

POLICY TITLE: COMPLIANCE PROGRAM**Former Policy Title:****1. POLICY PURPOSE:**

The purposes of the LG Health Compliance Program are to:

- 1.1 Set standards for the conduct of Covered Persons (as defined below) associated with LG Health;
- 1.2 Establish a Compliance Officer and define his/her role and responsibility as it relates to operating and monitoring the Compliance Program;
- 1.3 Routinely assist Covered Persons to know, understand and comply with legal and ethical requirements that apply to the business of Lancaster General Health;
- 1.4 Maintain Issue (as defined in Section 2.5) resolution mechanisms, including a hotline, and encourage Covered Persons to use these mechanisms to raise Issues regarding legal compliance and ethical conduct;
- 1.5 Develop methods of detection, prevention, and correction of wrongful or incorrect conduct or practices at an early stage as well as to investigate and remediate identified systemic problems;
- 1.6 Set forth policies addressing the non-employment of sanctioned individuals; and
- 1.7 Create a mechanism for resolving wrongful or incorrect conduct or practices which are identified, including enforcement of appropriate disciplinary action against Covered Persons who have violated LG Health compliance policies, applicable statutes, regulations or federal health care program requirements.

POLICY STATEMENT:

Covered Persons as described below shall conduct themselves in a lawful and ethical manner. Specifically, all business transactions and relationships shall comply with all federal, state, and local laws, rules and regulations which may be applicable, as well as with the policies and procedures contained in the Code of Conduct (described below). In addition, all Covered Persons shall conduct themselves so that their actions are at all times in compliance with federal, state, and local laws, rules and regulations, as well as with the policies and procedures contained in the Code of Conduct.

In this regard, Lancaster General Health (LG Health) has adopted this Compliance Program Policy. LG Health and each of its Affiliates (as defined in Section 2.1) shall maintain and be subject to the LG Health Compliance Program. The LG Health Compliance Program is comprised of this Policy, the Code of Conduct described herein, and such other policies and procedures which are adopted from time to time. Entities not falling within the definition of Affiliate shall have their own Compliance Program. Compliance in Human Subject Research is further described in Addendum A to this policy.

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APPLICABILITY/SCOPE/EXCLUSION:

The LG Health Compliance Program covers Board Members, Board Committee Members, officers, employees, High-Risk Health Care Industry Representatives (HCIRs), Medical and Dental Staff Members, (as defined in Section 2.6), certain Lancaster General Health Affiliates (as defined in Section 2.1). These individuals and entities shall collectively be referred to as “Covered Persons” throughout this Policy.

2. DEFINITIONS:

- 2.1 **Affiliate:** For the purposes of this Policy, the term “Affiliate” shall mean any entity which LG Health wholly owns, or has a controlling interest of 51% or greater and other related entities that have agreed with LG Health to adopt the LG Health Compliance Program. Affiliates include: Lancaster General Health Foundation; Lancaster General Hospital; Lancaster General Medical Group; The Heart Group of LG Health, Lancaster; Lancaster General Health Columbia Health Center; Pennsylvania College of Health Sciences; Lancaster General Community Care Collaborative, LLC; Lancaster General Community Care Collaborative II, LLC; The NeuroSpine Center, LLC; Lancaster General Services, Inc.; Novastream, LLC; Lancaster PET Partnership, LLP; and, the MRI Group, LLP.
- 2.2 **Audit and Compliance Committee:** The term “Audit and Compliance Committee” shall mean the standing committee of the LG Health Board of Trustees which is delegated oversight authority for the Compliance Program.
- 2.3 **Compliance Officer:** The term “Compliance Officer” shall mean the individual designated by the President of LG Health and the Audit and Compliance Committee of the Board of Trustees of LG Health as the person with overall responsibility for the implementation and oversight of the Compliance Program, as more fully described in Section 3.
- 2.4 **Issue:** The term “Issue” shall mean any question, problem, complaint or alleged violation relating to the LG Health Compliance Program, the Code of Conduct, legal compliance or ethical conduct.
- 2.5 **Medical and Dental Staff Members:** The term “Medical and Dental Staff Members” shall mean all active, courtesy, honorary and associate staff members, as well as medical affiliates, of any hospital or other institution which is an Affiliate of LG Health when: (i) such persons are acting in the capacity as an officer, department head, division chief, committee chairperson, or in any other capacity on behalf of the Medical and Dental Staff of that Affiliate; (ii) such persons are acting in any other official capacity on behalf of an Affiliate (e.g., Medical Director, Board Member); or (iii) any part of the Code of Conduct may specifically apply to such persons in accordance with its terms (e.g., policy on scientific research).
- 2.6 **Health Care Industry Representatives (HCIRs)** For the purposes of this policy, **HCIR** is a broad term describing individuals who are not employed by LG Health but who are employed by a third party, or who are independent contractors, or others needing or requesting access to clinical or nonclinical areas in order to conduct their business.
- 2.7 **High Risk HCIRs** Includes HCIRs (with exception of exclusive provider and pharmacy representatives delivering medication) who require access to High-Risk Areas for the performance of services related to patient care. High-Risk HCIRs may perform technical assistance and may operate patient care related equipment. High-Risk HCIRs may serve as

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primary clinical support product representatives while attending or observing a patient's procedure and may serve as the product resource to all medical staff. Additionally, High Risk HCIRs can be other non-employees, providing direct patient care, documenting in the electronic health record, or performing administrative services related to coding, release of information, billing, collections and/or cost reporting, and human subject research studies.

- 2.8 High Risk Area: LGH or WBH operating rooms and procedural areas including Electrophysiology, Invasive Vascular Unit, Endoscopy, Cath Lab, and perioperative (either sterile or non-sterile and/or restricted areas), inpatient and outpatient clinical care areas, such as hospital rooms and office exam rooms.

3. COMPONENTS

The components of the LG Health Compliance Program are:

- 3.1 Compliance Officer. Responsibility for implementing and managing the Compliance Program is assigned to the Compliance Officer, who is appointed by the Chief Executive Officer of Lancaster General Health and ratified by the Audit and Compliance Committee. The Audit and Compliance Committee shall assist the Board of Trustees in fulfilling its oversight responsibility relating to, among other things, the legal compliance and ethics programs established by the management and the Board. The Compliance Officer ultimately reports to and is accountable to the Audit and Compliance Committee for this purpose.
- 3.2 Compliance Steering Committee. LG Health shall develop a Compliance Steering Committee ("the Committee"). The Committee's functions include, but are not limited to:
- Advising the Compliance Officer and assisting in the implementation and maintenance of the Compliance Program,
 - Development and implementation of processes and/or policies in response to new or existing regulations,
 - Making recommendations for monitoring activities in order to mitigate non-compliance with federal, state, and local laws and regulations,
 - Reviewing the results of internal monitoring and assess the effectiveness of those activities,
 - Recommending corrective action steps in the event of non-compliance,
 - Reviewing Compliance Program education and training materials and methods; and
 - Periodically reviewing the LG Compliance Program and recommending changes.

Each Affiliate shall have Senior Management level (or designee) representation on the Committee. Members of the Committee shall be called Compliance Liaisons and will be chosen by the LG Health Compliance Officer in consultation with the executive responsible for the applicable entity or department, the LG Health General Counsel, and the Chief Executive Officer of LG Health. These individuals will have primary responsibility for oversight and assisting with the Compliance Program within their particular institution or department. Depending on the Affiliate, one individual may represent more than one entity or department. In addition, representation may be selected for a line of business where deemed necessary (e.g., laboratory, patient financial services).

- 3.3 Code of Conduct. The Code of Conduct sets forth standards by which all Covered Persons associated with LG Health are expected to conduct themselves. Copies of the Code of Conduct will be distributed to all new employees at New Employee Orientation. A copy will also be provided to each Medical and Dental Staff Member. The LG Health Code of Conduct is also available on the Intranet.

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Covered Persons who fail to comply with the Code of Conduct or other compliance policies will be subject to disciplinary action. Covered Persons who violate the law may also be subject to civil or criminal penalties.

- 3.4 Additional Standards of Conduct. In addition to the Code of Conduct described above, individual Affiliates, operating units, or product lines may develop specific policies and procedures which set forth specific standards applicable to the activities of that particular area, and which may reasonably assist Covered Persons associated with such areas with Compliance.
- 3.5 The Role of Management Personnel. All management personnel have a special responsibility to create and uphold LG Health's reputation for integrity and trust, to cultivate an environment that encourages ethical behavior. Management is to be held accountable for making sure that employees in their respective areas receive education on the Compliance Program, and understand and comply with the Code of Conduct and other LG Health policies. All managers are expected to be alert for areas of non-compliance, and to take action concerning matters that come to their attention. Managers who fail to detect non-compliance within their areas of responsibility may be subject to disciplinary action.
- 3.6 Reporting Violations of the Code of Conduct or other Improper Conduct. All persons governed by LG Health's Compliance Program are expected to report suspected improper conduct using the mechanisms described in this Policy. Any covered person who knows of or suspects any illegal, unethical, fraudulent or otherwise non-compliant activity is required to discuss the matter with his/her supervisor, another manager or the Compliance Officer.

In the event that an employee is uncomfortable discussing an Issue with his or her supervisor, or if the employee is not satisfied with the supervisor's response, the employee may address the Issue with any of the following individuals or utilize any of the following mechanisms: the Human Resources representative for the Affiliate involved; the LG Health Legal Department; the LG Health Compliance Officer; the LG Health Compliance Hotline 1-215-P-Comply (1-215-726-6259); the "Share Your Experience" program; or any other mechanism established by LG Health or an Affiliate for Covered Persons to raise Issues.

- 3.7 LG Health Compliance Hotline. Covered Persons who are uncomfortable discussing an Issue with their supervisor or other manager may call the LG Health Compliance Hotline. This phone number is answered by the Office of Institutional Compliance at the University of Pennsylvania between the hours of 8 a.m. and 5 p.m. Monday through Friday. A recorded message may be left during non-business hours. LG Health will protect the caller's anonymity to the extent permitted by law. Anonymous reporting to the Compliance Hotline is permitted, although not encouraged, as the identity of the caller is often necessary to adequately investigate a report. The Hotline is described in greater detail in Section 4.2 of this Policy.

The Compliance Hotline is not intended to replace the normal reporting process, but is another resource available when a Covered Person is not comfortable addressing an Issue through the usual means.

- 3.8 Investigating Reports of Non-compliance. All reports of non-compliance with the Code of Conduct or other suspected improper, illegal, or unethical conduct will be thoroughly investigated under the general supervision of the Compliance Officer. The Compliance Officer may refer the Issue to the appropriate manager or other LG Health employee for investigation. The Compliance Officer in conjunction with Human Resources will ensure that an appropriate corrective action plan is developed as necessary to prevent future recurrence of similar activity. All Covered Persons are expected to cooperate fully with any investigation undertaken.

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- 3.9 Non-retaliation and Retribution. Any type of retribution or retaliation against Covered Persons who in good faith report suspected violations of the Code of Conduct or other suspected improper, illegal, or unethical conduct is prohibited. Anyone violating this non-retribution/non-retaliation policy will be subject to disciplinary action, including possible termination. Concerns about possible retaliation or harassment should be promptly reported to the Compliance Officer.
- 3.10 Education and Training. The Compliance Officer will work with Human Resources and other Departments as applicable to assure that all Covered Persons receive the appropriate level of education and training as outlined in **Addendum B** regarding the LG Health Compliance Program, the Code of Conduct, and to ensure that all Covered Persons are familiar with how to report conduct that is inconsistent with the Code of Conduct or legal requirements.

At a minimum, new employees will receive training within two weeks of commencing employment. All current employees will receive mandatory compliance program training annually through a computer based training program. A component of the employee annual performance evaluation is whether the employee has completed all mandatory computer based training. Employees who have not completed all annual mandatory training may be subject to corrective action.

Members of the LG Board of Trustees and all members of Affiliate Boards of Trustees will receive periodic training regarding the LG Health Compliance Program, and new Board members will receive training at Board Orientation.

High Risk HCIRs will receive initial education upon presentation to our facilities, and annually thereafter. Representatives from the High Risk Areas, and Human Resources when applicable, are responsible for ensuring appropriate education takes place, and the Compliance Department will periodically monitor compliance with this requirement.

- 3.11 Monitoring and Auditing. In order to determine the compliance of LG Health, its Affiliates, and Covered Persons with the Code of Conduct and the LG Health Compliance Program, the Compliance Officer will develop and implement monitoring and auditing systems reasonably designed to detect conduct which may be in violation of this policy. The monitoring system will include the Compliance Hotline described in Section 4.2. The Compliance Officer shall develop a work plan annually which will reflect specific monitoring and auditing for compliance. In developing this annual work plan, the Compliance Officer shall include periodic review of the OIG Website, review of the OIG annual work plan, and other publications of the federal and state governments.
- 3.12 Records Retention. The Compliance Officer will develop and implement records retention systems which will document the effective implementation of the LG Health Compliance Program.
- 3.13 Non-hiring of Ineligible Persons/Sanctioned Individuals. LG Health will make reasonable and prudent efforts not to hire, contract with, or submit any claim for services ordered or rendered by an individual or entity that has been excluded from or is ineligible to participate in federal health care programs, including the Medicare or Medicaid programs. Further, individuals convicted of criminal offenses related to the provision of healthcare services or items are excluded from employment with LG Health. Sanction searches as well as background checks will be conducted on all new hires. At least annually, all Covered Persons will be checked against the Department of Health and Human Services' Office of Inspector General and General Services Administration's lists (at a minimum) of excluded and ineligible persons.

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- 3.14 Discipline and Enforcement. Violators of the LG Health Compliance Program, including the Code of Conduct, are subject to disciplinary action, which may include termination of employment, as defined in the Human Resources Policies of LG Health or its appropriate Affiliate. For Medical and Dental Staff members, violations of the LG Health Compliance Program, the Code of Conduct, or the Medical and Dental Staff Code of Conduct may entail termination of contractual relationships or referral to the Medical and Dental Staff for action in accordance with the Medical and Dental Staff Bylaws.
- 3.15 Compliance Program Evaluation: Periodically, the Compliance Program shall be evaluated for effectiveness.

4. PROCEDURE:

4.1 Establish and Distribute the Code of Conduct.

- 4.1.1 A Code of Conduct has been established and provided to Covered Persons which will set forth certain minimum expectations for the conduct of Covered Persons, and with which Covered Persons will be expected to comply. The Code of Conduct will be revised and re-published as needed, in the manner described in this document.
- 4.1.2 The Code of Conduct shall be approved by the Audit and Compliance Committee of the Board of Trustees of LG Health, and by the Board of Trustees of each Affiliate. The Code of Conduct and the Compliance Program Policy will be reviewed periodically by the Compliance Officer. Material additions and modifications will be reviewed by the Audit and Compliance Committee for its approval.
- 4.1.3 The standards contained in the Code of Conduct consist of both general guidelines and specific requirements. However, it is not possible to provide specific guidance for all situations. Therefore, Covered Persons will be expected to apply the general guidelines to their specific work situations.
- 4.1.4 The standards contained in the Code of Conduct describe expected conduct and behavior from Covered Persons in a variety of areas, including but not limited to the following:

Anti-trust; tax-exempt status; fraud and abuse; lobbying and political activities; environmental; discrimination; sexual and other harassment; drug free workplace; business ethics; billing for services rendered; cost reporting; honest communication; ineligible persons; research participation; misappropriation of proprietary information; confidentiality of patient information; confidentiality of personnel actions; conflicts of interest; gifts, gratuities and entertainment; and protection of assets.

4.2 Establishment and Maintenance of a Telephone Hotline.

- 4.2.1 The LG Health Compliance Officer shall be responsible for ensuring that hotline calls are investigated, where appropriate.
- 4.2.2 The purpose of the hotline is to permit Covered Persons and other interested persons or entities to bring Issues to the attention of LG Health management, including but not limited to alleged violations of the Code of Conduct or other non-compliant activity.
- 4.2.3 To the extent possible, the telephone hotline will give callers the opportunity to remain anonymous. However, anonymity is not encouraged since it may be more difficult or impossible to conduct an appropriate investigation without the ability to seek more information from the person making the initial report.

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4.2.4 To the extent possible, the telephone hotline will be operated in a manner so that callers may receive feedback on investigations and resolutions resulting from their call.

4.2.5 The Compliance Officer is responsible for maintaining a log of each call along with the status of any response or resolution.

4.3 Oversight of the Compliance Program.

4.3.1 The Board of Trustees of LG Health shall have a standing Committee known as the Audit and Compliance Committee, which will have the responsibility to oversee the Compliance Program. The membership of the Committee shall be as defined by the LG Health by-laws. All members of the Audit and Compliance Committee shall be independent of management, the Corporation's external auditors, and the Corporation, including its Affiliates. The Compliance Officer shall serve as a staff member to the Audit and Compliance Committee.

4.3.2 The Audit and Compliance Committee will meet as required, but not less than twice annually, for the purpose of fulfilling its oversight responsibilities related to (among other things) the legal compliance and ethics programs established by this policy, and to monitor the progress, efficiency, and effectiveness of the compliance program. Responsibilities of the Audit and Compliance Committee are more fully described in the Audit and Compliance Committee Charter.

4.4 Responsibilities and Authorities of the Compliance Officer.

4.4.1 The Compliance Officer ultimately reports to and is accountable to the Audit and Compliance Committee and the LG Health President for the purpose of reporting or resolution of any significant Issues which may arise. For day to day operations, the Compliance Officer shall work with the LG Health Senior Vice-President, General Counsel for Lancaster General Hospital.

The Compliance Officer shall have direct access to the Board of Trustees. The Compliance Officer shall have unfettered, direct access to all documents and information relevant to compliance activities including but not limited to all electronic media (e.g., Lawson), patient records, billing records, employment records, marketing records and contracts, and written arrangements or agreements with others. The Compliance Officer may retain and/or seek the advice of outside legal counsel, consultants, and other experts as may be reasonable and necessary to resolve compliance issues. The Compliance Officer shall advise the Chair of the Audit and Compliance Committee that such experts have been retained, and report on the progress and outcome of work performed by these outside resources.

4.4.2 The Compliance Officer shall (among other things):

- a. Administer the Lancaster General Health Compliance Program with direction from the Audit and Compliance Committee of the Board of Trustees.
- b. Monitor day to day compliance activities of Lancaster General Health and communicate any matter deemed potentially illegal, unethical, or otherwise improper to Senior Leadership and/or the Audit and Compliance Committee.
- c. Act as independent review and evaluation body to ensure that compliance issues/concerns related to Covered Persons are appropriately evaluated and resolved, and develop a system for uniform

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management of such issues/concerns or violations.

- d. Ensure that any matter potentially requiring external reporting is communicated to Senior Management and/or the Audit and Compliance Committee and external parties as required.
- e. Investigate or oversee the investigation of significant Issues relating to alleged non-compliance with this and other compliance related policies, federal and state laws, regulations, and the Code of Conduct.
- f. Oversee the process by which the Code of Conduct and other policies and procedures which are a part of the Compliance Program are distributed.
- g. Develop and maintain Compliance Department protocols, written policies, and procedures.
- h. Oversee the process by which the Compliance Program, including this Policy, the Code of Conduct and other applicable policies and procedures, is communicated to Covered Persons.
- i. Ensure that the activities required for Affiliates described in Section 4.5, below are accomplished.
- j. Institutes and maintains an effective compliance communication program for the organization, including promoting use of the compliance hotline (as described in 4.2), heightening awareness of LG Health codes of conduct, and understanding of new and existing compliance issues and related policies and procedures.
- k. Develop and maintain, in coordination with the LG Health or Affiliate Human Resources Departments, a mechanism to incorporate into personnel performance evaluations and assessment of the degree to which the person being evaluated complies with and promotes compliance with the standards of the Code of Conduct.
- l. Develop the Compliance Steering Committee and implement periodic meetings of the Committee.

4.5 Responsibilities of Affiliates.

Each Affiliate shall:

- 4.5.1 Have an individual designated to serve as the Affiliate's Compliance Liaison with regard to Compliance Program matters. This person should be a senior member of management (or designee, with approval of the Compliance Officer), accessible to employees, and have a reputation above reproach for his or her personal integrity. One individual may be designated as an Affiliate Compliance Liaison for more than one entity. The primary responsibility of each Affiliate Compliance Liaison will be to communicate with and be available to anyone who wishes to discuss Issues related to the Code of Conduct or the Compliance Program. This person should facilitate the resolution of any Issue which a Covered Person may raise. This person, along with the Compliance Officer and traditional sources of Issue investigation and resolution (e.g., Human Resources, Risk Management), will coordinate and conduct inquiries into alleged violations of the Code of Conduct, or suspected deviations from legal or ethical standards.
- 4.5.2 Promote the reporting of Issues and educate their employees how to do so.

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- 4.5.3 Ensure that all new employees are oriented to the Code of Conduct within the first two weeks of employment. Temporary employees scheduled to work longer than one month will also be oriented as described in this Section.
- 4.5.4 Maintain an ongoing program of communication to remind employees of LG Health's commitment to the standards in the Code of Conduct. This could include training, articles in the newsletters, bulletin board announcements, and personal presentations.
- 4.5.5 Ensure that vendors are advised of the Code of Conduct standards as they relate to our business contacts with them.
- 4.5.6 Maintain appropriate documentation to confirm the accomplishment of the actions described in this section.
- 4.5.7 Participate in the Compliance Steering Committee as requested by the Compliance Officer.
- 4.5.8 Report probable violations of the law to the Compliance Officer and in accordance with applicable regulatory requirements.

5. INQUIRY AND RESOLUTION OF ISSUES

5.1 Issues.

- 5.1.1 All Covered Persons will be encouraged to raise and resolve any issues which they may have.
- 5.1.2 This Policy shall not be construed as modifying, eliminating, or otherwise replacing any other Issue or complaint resolution mechanism that may already exist within any Affiliate. To the contrary, all such mechanisms shall be considered as part of the Compliance Program. Covered Persons shall be free to use any mechanism to resolve Issues which they may choose. However, they may be encouraged to use a resolution mechanism specifically designed for the type of Issue being raised (e.g., employment related Issues being resolved through the Human Resources Department), or employees may be encouraged to explore or exhaust the chain of command where appropriate (e.g., raising work related Issues with the employee's immediate supervisor first).
- 5.1.3 All Issues or alleged violations of the Code of Conduct will be treated in a confidential manner and discussed only with those who have a need to know.
- 5.1.4 The Compliance Liaison or the person regularly designated to handle the specific type of Issue (e.g., Human Resources for EEO complaints, benefits questions) initiates investigations and corrective actions, and reports all inquiries which are not routine and any subsequent actions to the Compliance Officer. All allegations of violations of the Code of Conduct must be reported to the Compliance Officer as soon as possible after the violation, or as soon as the Covered Person becomes aware of the violation.

5.2 Resolution.

- 5.2.1 The Compliance Officer will review significant cases and will report on such cases to the Audit and Compliance Committee as needed.
- 5.2.2 Covered Persons who violate the Code of Conduct are subject to disciplinary action up to and including suspension or discharge. Disciplinary action may be taken against supervisors and other members of

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management who personally violate the standards or knowingly condone or permit illegal or unethical conduct by others and do not take appropriate corrective action.

- 5.2.3 The Compliance Officer or appropriate Compliance Liaison will ensure that feedback on the results of an inquiry is given to the Covered Persons who initially reported the alleged violation.
- 5.2.4 When wrongful or incorrect practices or occurrences are identified, a corrective action plan must be developed and implemented as soon as is practicable, instituting such changes as are necessary to reasonably ensure that similar practices or occurrences will not recur. When money has been received from incorrect billings, the billings must be corrected as soon as possible and appropriate refunds made.

ROLES/RESPONSIBILITIES: As stated above.

APPENDICES:

Compliance Program – Addendum A – Compliance in Human Subject Research

Compliance Program – Addendum B – Tier Level Training

FORMS: N/A

REFERENCES: N/A

Addendum A

Lancaster General Health Compliance in Human Subject Research

Introduction

The Research Compliance Plan (RCP) of Lancaster General Health (LGH) is sanctioned under authority of the Audit and Compliance Committee of the LG Health Board of Trustees, the CEO of LGH and the LG Health Compliance Program to provide oversight of research activities, programs and processes. This addendum does not supersede the LG Health Compliance Program or any other policy. Rather, this addendum serves to supplement and further define specific responsibilities and expectations with respect to compliance in human subject research.

The RCP facilitates the coordination and monitoring of research activities occurring throughout LGH to ensure compliance with federal, state, and local laws and regulations and LGH policies. In addition, the RCP shall ensure that the operational activities of the Lancaster General Research Institute (LGRI) are also compliant with federal, state and local laws and regulations, as well as LGH policies. The Plan is established to continue LGH's commitment to adhering to the highest standards of research ethics, integrity, and responsibility.

The RCP is created so that all individuals engaged in human subject research under the auspices of LGH are familiar with compliance and regulatory expectations. This shall be achieved through education, monitoring and responding to allegations of non-compliance. LGH's commitment to compliance includes the development of general and specific research training, policies, and appropriate oversight and monitoring to assist individuals engaged in human subject research in conducting research activities. It is the expectation that research conducted at LGH shall be characterized by scientific merit, integrity, and excellence through teamwork and professionalism.

The Research Community for the purposes of the Plan includes all individuals engaged in human subject research under the auspices of LGH and members of the Institutional Review Board (IRB).

Goals and Objectives

The RCP helps LGH identify risks, mitigate potential liabilities, and enhance organizational research quality. This responsibility is fulfilled by protecting the safety and privacy of human subjects, preserving LGH's status as a federal healthcare program participant and a tax-exempt organization, and fortifying the community's trust in LGH as a provider of exceptional care.

It is the goal of the RCP to promote compliance with research-related laws, regulations and policies by:

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- Developing and maintaining policies;
- Providing research compliance and regulatory training and education;
- Monitoring compliance with laws and regulations;
- Responding to government and regulatory agencies; and
- Safeguarding the privacy and security of patient information

Personnel, Roles and Responsibilities

Day-to-day management and implementation of the RCP shall be the responsibility of the Administrative Director of the Lancaster General Research Institute, who serves as the Research Compliance Officer (RCO). The RCO will chair the Research Compliance Committee (RCC). Committee members are identified later in this document.

The Vice President of Risk Management and Corporate Compliance will report to the LGH Compliance Steering Committee, in part to provide them with routine updates about the activities of the RCC. Since LGH's Vice-President of Risk Management and Corporate Compliance chairs the LGH Compliance Steering Committee, and also sits on the LG Health Audit and Compliance Committee, the RCO will have dotted line reporting to this individual to ensure that institutional priorities for compliance program management are being met.

The RCO will manage several functions:

- 1) Research Compliance Education;
- 2) Conducting Annual and Ongoing Risk Assessment of Research Activities and Research Compliance Monitoring;
- 3) Investigations into allegations of non-compliance; and
- 4) Reporting to the RCC.

These functions are deemed vital to the RCO's ability to help members of the LGH research community understand their responsibilities, as well as the organization's expectations, in regard to the federal, state, local and LGH policies/regulations. The outcome of this effort shall be an enhancement of the overall scientific and research quality, and enhancement of the LGH Compliance Program. Moreover, the RCO will lead efforts to identify and assess research-related risks. An annual review shall form the basis for the monitoring plan; in addition, the review will influence the content of planned education and training activities provided by the RCP.

Oversight and Accountability

The RCO is the function at LGH that is charged with identification, development, maintenance and communication of LGH's policies and procedures for research. Areas of focus include:

- Research Code of Conduct

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- Research patient billing
- Research monitoring and quality assurance
- Research accounting and financial management
- Effort reporting
- Conflict of Interest
- Scientific Misconduct
- Human Research Protections
- Privacy and security of patient information

The RCO shall engage in assessments, quality reviews, and other assurance management activities in each of these areas. The RCO has responsibility and authority to evaluate, monitor and audit the practices of the IRB, the clinical department-based research administration, as well as individual members of LGH's research community, including investigators.

Each of these areas of oversight will require sufficient resources, tools and knowledge to best fulfill their compliance and regulatory mandated responsibilities in research. To that end, the RCO shall be accountable for developing a training curriculum that will be available in multiple formats to ensure ease of use and accessibility. The RCO will also review the existing set of templates, forms, documents, and electronic resources available to the research community.

The RCO will work closely with the Research Quality Assurance Office or LGRI to identify issues, challenges and opportunities. Integration of the RCP into the LGRI will lead to value-added compliance program initiatives and assist the RCO in his/her efforts to identify risks; strengthen auditing and monitoring; author more effective policies; and design useful, intellectually stimulating training programs.

Corrective Action and Discipline

In such matters where corrective action and/or disciplinary actions are appropriate, refer to the LGH Compliance Program.

Anonymous Reporting

The LG Health Compliance Program Hotline may be utilized to report research compliance concerns.

The Research Compliance Committee

The Research Compliance Committee (RCC) is chartered, under the authority of the Audit and Compliance Committee of the Board of Trustees (ACC), the CEO of LGH, and the LG Health Vice President of Risk Management and Corporate Compliance to review allegations of research misconduct, allegations of research noncompliance, conflicts of interests related to research, and other research compliance matters in accordance with LGH policies and procedures. The RCC reports to the ACC.

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The Research Compliance Officer in conjunction with the Vice President of Risk Management and Corporate Compliance shall appoint members to the committee. The committee will consist of the following:

- Administrative Director of the Lancaster General Research Institute – Research Compliance Officer (Committee Chair)
- Vice President of Risk Management and Corporate Compliance
- Senior Vice President, General Counsel, Corporate
- Vice President of Academic Affairs
- Physician member of the Research Leadership Advisory Council – (two year term)

The RCC will seek consultation from outside the committee whenever additional expertise is required. For example, the chair of the Institutional Review Board may be asked to provide input to review allegations and noncompliance of human subject protection requirements or research-related conflict of interest disclosures.

The Lancaster Research Institute will provide administrative support to the Research Compliance Committee.

The committee will meet quarterly; however, *ad hoc* meetings will be convened whenever necessary as determined by the committee chair. Meetings may be convened via teleconference and voting may occur via email.

Inh

7/18/14, revised 1/1/15, 12/19/22

Ref. LG Health Compliance Program
Conflict of Interest Disclosure Policy
Misconduct in Research Policy

Lancaster General Health Corporate Compliance

Addendum B - Tier Level Training

Compliance Education Tiers

Addendum B to Compliance Program Policy

| TIER | DESCRIPTION | EXAMPLES OF INCLUDED PARTIES |
|------|---|--|
| 1 | BASIC Requires training in general compliance concepts, responsibilities and expectations. All employees and certain other individuals receive, but are not limited to, New Employee Orientation and annual Computer Based Learning. Further education not required for the individual who is not responsible for the generation of claims (for example), does not treat or document in medical records, and/or is otherwise in a low risk position. | All employees, Vendors, Agency Staff, Independent Contractors, Clinical Students, Medical and Dental Staff members as defined by the LG Health Compliance Program, employees of Penn Home Health, formerly Affilia, and Horizon Healthcare Services. |
| 2 | SPECIALIZED Requires targeted training specific to role. Examples of those who qualify for this level of education are those responsible for revenue generation, has fiduciary responsibility. Individual has supervisory responsibility, and ability to enforce policy (non-retaliation, etc.). | Board Members, Board Committee Members, Officers, resident physicians, physicians and advanced practice providers, coders, credentialing, medical staff office, executive office, physician recruiting, directors, managers, nursing, and clinical research. |

Date : 1/1/2016