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