



TITLE: Continuation of Subjects in Expired Research

PURPOSE: Designated Reviewers can determine whether current subjects may continue in expired research.

RESPONSIBILITIES: Designated Reviewer
HSPP Staff

PROCEDURES:

Obtain from the investigator a coded list of subjects whom the investigator would like to continue on the expired protocol. Obtain specific justification that includes

- What procedure(s) are to continue per subject, and
- Why the procedure(s) are medically necessary and whether the procedure(s) can be obtained outside of the research context.

Under no circumstances are new subjects to be enrolled until the research has been re-reviewed and approved by the IRB.

- In general, research procedures should be safely discontinued. However, based on the following principles, determine which subjects can continue in the research: The only research procedures that should continue are those that are not available outside of the research context. If the required procedures can be provided as standard of care, they should be provided as such.
- Research procedures conducted to collect data with no direct benefit to the subject should not continue.

In some cases, an ethical issue may be raised where the above general principles are not followed.

Follow SOP-070: IRB Records.

MATERIALS:

- SOP-070: IRB Records
- Operations Manual
- HSPP Correspondence Form

REFERENCES:

None.



REVIEW/REVISIONS: From 10/01/2010 version: Removed reference to the VA; Added reference to the Operations Manual

From 01/2014 version: Renumbered from P&P-061; References to P&P-070 revised to SOP-070 to reflect new numbering system.