SOP 307: EXPIRATION OF APPROVAL

PURPOSE
The approval period of a study, whether during initial or continuing review is determined by the University of Utah Institutional Review Board (IRB). This SOP outlines how the expiration date is calculated. This SOP also outlines the expiration of IRB approval.

SCOPE
This policy applies to non-exempt human subject research conducted at the University of Utah.

DEFINITIONS

A. The **approval date** is the date the convened board voted to approve, the date the convened board voted to approve with modifications, or the date the designated expedited reviewer approved the research.
B. The approval **effective date** is the date the approval letter is sent to the investigator through the University of Utah Electronic Research Integrity and Compliance Administration system (ERICA).
C. The **expiration date** is the last day of approval and the date by which continuing review must occur.

POLICY
The length of the approval period for a study is determined by the University of Utah IRB considering the degree of risk, and according to the standards outlined in SOP 404: Continuing Review. When an approval period is determined, an expiration date is calculated to indicate the date by which continuing review must occur and approval ends.

ERICA populates the expiration date based on the determined approval period. For example, a study approved for one year would receive an expiration date that is one day earlier in the following year than the date the convened board approved the research. If the IRB determines the study requires continuing review more or less frequently than annually, the expiration date is manually adjusted in ERICA according to the IRB's determination.

For research that is approved with modifications by the convened board, the approval period is not effective and does not begin until the changes are accepted by the IRB Chair and the approval letter is sent.

Review of a change in a protocol (i.e., modification or amendment) does not alter the expiration date because continuing review is review of the full protocol, not simply a change to it.

Investigators are sent two automatic notifications regarding the need to apply for continuing review prior to the expiration date. There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. Extensions beyond the expiration date will not be granted. A continuing review application must be submitted in ERICA to be reviewed by the IRB even if the continuing review

cannot be conducted before the expiration date. For research which is expired and is reviewed after the expiration date, a new expiration date will be calculated as described above. The lapse in approval due to the expiration of the study and the dates of the lapsed approval are documented in ERICA. If required by the IRB, the investigator will provide the IRB with an action plan to prevent any future lapses in approval.

If the investigator fails to submit a continuing review application by the expiration date, the study will be administratively closed by an IRB staff member. Once the study is closed, the investigator must submit a new study application for initial review and approval to continue with the study.

All research activities must cease upon expiration of IRB approval or study closure.

Expiration of IRB approval does not require a report as a suspension or termination of IRB approval according to IRB SOP 904: Administrative Hold, Suspension and Termination of Approved Research, and IRB SOP 905: Institutional Reporting Procedures.

PROCEDURES

1. Assignment of Expiration Dates

1.1. During the initial and continuing review application review, the assigned board reviewer selects the approval period in the board reviewer checklist in ERICA. For expedited review, the board reviewer checklist documents the determined approval period. For convened board review, the minutes document the determined approval period.

1.2. The IRB administrator or coordinator selects the appropriate approval period based on the determined approval period (e.g., one year, no further continuing review, etc.) in ERICA. The IRB administrator or coordinator is responsible for verifying the correct expiration date when processing the study.

2. Expiration of Approved Studies

2.1. Once IRB approval for a study expires, an expiration notice is automatically generated and sent from ERICA to the investigator. The expiration notice informs the investigator the research is expired and no research activity may continue until the application for continuing review is approved by the IRB. The notice also informs the investigator that no new participants may be enrolled.

2.2. For VA research that has expired, the investigator must immediately submit to the IRB Chair a list of participants who could be harmed by stopping specified study interventions or actions. The VA Research Compliance Officer receives a copy of expiration notices for studies involving the VA Salt Lake City Healthcare System (VASLCHCS) and may contact the investigator for follow-up of the required actions. The IRB Chair, in consultation with the VA Chief of Staff will determine within 2 business days whether participants on the list may continue participating in the research interventions or interactions.

2.3. In order to conduct any study-related procedures after IRB approval expires, investigators must make a request in writing to the IRB Chair for review and approval. If the IRB Chair determines that subjects participating in an expired study would suffer a hardship because research procedures/medication must be discontinued, appropriate research procedures may continue beyond the expiration date for a reasonable amount of time. The IRB Chair will address on a case-by-case basis those rare instances where failure to enroll new subjects would seriously jeopardize the safety or well-being of an individual. Prospective research data cannot be collected until a continuing review application or other progress report is reviewed and approved. The IRB Chair will notify the Investigator of the decision by way of written documentation and this documentation will be attached permanently to the continuing review form, accessible by all IRB members. Documentation will be retained in ERICA.