

**Entity: Fairview Health Services**  
**Manual: Research Administration**

<b>Category:</b>	<b>Leadership</b>
<b>Subject:</b>	<b>Research Billing</b>
<b>Purpose:</b>	To provide clinical research billing that is accurate and in compliance with applicable regulations.
<b>Scope:</b>	This policy applies to all medical staff appointees, students, and physicians privileged to practice at Fairview, and employees of Fairview who participate in conducting research.
<b>Definitions:</b>	<p><b>Clinical Research:</b> For the purpose of this policy, “clinical research” is defined as a systematic investigation, including research development, testing and evaluation involving human subjects, their data, records or tissue and is designed to develop or contribute to generalizable knowledge. The policy does not apply to clinical research meeting the Institutional Review Board (IRB) criteria for exemption (per 45 CFR 46.101).</p> <p><b>Principal Investigator:</b> The individual who conducts research (i.e., under whose immediate direction the research activities are conducted).</p>
<b>Policy:</b>	<p>Clinical research often generates costs that are reimbursed differently. The Principal Investigator is responsible for determining which costs are to be charged to insurers or research participants, and which will be charged to the research study. These decisions need to be reflected in the clinical trial agreement and the consent form for all research studies.</p> <p>Fairview will provide access to billing experts if investigators wish consultative services when developing their budgets.</p> <p>Fairview, to the best of its ability, will not bill patients or their insurance when the research sponsor has agreed to pay for designated services or research related injuries. It is not acceptable to require billing of third party insurance companies in lieu of recovery of such costs from the sponsor.</p> <p>When appropriately documented by investigators, Fairview is responsible for correctly identifying research related charges within its</p>

	systems and directing them to the appropriate payers.
<b>Procedure:</b>	<p>Research related charges are defined on a billing grid (plan) prepared by the Principal Investigator and reviewed by Fairview Research Administration.</p> <p><b>For Research Charges Directed to Study Account</b></p> <p>Fairview Research Administration will capture research charges on study-specific research accounts and invoice the Principal Investigator monthly. Fairview Research Administration is responsible for account maintenance and follow-up for all study-specific research accounts</p> <p><b>For Research Related Charges Directed to Payers:</b></p> <p>Fairview Research Administration will assess each protocol to determine whether or not it meets Medicare’s criteria for a Qualifying Trial. Only protocols deemed as Qualifying Trials per Medicare’s Clinical Trial Policy will be approved for billing research related charges to payers.</p> <p>For studies using devices under an Investigational Device Exemption, or for clinical activity employing Humanitarian Use Devices, Research Administration will submit the proposed use to the local Medicare Administrative Contractor for prospective approval.</p> <p>Fairview Research Administration communicates with the researcher regarding billing grid approvals and revisions, as well as Medicare Contractor approvals as applicable.</p> <p>Fairview will use the billing grid and documented clinical encounter information communicated by researchers to direct clinical trial billing. Fairview Research Administration will identify and document applicable research diagnosis codes and modifiers.</p>
<b>External Ref:</b>	Center for Medicare/Medicaid Services’ Clinical Research Policy Modernization Act, 42 CFR 405.201; Medicare Benefit Policy Manual, Chapter 14; Common Rule 45 CFR 46.
<b>Internal Ref:</b>	University of Minnesota Academic Health Center’s Research Budgeting and Billing Policy; Fairview’s Research Documentation in Medical Records Policy

<b>Source:</b>	System Director, Research Administration
<b>Approved by:</b>	Chief Financial Officer
<b>Date Effective:</b>	
<b>Date Revised:</b>	6/28/2012
<b>Date Reviewed:</b>	6/28/2012