

System Policy

Code: S: (Code)

Entity: Fairview Health Services

Manual: Research Administration

Category:	(JC Category)
Subject:	Data Sharing for Research Activities
Purpose:	To ensure the use and release of Fairview data for research purposes follows federal, state, and institutional policies and regulations.
Scope:	All requests for Fairview data to be used or disclosed for research activities. This policy applies to Fairview employees and its agents and contractors.
Policy:	This policy acknowledges Fairview’s partnership with the University of Minnesota Academic Health Center in supporting the Information Exchange (AHC IE). Fairview’s electronic health record data is shared with the AHC IE via a secure environment and is governed by the articles defined in an information exchange agreement. Requests for access to and disclosure of Fairview data for research purposes will be through the AHC IE. Access is limited to authorized users. The Data Steward is responsible for reviewing requests for compliance with federal regulations under HIPAA, Minnesota state law to the extent state law provisions are more protective of individuals' privacy rights, and Fairview policies.
Definitions:	Authorized User: Applicable personnel who meet the criteria established by the Fairview Data Steward and the AHC IE Executive Leadership and Governance Committee as eligible to use the AHC IE. Criteria include HIPAA training and attestation to appropriate use of health information. Confidential Data: Proprietary information whose availability is for Fairview internal use only and cannot be publically disseminated. Within Fairview it is limited to the individuals and groups with relevant responsibilities. A breach involving such data may place Fairview in competitive disadvantage, may expose it to reputational risk, or may violate contractual obligations. Examples include but are not limited to, internal financial data, vendor and payor contracts,

	<p>pricing structure, and business intelligence.</p> <p>Data Steward: The appointed representative to serve as the gatekeeper for Fairview data shared with the AHC IE, including granting or denying permission for requests for data.</p> <p>Human Subject: A living individual about whom an investigator conducting research obtains:</p> <ol style="list-style-type: none"> 1. Data through intervention or interaction with the individual, or 2. Identifiable private information. <p>Institutional Review Board: A committee formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects with the aim to protect the rights and welfare of the human subjects.</p> <p>Opt Out: Minnesota statute permits patients to refuse the use of their medical records for research purposes. Fairview provides patients the opportunity to opt out on the Consent for Services.</p> <p>Protected Health Information: The demographic and health information collected from an individual that:</p> <ol style="list-style-type: none"> 1. Is created or received by a health care provider, 2. Relates to past, present, or future physical or mental conditions of an individual; the provision of care to an individual; or payment related to the provision of care to an individual, 3. Identifies the individual or provides for a reasonable basis to believe the information can be used to identify the individual, and 4. Is transmitted or maintained in any form (e.g., electronic, paper, oral). <p>Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.</p>
<p>Procedure:</p>	<p><u>Data Steward</u></p> <p>Fairview will appoint a Data Steward responsible for the review and approval of requests for Fairview data. The Data Steward will perform periodic reviews of user access, policies, and security risks for research data, and other responsibilities as outlined in the information exchange agreement.</p> <p><u>Data Requests</u></p>

Data requests are submitted via an application to the AHC IE. Research data is delivered to a secure environment within the AHC IE for authorized users to access and manipulate. Data may not be removed from the AHC IE without prior authorization from Fairview and the AHC IE Executive Leadership and Governance Committee.

Medical record data of a patient who has opted out of research will not be included in research data sets unless the patient has authorized the specific use.

PHI for Research

PHI will be used or disclosed for research purposes only if one of the following conditions is met:

1. The subject of the PHI provides appropriate authorization for the use and disclosure;
2. The IRB approves a modification of the authorization requirement and the modified requirements are met;
3. The IRB approves a waiver of the authorization requirement;
4. The PHI is part of a limited data set and a data use agreement is in place.

PHI may be used or disclosed without patient authorization, provided that:

1. Use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
2. No PHI is to be removed by the researcher in the course of review;
3. The PHI sought is necessary for research purposes; and
4. The researcher represents to Fairview that all of the preceding requirements are met.

PHI of decedents may be used or disclosed when the researcher represents that:

1. The PHI is necessary for the research purposes; and
2. The use or disclosure is solely for research on decedents.

Fairview may require that the researcher provide documentation of the death of the individuals who are the subject of the PHI sought.

PHI may not be used to contact patients for recruitment unless contact is made by a patient's treating provider or treating provider's practice.

Financial Data

Release of financial data is subject to the Data Steward's approval. In general, Fairview will provide cost and charge data for research purposes in addition to reimbursement data from government payers.

	<p>Reimbursement data from private payers will not be available for research purposes.</p> <p><u>Security</u></p> <p>Data must be accessed and stored in accordance with Fairview’s data security requirements unless governed by the Information Exchange agreement.</p>
External Ref:	<ul style="list-style-type: none"> • Health Insurance Portability and Accountability Act 45 CFR Parts 160 and 164; • Common Rule 45 CFR 46; • Minnesota Statute 144.295
Internal Ref:	<ul style="list-style-type: none"> • Research Involving Human Subjects Policy • External Disclosure of PHI Policy • Confidential Information Access via Information Systems • De-Identification of PHI Policy • Legal Medical Record Definition Policy • Legal Medical Record Content Policy • Workstation and Peripheral Device Security • Remote Access to Fairview Information Systems • Information Exchange Agreement
Source:	Privacy Director & System Director, Research Administration
Approved by:	Research Institutional Official
Date Effective:	7/2013
Date Revised:	7/2012, 5/2013, 11/1/13
Date Reviewed:	7/2012, 11/1/13