SCOPE: To describe the procedure for recruitment and information of patients and families who decided to participate in clinical research/investigation/trial at MLH.	**DOMAIN OF APPLICATION:** 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 - MA-F-35: Clinical Trial Application Form in Human Subjects
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-20: Review of clinical trials	**DEFINITIONS AND ABBREVIATIONS:** - CRO: Contract Research Organization - 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.

- Whenever a human subjects research is to be conducted at MLH, the sponsor/CRO submits the required documents (mentioned in MA-P-17) to the hospital's Ethics Committee and fills the form (MA-F-35) to describe the elements of the trial conducted.

- One of the ethics' committees roles being the oversight of all researches in the hospital involving human subjects (as per MA-L-06), the committee meets to approve or decline the submitted research protocol after:
  - Reviewing the protocol (as per MA-P-17 and MA-P-20)
  - Weighing the relative risks and benefits to subjects
  - Checking that it provides confidentiality and security of research information

  The chairperson assigns a reviewer with adequate clinical research credentials independent of the protocol to review the submitted protocol.

  The form (MA-F-30) is filled to ensure that all required documents are submitted and that the informed consents elements are present.

- If the submitted research protocol is approved by the ethics committee, the latter informs the principal investigator by a letter about the final decision of the ethics committee.

- Appropriate patients and families are identified by the physician, where patients and families are informed about how to gain access to clinical research/investigation/trials relevant to their treatment needs. Patients and families asked to participate are informed about:
  - The research and the patient's role in the research
  - The expected benefits
  - The potential discomforts and risks

- The alternatives that might also help them
- The procedures that must be followed
- The patient's rights related to refusal to participate or withdrawal from participation in research, with insurance that this will not compromise their access to the hospital's services
- The patient's right to confidentiality and security of information
- The hospital's process for obtaining consent

- When patients and families decide to participate in clinical research/investigation/trial, they must grant an informed consent. This informed consent is edited in a language understood by the patient, and the identity (name and signature) of the individual(s) providing the information and obtaining the consent is noted. The consent is documented and dated in the patient's record by signature.
- Patients and families are informed about how patients who choose to participate in clinical research, clinical investigation or clinical trials are protected. They are informed about:
  - The research and the potential benefits and risks.
  - Their right related to withdrawing for participate.
  - Their right to confidentiality and security of information.
  - The hospital's process for obtain consent.