LOMA LINDA UNIVERSITY
MEDICAL CENTER

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OPERATING POLICY

CATEGORY:	PROFESSIONAL PRACTICE	**CODE:**	Q-4
		EFFECTIVE:	08/2017
SUBJECT:	HUMAN STUDIES	**REPLACES:**	09/2014
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Philosophy: The ethical conduct of biomedical research assumes that the researcher and the subjects are always fellow human beings, equal in dignity and rights. The researcher's quest for knowledge must always be balanced with respect for the participants, their rights and welfare. Thus LLUMC policy is intended to support the legitimate impulse for scientific inquiry within the context of human values and ethical principles.

1. LLUMC shall participate with LLUH in a joint Human Studies Committee known as the Institutional Review Board (IRB). LLUMC shall provide specialized members for the Board to ensure that patient, staff, and institutional coordination is achieved.

   NOTE: The IRB can be contacted through the Loma Linda University Health (LLUH) Office of the Vice President for Research Affairs (VPRA).

2. Any research or investigational study or clinical trial involving human subjects and conducted at LLUMC, on its premises or under its sponsorship, whether or not supported by outside funds, shall be submitted for review and approved by the LLUH IRB.

   2.1 The IRB shall review all proposed research studies for adherence to ethical, scientific, regulatory and institutional standards, and adequacy of the informed consent process.

   2.2 The IRB shall have continuing oversight of studies presented for its review, including the authority to:

   a) Approve, require modifications to, or disapprove all new and continuing human subject research.
   b) Suspend or terminate approval of research that has been associated with non-compliance of IRB requirements and/or unexpected serious harm to participants.
   c) Observe, or have a third party observe, the consent process and/or the conduct of research

   2.3 In consultation with the Research Oversight Committee, the LLUH President or VPRA or LLUMC CEO may disallow research that is not in harmony with the institution's mission, policies, or interests. No individual or group may approve human subject research that has been disapproved by the IRB.

3. The IRB Chair shall bring to the attention of the VPRA any research posing unusual or excessive institutional risk. The VPRA shall coordinate appropriate institutional reviews.

4. All personnel engaged in human studies shall be required to have current certification for education in human studies as defined and coordinated by the LLUH VPRA.

5. In requiring IRB review of proposed research on human subjects, LLUMC affirms its commitment to the principles of human subject research ethics embodied in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978).

6. In all human studies, the principal investigator shall ensure that:

   6.1 Informed consent is obtained in an ethical and legal manner, unless waived by the IRB

   6.2 Unexpected Problems are reported to the IRB

   6.3 Periodic reports are submitted as required by the IRB

   6.4 All participating researchers, staff, and other key personnel are aware of their responsibility to comply with all applicable policies regarding human studies research.

   6.5 The budget for human studies adequately reimburses LLUMC for services and use of facilities.

   NOTE: The budget for all human studies involving extramural funding shall be reviewed and approved by the office of the LLUH VPRA on behalf of LLUMC.

APPROVED: Hospital Executive Leadership, LLUMC Board, LLUMC Chief Executive Officer, LLUMC Chief Nursing Officer, LLUMC Ethics Committee, LLUMC Medical Staff President and Chair of MSEC, Travis Losey
Chair, Institutional Review Board