MAIN LINE HOSPITALS INSTITUTIONAL REVIEW BOARD
POLICY AND PROCEDURE MANUAL

Policy No. V.

Subject: RESEARCH DETERMINATION AND ACTIVITIES REQUIRING IRB REVIEW

POLICY

Research involving human subjects requires the review of an Institutional Review Board for any research or clinical investigation that involves human subjects as defined below. Research that does not meet the regulatory definition of human research or clinical investigations does not require IRB approval.

DEFINITIONS

1. Research:

a. Department of Health and Human Services (DHHS) Regulations - "a systematic investigation, including research, development, testing and evaluation designed to develop or contribute to generalizable knowledge."

i. Systematic investigation - A study following a methodical plan to establish factual information concerning the truth of a specific hypothesis or theory.

ii. Generalizable knowledge - Knowledge that may be justifiably transferred or extrapolated to a broader population or situation than that in which it has been derived

b. DHHS Regulations – "clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes."

c. Food and Drug Administration (FDA) Regulations – a clinical investigation means "any experiment that involves test article(s) and one or more human subjects."

i. Test article - Any drug (including a biological product for human use, medical device for human use), human food additive, color, adaptive, electronic product, or any other article subject to regulation under the jurisdiction of the FDA.

2. Human subject:

a. DHHS Regulations - "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) obtains, use, studies, analyzes or generates identifiable private information or identifiable biospecimens."

i. *intervention* includes both physical procedures by which information or biospecimens are gathered (e.g. venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

ii. *Interaction* includes communication or interpersonal contact between investigator

and subject.

iii. *private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.,* a medical record).

iv. *identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

v. *identifiable biospecimen* is a biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated with the biospecimen.

b. FDA Regulations - "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."

3. Research involving human subjects[5]:

a. DHHS Regulations - Meets the definition of research involving human subjects as referenced in Sections 1 and 2 above.

b. FDA Regulations - Meets the FDA definition of clinical investigation involving human subjects as referenced in Sections 1 and 2 above.

PROCEDURE

Any individual who is unsure whether or not a proposed activity should be classified as research should contact the IRB for guidance with a written description of the project. Investigators have the option to obtain from the IRB documentation that the activity is not subject to IRB review. To obtain documentation, investigators must submit a description of the proposed activity in writing. The IRB Chair or Office of Research Protections (ORP) Director or their designees make the determination.

A. Activities which require IRB review include, but are not limited to:

1. Any experiment that involves a test article and one or more human subjects, that are regulated by the Food and Drug Administration or support applications for research or marketing permits for products regulated by the FDA. Products regulated include foods, including dietary supplements, medical devices, drugs, biological products human food additives, colors, adaptive and electronic products.

2. Collection and use of data about a series of standard procedures or treatments for dissemination or generalization if the activity meets the definition of research involving human subjects".

3. Patient care or the assignment of normal subjects to any intervention that is altered for research purposes in any way.

[5] Although not meeting the regulatory definition of research involving human subjects, the privacy rights of non-living individuals are protected under the Privacy Rule. Review by the MLH IRB, acting as the Privacy Board for research may be required. Refer to Administrative Policy VII 17 on *HIPAA: Use of Protected Health Information for Research* for more information.

4. A diagnostic procedure for research purposes that is added to a standard treatment.

5. Systematic investigations of innovations in diagnostic, therapeutic procedure or instructional method in multiple subjects in order to compare standard procedure. The investigation is designed to test a hypothesis, permit conclusions to be drawn, thus to develop or contribute to generalizable knowledge.

6. Emergency Use of an Investigational Test Article. One time emergency use of an investigational test article may proceed without *prospective* IRB review and approval. The patients receiving an investigational test article in an emergency setting are generally not considered research subjects and data obtained from patients may not be classified as human research and may not be included in any report of research activities subject to DHHS regulations. **NOTE: The investigator has additional responsibilities, including notifying the IRB, before and/or after the emergency use of an investigational test article. Refer to Policy VIII Emergency Use of an Investigational Test Article for more information**

7. Emergency Medicine Research. Prospectively planned emergency medicine research with investigational drugs, devices, or biologics requires IRB approval. If the investigator intends to request a waiver of the requirement for informed consent, additional requirements must be met including community consultation and public disclosure.

8. In Vitro Device (IVD) Studies. Current FDA guidance indicates that IRB review is required for any IVD study involving human specimens/samples, even when the specimens are leftover human specimens, the research involves no identifiers or the biological materials cannot be linked to any identifying information. (FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable and or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.) See 2006 FDA *Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable*.

9. Individually Identifiable Data and Human Tissue. Use of data or human tissue for research which is identifiable requires IRB review.

10. Investigator Initiated Research. An investigator who both initiates and conducts, alone or with others, a research project or clinical trial regardless of source of funding or support.

11. Resident/Fellow Research. Directed or independent human research projects which employ systematic data collection with the intent to contribute to generalizable knowledge.

12. Access/review of protected health information for research purposes. Protected health information belonging to Main Line Health, Main Line Hospitals, or other MLH Affiliate may not be used internally or disclosed to any persons or

organizations outside MLH for research purposes without prior approval. Refer to the MLH IRB Policy on HIPAA-Use of Protected Health Information (PHI) for Research (XXIII).

13. Collaborative Research. Collaborative research requires IRB review by each site unless an IRB Authorization or Independent Investigator Agreement is in place.

14. Decedent Research. Access to protected health information of decedents requires IRB review and approval up to a period of 50 years following the death of the individual. Refer to the MLH IRB Policy on HIPAA: Use of Protected Health Information for Research (XXII).

B. Activities Not Subject to IRB Review include, but are not limited to:

1. Proposals that do not meet the definition of human subjects' research will not require IRB review.

2. Quality Assurance/Quality Improvement. Systematic, data-guided activities designed to implement promising ways to improve clinical care, patient safety and health care operations do not require IRB review. The activity is designed to bring about immediate positive changes in the delivery of health care, programs or business practices in the local setting and is not designed to develop or contribute to generalizable knowledge. QA/QI activities with research intent require IRB review.

3. Activities such as program and fiscal audits and certain disease monitoring as prescribed by the Public Health Department generally do not qualify as research.

4. Case Reports. A retrospective review of medical records for publication of a case report is not considered human research and does not require IRB review and approval. Generally this involves three or less clinical cases and all data must be de-identified. Prospective intent to use data that would not ordinarily be collected in the course of treatment requires IRB review.

5. Innovative therapies / practice to provide diagnosis, preventative treatment or therapy to particular patients that does not involve research as previously defined. Care of a patient is considered research if there is clear intent before treating a patient to use systematically collected data which would not ordinarily be collected in the course of clinical practice in reporting and publishing a case study.

6. Coded private information or biological specimens that were not collected for the currently proposed projects do not need IRB review as long as the information cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. The investigators and the holder of the key enter into an agreement (generally referred to as a data use agreement) prohibiting the release of the key to the investigators under any circumstances. The agreement should be kept by the investigator and available for review when requested.

7. Public Health Activities where the purpose of the activity is to identify and control a health problem or improve a public health program or service; intended benefits of the project are primarily or exclusively for the participants (or clients) or the participants' community; data collected are needed to assess or improve the program or service, the health of the participants or the participants' community; knowledge that is generated does not extend beyond the scope of the activity; and project activities are not experimental. For more information refer to

http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf

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