ADMINISTRATIVE POLICY AND PROCEDURE MANUAL
MAIN LINE HOSPITALS INSTITUTIONAL REVIEW BOARD

Part 1 **Policy No. I**

Subject: **MAIN LINE HOSPITALS EDUCATION REQUIREMENTS FOR INDIVIDUALS INVOLVED IN HUMAN SUBJECTS RESEARCH ACTIVITIES AT MAIN LINE HOSPITALS**

Policy

Main Line Hospitals is responsible for providing, through the Office of Research Affairs at Lankenau Institute of Medical Research (LIMR), an education program on the ethics of conducting human subjects research and the federal regulations pertaining to such research for all personnel involved in the conduct of clinical research studies using human subjects at Bryn Mawr Hospital, Lankenau Medical Center, Paoli Hospital, Riddle Hospital and Bryn Mawr Rehabilitation Hospital. This policy also applies to all IRB administrative staff, and all IRB members. Each person covered by this policy must successfully complete the education program administered by LIMR. Certification of successful completion of the training must be renewed every three years.

Procedure

The Education Program in Human Subjects Research at MLH consists of the following:

1. An on-line computer based training program that must be completed by all current and new investigators, their research support staff, IRB Members and IRB administrative support staff. Successful completion of the computer based program will provide a certification of the training in Human Subjects Research.
2. Continuing education and training is required of clinical investigators, their research support staff, IRB Members and IRB administrative support staff.

Process

Computer Based Training and Continuing Education:

The LIMR Office of Research Affairs uses a subscription on-line service to complete the training requirement for human subjects researchers, research support staff, IRB members, and IRB Administrative staff. The program is sponsored by the Collaborative IRB Training Initiative (CITI) . Completion of the computer based curriculum is required for certification to conduct or be involved in human subjects research. Investigators and their research support staff, IRB administrative staff, and IRB members are required to renew their certification in human subjects research every three years by successfully completing the on-line CITI Program.

The IRB requires all individuals responsible in the design, conduct and reporting of a study to complete and remain current with the training requirements before approval will be granted. This includes, but is not limited to, investigators, sub-investigators, staff, coordinators and nurses involved

in the conduct of a study. Such individuals are required to renew their certification in human subjects research every three years from the time they successfully complete the Basic CITI training course.

The link to the on-line CITI Training course is available on the Office of Research Affairs website at http://www.limr.org/ORA or directly at www.citiprogram.org There are several groups to choose from as outlined below.

Group 1 - Biomedical Research: For research personnel who engage in Biomedical research

Group 2 - Social and Behavioral Research: For research personnel who engage in Social and Behavioral research which does not involve biomedical procedures. Research personnel who engage in biomedical research must also complete the Group 1 Module.

Group 3 - Data or Specimen ONLY Research: for research personnel who engage exclusively in secondary data analysis of data, human tissues and/or samples. This group does **NOT** satisfy the educational requirements for Biomedical or Social and Behavioral Research. If you are planning to conduct Biomedical or Social and Behavioral research you are required to take Group 1 and/or Group 2.

Group 4 - IRB Members: for IRB members and staff. This group does **NOT** satisfy the educational requirements for Groups 1, 2 or 3.

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