Policy

Geisinger

Title: **Geisinger Human Research Protection Program Policy**	
Joint Commission Chapter Section: Select a section for this policy (REQUIRED)	*Date ORIGINAL policy was created:* July 31, 2009
This policy belongs to: Institutional Review Board	
Committee/Council Approval(s): N/A	*Date of COMMITTEE Approval(s):* Month DD, YYYY

☐ **This Policy contains one or more PROCEDURES outlining the methods and applicability of this Policy.**

This policy applies to the following Geisinger Entities:

CLINICAL ENTITIES *(includes Geisinger entities providing health care services, i.e., hospitals, group practices, clinics)*	
☒ Community Medical Center (CMC or GCMC)	☒ Geisinger Jersey Shore Hospital (GJSH)
☒ Endoscopy Center of Geisinger Lewistown Hospital; an entity of GLH	☒ Geisinger Lewistown Hospital (GLH)
☒ Family Health Associates of GLH (FHA)	☒ Geisinger Medical Center (GMC)
☒ Geisinger Bloomsburg Hospital (GBH)	☒ Geisinger Medical Center Muncy (GMCM)
☒ Geisinger Clinic (GC)	☒ Geisinger Pharmacy, LLC
☒ Geisinger Community Health Services (GCHS)	☒ Geisinger Wyoming Valley Medical Center (GWV)
☒ Geisinger Encompass Health, LLC	☒ GMC Outpatient Surgery - Woodbine; an entity of GMC
☒ Geisinger Endoscopy-Montoursville; an entity of G-HM	☒ Lewistown Ambulatory Care Corporation (LACC)
☒ Geisinger Gray's Woods Outpatient Surgery and Endoscopy Center; an entity of GC	☒ Marworth
☒ Geisinger-HM Joint Venture (G-HM)[1]	☒ West Shore Advanced Life Support Services, Inc. (WSALS or Geisinger EMS)
☒ GWV Outpatient Surgery – CenterPoint; an entity of Geisinger Wyoming Valley Medical Center	

NON-CLINICAL ENTITIES *(includes Geisinger business/corporate entities not providing health care services)*	
☒ Geisinger Commonwealth School of Medicine (GCSOM)	☐ Geisinger System Services (GSS)
☒ Geisinger Health (GH or GHF)	☒ GNJ Physicians Group (GNJ)
☒ Geisinger Health Plan (GHP)	☐ ISS Solutions, Inc. (ISS)
☐ Geisinger Quality Options, Inc. (GQO)	☐ Keystone Health Information Exchange, Inc. (KeyHIE)

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.

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

[1] Geisinger-HM Joint Venture is an LLC representing a joint venture between Geisinger Medical Center and Highmark Health.

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.

PERSONS AFFECTED

This is a system-wide Policy that applies to all Investigators who conduct Research at Geisinger.

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, policies and procedures outlined in the HRPP Handbook and Guidance Documents. 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

Research (HHS 45 CFR 46): A systematic investigation, including research development, testing and evaluation, designed to develop
or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research.

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess or investigate potential public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during an event or crisis that threatens public health (including natural or man-made disasters).
3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Clinical Investigation (**FDA – 21 CFR 50):** means any experiment that involves a test article and one or more human subjects 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 Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies.

'Human participant', **"Human subject", 'Participant',** or **'Subject' (HHS – 45 CFR 46):** A living individual about whom an investigator (whether professional or student) conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtain, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Human subject *(*FDA – 21 CFR 50): means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

RESPONSIBILITIES

N/A

EQUIPMENT/SUPPLIES

N/A

PROCEDURE

N/A

ATTACHMENTS

N/A

REFERENCES

N/A