I. Background
Non-exempt human subjects research projects require ongoing review to ensure that research still meets criteria for IRB approval from DHHS 45 CFR 46. This policy outlines the expiration period and procedures for continuing review of active projects.

II. Approval Periods
a. Federally funded (Public Health Service agencies and other agencies that adhere to 45 CFR 46) and Greater than minimal risk studies: The Common Rule 45 CFR 46 requires human subjects research to be reviewed at least annually. UCSC requires greater than minimal risk human subjects research to be reviewed at least annually.

b. Projects that require review more often than annually: The IRB may require some greater than minimal risk studies to receive continuing review more often than annually. Examples of this are complex, novel projects where risks to subjects are unknown or studies where there is a history of investigator noncompliance.

c. Minimal risk studies and exemptions: Studies that are not greater than minimal risk and are not federally funded are on a 3-year expiration. Researchers are expected to submit and get approval for any changes to these studies and to close out the study once the research is complete.

III. Continuing Review Requirements and Procedures
a. Researchers: The Principal Investigator/Faculty Sponsor is required to keep track of approval periods and submit a Renewal Form for non-exempt research for IRB review 30 days or more ahead of expiration. Researchers must also submit the currently approved informed consent document(s), recruitment materials if still recruiting, and study instruments unless in data analysis only.

b. IRB: As a courtesy, ORCA sends email reminders to researchers 2 months and 1 month before expiration to submit their continuing reviews. Once received, ORCA does an administrative review, sends comments to researchers as appropriate, then sends expedited reviews to the Chair or their designee, and sends full committee reviews to the next available committee meeting.
IV. IRB Review and Actions
The IRB expedited reviewer, or the convened IRB, will review the continuing review, focusing working presumption that the research, as previously approved, does satisfy 45 CFR 46.111. Review includes consideration of new federal regulations, guidance, or institutional policy, amendments being made at time of continuing review, review of subject complaints and unanticipated problems, and information brought forth to the IRB from outside entities and focus on:
   a. Risk assessment and monitoring: is any new information provided that would alter the IRB’s previous conclusion that (1) the risks to subjects are minimized, and (2) the risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result?
   b. Adequacy of the process for obtaining informed consent
   c. Investigator and institutional issues
   d. Research progress

V. Expiration
Approval is needed before the expiration date; otherwise all research activities must cease until the IRB reinstates approval. The application must be received with adequate time for the IRB to conduct their review. If the application is not received before the expiration date, the researchers must submit a new non-exempt application.

VI. References
   a. OHRP Guidance on Continuing Review
   b. 45 CFR 46.109, 45 CFR 46.110, and 45 CFR 46.111
   c. 21 CFR 56.109 and 21 CFR 56.111