

PARKVIEW HEALTH	INSTITUTIONAL REVIEW BOARD MANUAL
Policy & Procedure Title: Study Closures Category: IRB Review Process	

I. Policy Statement

A study Protocol should be closed when the study is closed to accrual, and all patients have completed the long-term follow-up phase of the study, and when all research-related interventions or interactions with human subjects have been completed, and/or all study patients have died, and if all data collection and analysis of identifiable private information described in the PH IRB-approved research plan have been finished and no further data will be requested from your site. As long as subjects (patients or otherwise) are still being followed, even if the Study is closed to subject accrual, a Study is considered ongoing and Continuing Reviews must be completed.

II. Definition of Terms

(This section intentionally left blank.)

III. Procedure

- A. To close a study the responsible Investigator must complete and submit a PH IRB Study Closure Form to the PH IRB.
- B. The following information must be provided on the form:
 - 1. Total number of subjects approved for enrollment, entered, withdrawn, completed all ongoing and long-term follow-up;
 - 2. Reason for any subject withdrawals;
 - 3. Research results obtained thus far, if available;
 - 4. A summary of all SAE, serious unanticipated events, hospitalizations, and deaths which have occurred in the Study;
 - 5. Reason and explanation for Study Closure.
- C. The PH IRB shall review and determine if all information is present to close and retire the study.
- D. A Review Certificate will be provided to the Investigator after the PH IRB meeting.

IV. References

(This section intentionally left blank.)

Origination Date: 04/2007 Revision Date(s): 04/09	Source: PH IRB Authorized by: Institutional Official
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