SCOPE:	DOMAIN OF APPLICATION:
To describe the procedure for the review of clinical trials.	All individuals participating in clinical research/investigation/trials involving human subjects
	ANNEXES: - MA-L-06: Ethics and Research Committee - MA-F-30: Ethics committee reviewer form
REFERENCE DOCUMENTS: - Regulation number 141 issued by the ministry of public health, 2016 - Joint Commission International Accreditation Standards for Hospitals, 6th Edition - MA-P-17: Human Clinical Trial Submission - MA-P-18: Human Subjects Research	**DEFINITIONS AND ABBREVIATIONS:** - CV: Curriculum Vitae - NIH: National Institute of Health - CITI: Collaborative Institutional Training Initiative - MLH: Mount Lebanon Hospital

POLICY:

MA-PO-59:

Human subjects research within Mount Lebanon Hospital not is guided by regulations and by the executive committee. The executive committee:

- Appoints a responsible for maintaining the development of and compliance with all human subjects research policies and procedures
- Assumes responsibility for patient protection irrespective of the research
- Recognizes and establishes mechanisms for compliance with all regulatory and professional requirements related to research
- Ensures that there is a source of indemnity insurance to adequately compensate patients participating in clinical research who experience and adverse event

Human subject research within Mount Lebanon Hospital is not conducted to inpatients but only outpatients; therefore admission and/or transfer criteria to a specialized ward due to research and/or another specialized program is not required.

The steps to be followed in case of trials are as follows:

- The ethics committee safeguards the rights, safety and well-being of all trial subjects. Special attention is paid to trials that may include vulnerable subjects.
- The committee obtains the following documents: trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in clinical trial, subject recruitment procedures, written information to be provided to subjects, investigator's brochure, available safety information, information about payments and compensation available to subjects, the investigator's current CV and/or other documentation evidencing qualifications and any other documents that the committee may need to fulfill its responsibilities.
  The committee reviews a proposed clinical trial within a reasonable time and documents its views in writing (on MA-F-30), clearly identifying the trial, the documents reviewed and the dates for the following:
  - Approval / favorable opinion
  - Modification required prior to its approval/favorable opinion
  - Disapproval / negative opinion
  - Termination / suspension of any prior approval / favorable opinion
- The investigator and all other study personnel should have conducted a NIH or CITI exam on protection of human subject involved in clinical research.
- The committee considers the qualifications of the investigator for the proposed trial, as documented by a current CV and/or by any other relevant documentation the committee requests.
- The committee conducts continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year.

- The committee may request more information to be given to subjects when, in the judgment of the committee, the additional information would add meaningfully to the protection of the rights, safety and well-being of the subjects.
- When a non-therapeutic trial is to be carried out, the consent of the subject's legally acceptable representative is needed; the committee determines that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials.
- Where the protocol indicates that prior consent of the trial subject's legally acceptable representative is not possible, the committee should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials.
- If subjects are to be paid, the committee reviews both the amount and method of payment to assume that neither presents problems of coercion or undue influence on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject.
- The committee ensures that information regarding payment to subjects, including the methods, amounts and schedule of payment to trial subjects, is set forth in the written informed consent form and any other written information to be provided to subjects. The way payment will be prorated should be specified.
- The committee performs its functions according to written operating procedures, maintains written records of its activities and minutes of its meetings and should comply with the applicable regulatory requirements.
- Archiving is done for 15 years at MLH.
- The committee makes its decisions at announced meetings at which at least a quorum is present.
- Only members who participate in the committee's meetings review and discussion are allowed to vote / provide their opinion and/or advice.
- The investigator cannot participate in the deliberations of the committee or in the vote/opinion of the committee.
- Nonmembers with expertise in special areas can be invited by the committee for assistance.
- Concerning the management of procedures, the committee:
  - Conducts initial and continuing review of trial.
  - Provides, according to the applicable regulatory requirements, expedited review and approval / favorable opinion of minor change(s) in ongoing trials that have the approval / favorable opinion of the committee
  - Specifies that no subject should be admitted to a trial before the committee issues its written approval / favorable opinion of the trial.
  - Specifies that no deviations from, or changes of, the protocol should be initiated without prior written committee approval / favorable opinion of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involves only logistical or administrative aspects of the trial (ex: change of monitor(s), telephone number(s)).
  - Specifies that the investigator should promptly report to the committee:
    - Deviations from, or changes of, the protocol to eliminate immediate hazards to the trial subjects
    - Changes increasing the risk to subjects and/or affecting significantly the conduct of the trial
    - All adverse drug reactions that are both serious and unexpected
    - New information that may affect adversely the safety of the subjects or the conduct of the trial
  - Ensures that the committee promptly notifies in writing the investigator / institution concerning:
    - Its trial-related decisions/opinions
    - The reasons for its decisions/opinions
    - Procedures for appeal of its decisions/opinions
  - Ensure that the investigator(s) and study personnel follow good clinical practice – international conference or harmonization's guidelines.