Policy on Closing a Study

Effective date: 9/20/2019

I. Background
An approved research protocol is considered active until IRB approval for it expires or the researchers close the study. An application for IRB review of proposed research may also be withdrawn due to non-responsiveness of researchers. Once a study is completed or is no longer being pursued, the researcher should notify the Office of Research Compliance Administration (ORCA) and the study will be closed as described in this policy.

II. Administrative Closure/Withdrawal
a. If a researcher does not request to renew a given study prior to its expiration (see Policy on Continuing Review) or notify ORCA that the study should be closed prior to its expiration, the protocol will be administratively closed after expiration. Once a study expires, all human research activity (e.g., recruitment, consent, study procedures, analyzing identifiable data, etc.) must cease.

b. If ORCA sends comments or questions related to an initial application for IRB review and there is no response from the researcher after 90 days or more, the application may be administratively withdrawn. ORCA will make a reasonable effort to remind the researcher to respond and/or investigate technical issues.

III. Closure by PI Request
The Principal Investigator may inform ORCA at any time before expiration that they wish to close an active study or withdraw proposed research. This request must be sent via email to orca@ucsc.edu.

IV. Process
a. When ORCA receives an email request to close a study, ORCA will ask the PI to confirm that all human subjects research activity under the protocol has permanently stopped.
b. Upon protocol expiration or PI closure request, ORCA will mark the study as closed in the relevant electronic system(s), calculate a destruction date based on applicable retention requirements, and move any paper or digital files to the appropriate long-term retention repository.
c. ORCA will notify the researcher by email that the study has been closed (whether due to PI request or expiration) or withdrawn due to non-responsiveness, as applicable.
1. If there has been a mistake and the researcher wishes to continue conducting approved research, they may contact ORCA prior to the expiration date and the study closure can be cancelled. However, once the protocol expires, closure cannot be reversed and a new application must be submitted and will be re-assigned to the pending queue.

2. If there has been a mistake and the researcher wishes to pursue an application that has been administratively withdrawn, ORCA staff may choose to re-open the review process at its discretion, taking into consideration such factors as whether there was justification for the delay and whether the researcher can commit to a date by which previous comments/questions will be addressed.

V. **Records Retention**
Researchers must maintain administrative and study records for a minimum of 3 years after the close of a study (see [Policy on Records Retention](#)).

VI. **References**
   a. UC Irvine Policy Completion of Study/Study Closure
   b. UC Irvine Procedure for Reporting of Study Closure