received the same day as a request for continuing approval of either an expired study or a study expiring the day it is received
- The Investigator will be responsible for reporting that the research is expired (or expiring) and addressing the following:
 1. If appropriate/necessary, a request for approval of conduct of any research related activity during the lapse and the rationale for allowing this occur,
 2. Rationale for the delay in submission, and
 3. A corrective action plan to avoid delayed submissions in the future.

Thank you for your cooperation.

Sincerely,

Jessica L. Yoos, MA, M.Phil., CIP
Director, Human Research Protections