

ADMINISTRATIVE POLICY

Subject: Information Security	Page 1	Policy # Version: 1.0
Title: Research Use of Electronic Medical Record Data	Revision of:	Effective Date: 4/1/2015
		Removal Date:

I. **PURPOSE:**

To ensure research data is obtained through authoritative data sources with evidence of approval and only through approved pathways consistent with existing agreements for NMHC data.

II. **POLICY STATEMENT:**

Data recorded in Northwestern Medicine electronic medical records systems (e.g., EPIC, Cerner) for clinical care and desired to be used for research must be obtained from the Northwestern Medicine Enterprise Data Warehouse (NMEDW) following procedures required of the NMEDW. NMEDW procedures (edw.northwestern.edu) will require evidence of data steward approval prior to any data reporting.

Chart abstraction for research purposes or chart abstraction for clinical care purposes then later re-purposed for research purposes is prohibited.

All NMEDW data requests should be limited to data that is required to conduct the study consistent with the approved IRB protocol or with policies and laws governing preparatory-to-research requests.

A determination if the NMEDW is insufficient to meet research needs will be derived from a collaboration of the NMHC Data Steward, the principal investigator, and the Chief Information Security Officers (CISOs) of FSM and NMHC. This determination and recommendation for an exception will be submitted by the principal investigator to the FSM CISO for final evaluation and determination by the FSM IT Steering Committee, as appropriate.

Scope

This policy encompasses all data recorded in NMHC systems and that is desired to be used for research.

Out of Scope

Data not recorded in Northwestern Medicine electronic medical records system (e.g., EPIC, Cerner) but collected for research purposes such as patient reported outcomes and patient/family interview results conducted in a non-clinical care research setting are not in scope of this policy.

Compliance and Enforcement

Failure to comply with these policies will lead to sanctions, up to and including administrative suspension of activities, loss of faculty appointment, department or unit financial penalties, and/or dismissal from the University.

III. **PERSONS AFFECTED:**

All FSM faculty, staff, students and trainees.

IV. **POLICY UPDATE SCHEDULE:**

No less than every five (5) years, but more frequent updates may be conducted as required.

V. **RELEVANT REFERENCES:**

Feinberg Information Security & Access Policy (<http://www.feinberg.northwestern.edu/it/standards-policies/information-security/index.html>)

FSM Clinical Research Participant Tracking Policy
(https://enotis.northwestern.edu/extra/FSM_Clinical_Research_Participant_Tracking_Policy.pdf)

NMEDW Policies & Procedures (<https://edwapps.nmff.org/EDWPortal/Home/About?Length=0>)