System Policy

Code: S:RC-2020

Entity: **Fairview Health Services**

Manual: **Research Administration**

Category:	**Record of Care**
Subject:	Research Documentation in Medical Records
Purpose:	To inform providers of patient participation in research in order to promote safety and continuity of care.
Scope:	This policy applies to medical staff appointees, students, and physicians privileged to practice at Fairview and Fairview employees who conduct research involving human subjects within the Fairview system. The policy applies to studies that involve greater than minimal risk to the patient as determined by the IRB of record.
Policy:	Healthcare providers need to be aware of all treatments and medications to which a patient is exposed in order to maximize the safety and quality of prescribed care. Therefore, Fairview requires researchers include information in the medical record such that: 1) a healthcare provider can reasonably identify and contact research personnel for more information; and 2) Medicare requirements for research documentation are met. The defined research elements to be contained in the medical record include: 1. Institutional Review Board (IRB) number 2. Principal Investigator's phone and/or pager number 3. Study Coordinator's phone and/or pager number 4. Date of patient enrollment and date of anticipated end to study participation. Additional documentation is required in the following cases: 1. If research charges are directed toward the patient or insurance, the following documentation is needed: a. Clinical trial name b. Sponsor name c. Sponsor protocol number 2. If the research involves use of a significant risk investigational device, the following documentation is needed:

	a. Investigational Device Exemption (IDE) number **<u>Researchers as Attending Physicians</u>** If the Principal Investigator is the human subject's attending provider, it is expected that the Principal Investigator will conform to Fairview medical record documentation policies in addition to this policy. If another individual is the human subject's attending provider, the Principal Investigator is only required to document the defined research elements. **<u>Certificates of Confidentiality</u>** Principal Investigators holding a Certificate of Confidentiality ("COC") are required to document the defined research elements. The anonymous nature of these elements prevents disclosure of confidential information to the fullest extent possible.
Definitions:	**Certificate of Confidentiality:** A document obtained by the Principal Investigator from the National Institutes of Health that protects the confidentiality of the participants in research of a sensitive nature. **Human subject:** A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. **Minimal risk:** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Studies that are greater than minimal risk may include: regimented medications, invasive procedures, and investigational devices or medications. **Principal Investigator:** The individual who conducts research (i.e., under whose immediate direction the research activity occurs). **Research:** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge.
Procedure:	The Principal Investigator (or designee) is responsible for documenting the defined research elements in the medical record (Epic). 1. Documentation is required for human subjects who are both: a. Fairview patients (e.g. have a Fairview medical record number) b. Enrolled in a research study occurring within Fairview. 2. Documentation is required prior to initiation of subject intervention.

	3. Documentation of defined research elements must be in the Research Studies section in Epic. Fairview Research Administration will provide training for completing this documentation. The defined research elements cited in the policy section above represent a minimum requirement to fulfill the stated purpose. Researchers are encouraged to document as much information as appropriate to foster safe and effective care while protecting confidentiality.
External Ref:	• Joint Commission • 45 CFR 46 • Guideline for Good Clinical Practice E6(R1) • CMS Clinical Trial Policy (NCDCAG-00071R) • Medicare Claims Processing Manual; Chapter 32 – Billing Requirements for Special Services
Internal Ref:	• Legal Medical Record Content; • Legal Medical Record Definition; • Legal Medical Record Documentation Standards; • Legal Medical Record – Using Addendums/Late Chart Entries; • Research Billing.
Source:	System Director, Research Administration
Approved by:	Research Institutional Official
Date Effective:	1/2008
Date Revised:	5/2011; 7/2012
Date Reviewed:	