RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS, CO-INVESTIGATORS, AND RESEARCH STAFF FOR RESEARCH INVOLVING HUMAN SUBJECTS GUIDELINES

1. Overview

Principal investigators (PIs) are ultimately responsible for the ethical conduct of human subjects research and for compliance with federal regulations, applicable state and local law, and institutional policies. These responsibilities are shared with investigators' research staffs and the Main Line Health Human Research Protection Program (HRPP), including the Main Line Hospitals Institutional Review Board (MLH IRB) and Office of Research Affairs (ORA). This policy describes the scope of responsibilities for principal investigators, co-investigators and research staff who conduct human subjects research at Main Line Health.

2. Definitions

Principal Investigator (PI): An individual with the appropriate scientific and/or scholarly training and expertise to assume direct responsibility for the ethical conduct of a study involving human subjects, providing technical and administrative oversight of the research and making important study-related decisions. *Note: For purposes of HRPP policy, only one individual is designated as the principal investigator of a human research study.*

3. General Information

A. All investigators and research staff will adhere to the principles outlined in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report entitled, Ethical Principles & Guidelines for the Protection of Human Subjects of Research ("Belmont Report") when conducting research involving human subjects.

B. All investigators and key personnel will conduct research according to all applicable Main Line Health and MLH IRB policies, as well as federal, state, and local laws and guidance for the protection of human subjects in research. Researchers will also consider the applicable professional practice standards of their disciplines and other generally accepted good research practice guidelines in the development and performance of human research studies.

4. Principal Investigator Qualifications, Oversight, and Resources

A. PIs will have appropriate education, training, and experience to assume overall responsibility for the ethical conduct of their human subjects research. This includes training in human subjects protection requirements. Refer to the MLH IRB Policy and Procedure on the Main Line Hospitals Education Requirements for Individuals involved in human subjects research activities at Main Line Hospitals (I) for more information on the requirements. Additional training requirements may also apply for investigators receiving funding from specific sponsors (e.g., NIH).

B. Only one individual may be designated as the principal investigator of a human research study.

C. PIs are responsible for knowing when proposed activities are defined as "research involving human subjects" or for seeking guidance, as appropriate. PIs will provide the IRB (or designees) with sufficient information and materials to make the determinations required. Refer to the MLH IRB Policy and Procedure on Research Determinations and Activities Requiring IRB Review (V) for more information.

D. PIs will ensure that research does not begin until IRB approval or exemption has been obtained.

E. PIs are responsible for the selection and training of individuals who may assist with their research and will obtain IRB approval for the involvement of (and any changes in) co-investigators and research staff. Training of study personnel should provide staff a general familiarity with the research methods and objectives (as applicable), as well as study-specific information relevant to the tasks to be performed.

F. PIs may delegate study-related tasks to appropriately qualified and trained study personnel. PIs will maintain oversight of and retain ultimate responsibility for the conduct of those who perform delegated functions.

G. PIs will ensure that all researcher staff assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies.

H. PIs will keep co-investigators and research staff informed of any changes made to the research while the study is ongoing.

I. PIs will ensure that they have sufficient time to properly conduct and/or supervise proposed research and study personnel and that adequate resources (e.g. qualified staff, facilities, medical/psychosocial services) are available to safely carry out the approved project.

J. If a PI leaves the institution or is unavailable to personally conduct or supervise ongoing research (e.g., on extended leave), he/she must make arrangements to amend (including a change in PI) or terminate the research, as appropriate.

K. PIs and their co-investigators and research staff will disclose all personal financial interests relevant to their institutional commitments, as required by regulations and institutional policy, and will work to eliminate or manage potential conflicts of interest when applicable.

5. Conduct of Human Subjects Research

A. PIs are responsible for designing and conducting research in a manner that minimizes risks, using sound research design and generally accepted scientific and/or scholarly standards. Investigators performing research involving investigational drugs, biologics, or devices will comply with applicable FDA regulations and MLH IRB Policies and Procedures.

B. PIs and research staff will perform the research as approved by the MLH IRB (or as determined exempt) and will follow the terms of an associated grant, contract, and/or signed funding agreement, if any. Researchers will not make changes to the research or informed consent process until approved by the IRB, except where necessary to eliminate apparent immediate hazards to subjects, and will inform the IRB (and sponsor as applicable) of any such changes.

C. PIs will obtain continuing review and approval of ongoing non-exempt research (i.e., until research-related interactions/interventions with human subjects or analysis of individually identifiable private information have been completed) at the interval determined by the IRB (at least annually) to avoid expiration of IRB approval and cessation of all research activities.

D. PIs will comply with all IRB determinations, conditions, and requirements.

6. Protecting the Rights, Safety, and Welfare of Research Subjects

A. PIs and research staff will recruit subjects in a fair and equitable manner that avoids the potential for coercion and undue influence.

B. Using the IRB-approved consent process(es), PIs and research staff will obtain and document informed consent (unless waived) and HIPAA research authorization (when applicable) from subjects or their legally authorized representatives prior to the subjects' involvement in the research. Researchers will provide subjects or representatives sufficient opportunity to consider whether to participate and will ensure that subjects' (or representatives') choices are voluntary and based upon informed decisions.

C. To minimize risks to subjects, investigators and research staff will follow procedures to protect the privacy of subjects and maintain the confidentiality of research data.

D. When vulnerable populations such as children, prisoners, pregnant women, adults unable to consent for themselves, or economically or educationally disadvantaged persons are included in research, investigators will provide additional required protections.

E. For greater than minimal risk research, investigators will appropriately monitor research data to ensure subject safety.

F. PIs and research staff will respond promptly to subjects' complaints and/or concerns or requests for information. Researchers will involve the IRB (or designees) in their responses when appropriate.

G. During and following the conduct of the research, PIs will provide subjects with significant new findings that may relate to the subjects' well-being and/or willingness to continue to participate.

7. Reporting and Recordkeeping Requirements

RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS, CO-INVESTIGATORS, AND RESEARCH STAFF FOR RESEARCH INVOLVING HUMAN SUBJECTS GUIDELINES

A. Investigators and research staff will report promptly unexpected or serious adverse events, protocol violations, deviations, incidents and complaints to the IRB according to the MLH IRB Policy and Procedure on Unanticipated Problems Involving Risks to Subjects or Others (XVVIII) for more information.

B. PIs and research staff will follow the MLH IRB Policy and Procedure Manual on Noncompliance (XX) for reporting any potential noncompliance with applicable regulations, state or local laws or the requirements or determinations of the IRB.

C. PIs will provide a final study report to the IRB and any other required reports to sponsors or funding/regulatory agencies, as applicable, when all research activities have ended (including data analysis with individually identifiable private information).

D. PIs will promptly report updated study safety information to and from regulatory agencies.

E. PIs will promptly report to the IRB requests for inspections, or other research-related inquiries from a federal agency.

F. PIs will maintain research-related records (including original or “source” documents) in a manner that documents the validity of the research and integrity of the data collected, while protecting the data’s confidentiality and the privacy of research subjects. Investigators are responsible for the accuracy, completeness, legibility, and timeliness of the data recorded and reported in research and in research publications.

G. Investigator records are considered the official research file. PIs will retain research-related records (e.g., the study protocol, consent forms, IRB correspondence, etc.) in accordance with the MLH Administrative Policy on Records Management (Retention and Destruction) (I.96). Additional requirements for records retention may apply depending on the type and/or sponsor of the research

H. Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with applicable MLH Policies and sponsor or funding agency requirements.

I. PIs must assure that the Protected Health Information (PHI) created or used in the research study, if any, is the minimum necessary to meet the research objectives, and that PHI is not reused or disclosed to any parties other than those described in the IRB-approved protocol, except as required by law. Note: Users are prohibited under any circumstance to use personal electronic equipment to access MLH proprietary data or download Protected Health Information. Refer to Information Systems Policy: Personal Electronic Equipment [Policy (VIII.35) for more information.