

**System Policy**

**Code: S: (Code)**

**Entity: Fairview Health Services**

**Manual: Research Administration**

<b>Category:</b>	(JC Category)
<b>Subject:</b>	<b>Research Involving Human Subjects</b>
<b>Purpose:</b>	To ensure research at Fairview Health Services (“Fairview”) involving human subjects is conducted ethically and in full conformity with all applicable laws and regulations.
<b>Scope:</b>	This policy covers the entire Fairview system and all Fairview researchers.
<b>Policy:</b>	<p>Research involving human subjects conducted at Fairview shall be performed ethically and in full compliance with the laws and regulations governing the protection of human subjects including, but not limited to, the Department of Health and Human Services’ <i>Guidelines for Protection of Human Research Subjects</i> 45 Code of Federal Regulations (CFR) 46, and Food and Drug Administration regulations to protect human subjects, 21 CFR 50, 56, 312, 812.</p> <p>Fairview will maintain a Federalwide Assurance (“FWA”). Fairview designates the University of Minnesota Institutional Review Board (“IRB”) as its IRB of record, and has documented this as part of the FWA. Research protocols from the Metro Minnesota Community Clinical Oncology Program shall be reviewed by the Park Nicollet Institute IRB only. The Park Nicollet Institute IRB is listed on Fairview’s FWA.</p>
<b>Definitions:</b>	<p><b>Institutional Review Board:</b> 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><b>Fairview Researcher:</b> All medical staff appointees, students, physicians privileged to practice at Fairview, and employees of Fairview who participate in research involving human subjects at any Fairview facility. This definition specifically excludes University of Minnesota faculty and students.</p> <p><b>Federalwide Assurance:</b> A document that designates the Institutional Review Board that will review and oversee the research,</p>

	<p>specifies the ethical principles under which the research will be conducted, and names the individuals who will be responsible for the proper conduct of the research.</p> <p><b>Human Subject:</b> A living individual about whom an investigator (whether professional or student) conducting research obtains:</p> <ul style="list-style-type: none"> <li>(1) Data through intervention or interaction with the individual, or</li> <li>(2) Identifiable private information.</li> </ul> <p>Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.</p> <p><b>Research:</b> A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.</p>
<p><b>Procedure:</b></p>	<p>Fairview Researchers are responsible for:</p> <ul style="list-style-type: none"> <li>1. Sending IRB applications to Fairview Research Administration for review prior to submission to the IRB;</li> <li>2. Including Fairview Research Administration on all official correspondence to and from the IRB</li> <li>3. Completing human subjects protections training every three years</li> <li>4. Submitting conflict of interest disclosures annually</li> </ul> <p>Fairview Research Administration is responsible for:</p> <ul style="list-style-type: none"> <li>1. Reviewing IRB applications from Fairview Researchers for completeness prior to submission to IRB;</li> <li>2. Confirming Fairview Researchers engaged in research:</li> </ul>

	<ul style="list-style-type: none"> <li>a. Are appropriately documented in the IRB application for each study;</li> <li>b. Complete human subjects protections training every three years;</li> <li>c. Submit conflict of interest disclosures annually</li> </ul> <p>Employees and those conducting research at Fairview are required to report promptly all known or suspected violations of this policy or any law or regulation involving research on human subjects. No reprisal will be taken against any employee for making a good faith report of a violation.</p>
<b>External Ref:</b>	<ul style="list-style-type: none"> <li>• University of Minnesota Board of Regents Policy <i>Research Involving Human Subjects</i></li> <li>• 45 CFR 46</li> <li>• 21 CFR 50, 56, 312, 812</li> </ul>
<b>Internal Ref:</b>	<ul style="list-style-type: none"> <li>• Conflict of Interest: Research</li> <li>• Research and Education Enabling Policy</li> </ul>
<b>Source:</b>	System Director, Research Administration
<b>Approved by:</b>	Research Institutional Official
<b>Date Effective:</b>	12/1998
<b>Date Revised:</b>	4/2007; 5/2011; 7/2012
<b>Date Reviewed:</b>	4/2007; 5/2011; 7/2012