**System Policy**

**Code:** S:RC-2020

**Entity:** Fairview Health Services

**Manual:** Research Administration

<table>
<thead>
<tr>
<th>Category:</th>
<th>Record of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subject:</strong></td>
<td>Research in the Electronic Medical Record</td>
</tr>
<tr>
<td><strong>Purpose:</strong></td>
<td>To provide guidelines for required and appropriate use of the electronic medical record for research purposes.</td>
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<tr>
<td><strong>Scope:</strong></td>
<td>This policy applies to Fairview employees; medical staff appointees, students, and physicians privileged to practice at Fairview; and those approved under the Non-Fairview Employed Research Staff policy.</td>
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<tr>
<td><strong>Policy:</strong></td>
<td>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. Additional information is encouraged. Research activities must be documented or initiated by researchers within their scope of practice.</td>
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</table>

**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.
- **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:** Required Information
The Principal Investigator (or designee) is responsible for providing information to Fairview about each research study occurring within Fairview, including studies with a Certificate of Confidentiality, to be included in Fairview’s electronic medical record. This information is required prior to Fairview research billing account creation.

1. Institutional Review Board (IRB) number
2. Principal Investigator’s phone and/or pager number
3. Study Coordinator’s phone and/or pager number

If research-related services are to be billed to the patient or insurance, the following information is required in addition:

1. Clinicaltrials.gov number
2. Clinical trial name
3. Sponsor name
4. Sponsor protocol number
5. Investigational Device Exemption (IDE) number if applicable

For each patient enrolled in the research study, the date of consent and anticipated end date (if identifiable) are required.

Additional Documentation

Researchers are encouraged to document as much information as appropriate to foster safe and effective care while protecting confidentiality. The Principal Investigator must ensure any documentation is permitted by the patient via the study consent form.

Researchers who are licensed practitioners may document as appropriate under their scope of practice.

Non-licensed research staff may work independently under the direction of the Principal Investigator for research protocol-driven activities if approved by the Principal Investigator and Fairview Research Administration. This includes documenting, entering orders, and assigning therapy plans and order sets.

Any documentation entered by non-licensed staff must be clearly identifiable as research activity. Designated research encounters and notes are available in the ambulatory and inpatient environments in the medical record. All orders must be signed by a study investigator who is a Fairview provider prior to release. Any deviations from the research protocol must be ordered by a Fairview provider.

The Principal Investigator is responsible for the content of the documentation entered by his/her designee.
| **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.  
• Non-Employed Research Staff Policy |
| **Source:** | System Director, Research Administration |
| **Approved by:** | Research Institutional Official |
| **Date Effective:** | 1/2008 |
| **Date Revised:** | 5/2011; 7/2012, 5/2013; 10/2013; 10/2014 |
| **Date Reviewed:** | 01/2015 |