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:

- 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 planed 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

- 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.

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