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Subject: Study Close-Out
Division: IRB
Date: March 1, 2012

IRB Policy 112.1: STUDY CLOSE-OUT

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 providing information that may be used by the IRB in the evaluation and approval of related studies.

Determining When a Project Can be Closed

A research project no longer involves human subjects once the investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects, which includes the using, studying, or analyzing identifiable private information. Once all such activities described in the IRB-approved protocol are finished, the research project can be closed-out. For example, when the only remaining activity of a research project involves the analysis of aggregate data sets without individual subject identifiers, no further IRB review is necessary. At that point the IRB will formally close the IRB file for that project and advise the investigator of that action.

Similarly, simply maintaining individually identifiable private information without using, studying, or analyzing such information is not human subjects research and thus does not require IRB review.

Multi-site industry studies may be closed when the Investigator submits his or her final report.

Final Reports

Completion reports should be submitted to the IRB within 30 days after completion or termination of the study. Completion reports should be submitted via the Application for Final Review. With the completed Application for Final Review, the investigator should also submit a final report, and any manuscripts or publications that have emanated from the study.

The IRB Administrator will review all reports of study completion and, if needed, request further information from the Investigator to clarify any questions that may arise.

Closed studies will be presented to the IRB at the next meeting, and copies of the Final Report and supplementary information will be made available to the IRB members.

Responsibility

IRB Administrators are responsible for ensuring all study completion documentation is received,

reviewed, presented to the IRB, and filed appropriately.

Applicable Regulations and Guidelines

21 CFR 56.108, 56.109
45 CFR 46.103, 46.109
OHRP Guidance on IRB Continuing Review of Research (November 10, 2010)