

Policy on Study Closure or Withdrawal

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I. Background

- (a) An IRB approved or exempt certified study is considered active until approval for it expires or the Principal Investigator (PI) closes the study. An application for review of proposed human subjects research (Initial Submission) may also be withdrawn due to non-responsiveness of investigators.
- (b) Studies should be closed when all activities involving human subjects described in the IRB-approved/exempt certified study are completed, including research-related interaction/intervention with participants and analysis of identifiable private information (data).

II. Administrative Closure/Withdrawal

- (a) If a Renewal Submission for a given study is not submitted prior to the study's expiration, the study will be administratively closed after expiration. Once a study expires, all study activities involving human subjects must cease. This includes; recruitment, consent, study procedures, analyzing subject identifiable data, etc.
- (b) If ORCA sends comments or questions related to an initial application for review of proposed human subjects research and there is no response from the investigator after 90 days, the application may be administratively withdrawn. ORCA will make a reasonable effort to remind the study investigators to respond and/or investigate technical issues.

III. Closure by PI Request

- (a) The PI may inform ORCA that they wish to withdraw an initial application for review of proposed human subject research (Initial Submission).
- (b) The PI may inform ORCA at any time before expiration that they wish to close an active study or withdraw an initial application for review of proposed human subject research.
- (c) If a PI leaves the University prior to expiration of a study, the study must be closed or transferred to another eligible UC Santa Cruz PI. This includes the transfer of all study files, both hard copy and electronic.
- (d) Student-led studies must be closed or transferred to another eligible UC Santa Cruz PI before the student's graduation or departure from UCSC. This includes the transfer of study files, both hard copy and electronic.
- (e) Closure of student-led studies which remain open after the student's graduation or departure from UCSC are the responsibility of the student's faculty advisor (PI).

IV. Process

- (a) Once an IRB approved or exempt certified study is completed, or is no longer being pursued, the PI will need to confirm that all research activity involving human subjects

being conducted as part of the study has permanently stopped.

- (b) Upon study expiration or PI closure request, the study will be closed, a destruction date will be calculated based on applicable retention requirements, and any paper or digital files will be moved to the appropriate long-term retention repository.
- (c) ORCA will notify the PI 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 PI wishes to continue conducting research activities involving human subjects outlined in a previously IRB approved or exempt certified study that has been closed, a new application for review of proposed human subject research (Initial Submission) must be submitted and will be reassigned to the pending queue. Once a study expires, closure cannot be reversed.
 - (2) If there has been a mistake and the PI wishes to pursue an application for review of proposed human subject research that has been administratively withdrawn, a new application must be submitted and will be reassigned to the pending queue.

V. Records Retention

- (a) OHRP and UC Records Retention policies require ORCA (the IRB administrative office) to retain their business records. While OHRP only requires IRB records to be retained for 3 years after close of study, UC requires IRB records to be retained 10 years after close of the study, including studies in which no subjects were enrolled. See UCSC IRB Policy on Records Retention.
- (b) The study PI must maintain administrative and study records for a minimum of 3 years after the close of a study, or for the length of time specified in applicable regulations or applicable institutional or sponsor requirements, whichever is longer, and should take measures to prevent accidental or premature destruction of these documents. See UCSC IRB Policy on Records Retention.
- (c) Once a study has been completed, study investigators may keep the data they collected, including identifiable private data, if consistent with the IRB-approved/exempt certified study. Study investigators should continue to honor any data confidentiality protections outlined in the IRB-approved/exempt certified study.
- (d) Study investigators also should honor any other commitments that were agreed to as part of the approved/certified study. For example, providing information about the study results to research subjects, or honoring commitments for compensation to research subjects for research participation.

VI. References

- (a) UC Irvine Policy Completion of Study/Study Closure
- (b) UC Irvine Procedure for Reporting of Study Closure