Research Policy Manual

GEISINGER	*Policy*	*Section*	*Title*
	09.101	**9.0 Ethics, Rights & Responsibilities**	**Geisinger Human Research Protection Program Policy**

This policy applies to:			
X	***Geisinger Medical Center campus***		*Geisinger Health System Foundation*
X	***Geisinger Wyoming Valley Medical Center campus***		*Geisinger Lewistown Hospital*
	GMC Center for Aesthetics & Cosmetic Surgery		*Holy Spirit Hospital of the Sisters of Christian Charity*
	GMC Outpatient Surgery-Woodbine		*Spirit Physician Services, Inc.*
			Holy Spirit Corporation
	Community Practice Service Line		*Holy Spirit Ventures, Inc.*
	Geisinger Community Health Services		*West Shore Advanced Life Support Services, Inc*
	Marworth		*Holy Spirit Health System*
	Geisinger Medical Laboratories		*SUN Home Health*
X	***Geisinger Clinic***		*Geisinger-Shamokin Area Community Skilled Nursing Facility, a service of Geisinger Medical Center*
X	***Geisinger System Services***		
	Geisinger Gray's Woods Outpatient Surgery & Endoscopy Center		
	Geisinger Health Plan		
	Family Health Associates of Geisinger Lewistown Hospital		
	Geisinger Medical Management Corporation		
	Geisinger Gastroenterology and Endoscopy Center - Lewistown		
	Geisinger Community Medical Center		
	Mountain View Care Center		
	Geisinger Bloomsburg Hospital		
	Geisinger Bloomsburg Health Care Center		

PURPOSE:
The purpose of this policy is to ensure Geisinger's compliance with all federal, state, and institutional policies for the protection and oversight for all human subjects research. This includes all human subjects research conducted by members of the Geisinger community, using Geisinger facilities or resources, or involving use or disclosure of identifiable private information created or maintained by Geisinger. The Human Research Protection Program (HRPP) is guided by the ethical principles of the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report") and performed in compliance with applicable federal and state law.

Geisinger has established a Human Research Protection Program (HRPP), which is an integrated system of the Institutional Review Board (IRB), Office of Research Compliance (ORC), Office of Sponsored Projects (OSP), other review units, oversight functions, and educational and quality assurance activities that together seek to assure the rights and welfare of

human subjects participating in research and promote excellence in all aspects of human subjects research. The HRPP not only promotes compliance with relevant laws, regulations and professional and ethical standards at all levels, it addresses the needs and concerns of researchers and enhances support of their endeavors.

POLICY:
Geisinger established the HRPP to ensure compliance with:

- relevant laws and regulation (federal state, local, and institutional)
- professional and ethical standards
- the needs and concerns of researchers
- enhancing the support of human research endeavors.

All researchers involved in human subject research must abide by the specific operational standards, processes and procedures outlined in the HRPP Handbook and other policies specifically identified in the "handbook". The HRPP exists to promote high quality, ethical research. The HRPP serves as the advocate for the rights and welfare of persons who participate in human subjects research conducted at Geisinger and all affiliate organizations for which there is an agreement to provide services related to the HRPP.

Geisinger's policy for the protection of human participants is guided by ethical principles, Federal law, and institutional standards. The guiding ethical principles are embodied in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Compliance with this policy provides protections for human participants as mandated by applicable laws, regulations, and standards of local, state and Federal government agencies concerning the protection of human participants, including the U.S. Code of Federal Regulations (CFR):

- Title 45 CFR 46, Protection of Human Subjects, U.S. Department of Health and Human Services (DHSS), Office for Human Research Protections (OHRP) and
- Title 21 CFR 50, 56, 312, 600 and 812 of the Food and Drug Administration (FDA)

DEFINITIONS:
"**DHHS Research**" means a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR §46.102[d])

"Human participant", **"Human subject", "Participant",** or **"Subject"** means a "living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information" (45 CFR §46.102[f]). Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and participant. Private information includes information about behavior that occurs in a context in which an individual can reasonable 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 reasonable expect will not be made public (for example, a medical record). Private information must be individual identifiable (i.e., the identity of the participant 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 participants.

"**FDA Research**" under the FDA regulations means any experiment that involves a test article and one or more human participants and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by the FDA as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study and clinical investigation are deemed synonymous for purposes of the FDA regulations (21 CFR §56.102[c]). In practice, all uses of drugs or medical devices constitute "research" under this definition unless the drug or device is both approved and being used in the course of medical practices. In addition, all uses of FDA-regulated test articles in which the results will be submitted to the FDA or held for inspection by the FDA constitute "research" under this definition.

"**Human participant**" or "**Human subject**" under the FDA regulations means an individual who is or becomes a participant in research, either as a recipient of a test article or as a control. For medical device studies in which data will be submitted to

the FDA or held for inspection by the FDA, a human participant includes a human on whose specimen an investigational device is used.

Developed	*Revised/Reviewed**	*Policy Owner*	*Approved by*	*Date*
05/23/2007	01/07/2016 *	Director of Research Compliance	Associate Chief Research Officer Assoc. Vice President	01/11/2016 01/11/2016
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