OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: HSRC
	SUBJECT	Study Closure
	SOP #	3.4
	EFFECTIVE DATE	August 6, 2008
	REVISION DATE	October 17, 2017

OBJECTIVE

Outline the responsibilities of the research team for submitting a study closure report to the Human Subjects Research Committee. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the Hennepin County Medical Center campus.

APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46	Protection of Human Subjects
21 CFR 50	Protection of Human Subjects
21 CFR 56	Institutional Review Boards
21 CFR 312	Investigational New Drug Application
21 CFR 812	Investigational Device Exemptions

REFERENCES TO RELATED SOPs

SOP 2.1
SOP 2.2
SOP 2.12
SOP 3.2

ATTACHMENTS

None

1) Receive notification from the sponsor that the study has closed (if applicable) and that the site's study closeout visit has been completed.

2) If the study is an investigator-initiated study, ensure that enrollment, follow-up, data collection, and analysis are completed.

3) Submit final site closeout reports to the HSRC.

4) Submit final study closeout reports to the HSRC.

5) Place copies of closeout reporting in the regulatory binder.

6) When applicable, upload required information into ClinicalTrials.gov