

Entity: Fairview Health Services

Manual: Research Administration

Subject:	Investigational Drug Policy
Purpose:	The purpose of this policy is to ensure that the use of investigational drugs is conducted ethically and in full conformity with all applicable laws and regulations.
Policy:	All investigational drugs shall be dispensed in accordance with all Federal and State Regulations. Employees are required to promptly report all known or suspected violations of this policy or any law or regulation involving investigational drugs. No reprisal will be taken against any employee for making a good faith report of a violation.
Definitions:	<p><i>Investigational Drug:</i> A drug is not generally recognized as "safe and effective" unless it is used as per its labeled indications as approved by the FDA. FDA regulations specify when an IND is required. There are two basic categories of investigational drugs:</p> <ul style="list-style-type: none"> ▪ <i>New Drugs:</i> An investigational drug shall be considered as any new drug that is not approved by the Food and Drug Administration (FDA) for use in humans. This definition specifically includes any newly invented or discovered substance undergoing Phase I, II, III, OR IV planned investigation. ▪ <i>New Uses for Old Drugs:</i> Commercially available drugs used in new ways or on new patient populations in connection with a research study are also considered investigational drugs. Studies with commercially available substances are usually considered to be undergoing Phase IV clinical trial. However, some studies with commercially available substances may be undergoing various Phase trials based on the new patient population. <p><i>Inpatient:</i> For purposes of this policy, "inpatient" shall be defined as all research subjects whose clinical condition is such that they meet Fairview's criteria for inpatient admission or any research subject who does not meet such criteria but who receives the investigational drug in an area of the hospital that is generally considered an inpatient unit. Any research studies involving inpatients, as defined in this policy, shall be considered "inpatient studies."</p>
Procedure:	Application: This policy applies to all medical staff appointees, students, physicians privileged to practice at Fairview, and

employees of Fairview who participate in studies involving investigational drugs.

Inpatient Studies: Any clinical research project performed at a Fairview Health Services site involving the use of an investigational drug in an inpatient setting will require involvement of the Department of Pharmaceutical Services.

For all inpatient studies the Investigational Drug Service of the Department of Pharmaceutical Services shall serve as the coordinator and control center for all investigational drugs. The Investigational Drug Service will assume responsibility for maintaining records of the drugs delivered to the Investigational Drug Service, inventory of the drug, dispensing of drugs to research subjects, and the return to the sponsor or alternative disposition of unused product. The Investigational Drug Service will store and dispense the investigational drug as specified by the sponsor and in accordance with applicable regulatory requirements.

Outpatient Studies: Any clinical research project performed at a Fairview Health Services site involving the use of an investigational drug in an outpatient setting will require that the study be registered with the Department of Pharmaceutical Services. The Department of Pharmaceutical Services will also have the right to audit the processes in place to monitor and control the use of investigational drugs and to require corrective action.

Responsibilities: All investigational drugs shall be properly labeled and stored, and shall be used only under the direct supervision of the principal investigator. Investigational drugs shall be administered in accordance with any applicable State or Federal Regulations and in accordance with any policies or procedures set forth by the Institutional Review Board. Responsibility for investigational drugs at clinical trial sites rests with the investigator and the institution. Responsibilities include maintaining records of an investigational drug delivery to the site, inventory at the site, use of the drug by each research subject, return of unused product to the sponsor, and maintaining appropriate storage conditions. Investigators will maintain records that document that subjects were provided the doses specified by the protocol. The investigator will ensure that the investigational drugs are used in accordance with the approved protocol. The investigator, or a person designated by the investigator, will explain to each subject the correct use of the investigational drug and will check at intervals appropriate to the trial that each subject is following the instructions properly.

Only a physician or a physician's designee shall administer an investigational drug to a patient. On approval of the principal investigator, designees may administer investigational drugs only

	after they have been given, and have demonstrated an understanding of basic pharmacologic information about the drug. Investigational drugs are to be administered in accordance with research protocol and in accordance with any other hospital or clinic policy pertaining to the administration of medications.
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