

SOP: RR 405 Version No.: 05 Effective Date: 12/3/10	STUDY COMPLETION	Supersedes Document Dated: 7/1/08
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Steering Committee approved 9/19/11

1. POLICY

The completion or termination of the study is a change in activity and must be reported to the IRB. Although subjects will no longer be “at risk” under the study, a final report/notice to the IRB allows it to close its files as well as provides information that may be used by the IRB in the evaluation and approval of related studies.

Specific Policies

Terms used in this policy, but not defined herein shall have the meanings set forth in the Glossary.

1.1. Determining When a Study May be Closed.

When individually identifiable data are no longer being collected, maintained for analysis or verified at the local site, and there is no further interaction or interventions to collect data about subjects, the study may be closed when the Investigator submits his/her Final Report (form RR 404-A).

1.2. Final Reports.

Investigators or their designee should submit a final report to the IRB upon completion or termination of the study but prior to the expiration date of the research. Final reports must be submitted on Form RR 404-A along with other necessary documents that provide adequate information about the status of the study. The RSP staff will review all reports of study completion and, if needed, request further information from the investigator to clarify any questions that may arise.

A listing of closed studies will be included on the IRB meeting agenda, and copies of the Final Report and supplementary information are made available to the IRB members upon request.

2. SCOPE

These policies and procedures apply to all research submitted to the IRB.

3. APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS

21 CFR 56.108, 56.109

45 CFR 46.103, 46.109

AAHRPP Elements II.2.D.2., II.2.D.3., II.2.E.2., and II.2.E.3.

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4. REFERENCES TO OTHER APPLICABLE SOPS

SOP 404