LAC+USC MEDICAL CENTER POLICY

Subject:	Original Issue Date:	Policy #
HUMAN SUBJECTS RESEARCH APPROVAL	6/93	**233**
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Departments Consulted:	Reviewed & Approved by:	Approved by:
Risk Management Institutional Review Board (IRB) Ethics Resource Committee	Attending Staff Association Executive Committee Senior Executive Council	Chief Medical Officer Chief Executive Officer

PURPOSE

To describe the process by which human subjects research conducted within the LAC+USC Medical Center is approved and monitored.

POLICY

Human subjects research conducted within LAC+USC Medical Center must comply with applicable state and federal regulations governing research, and must adhere to the ethical principles contained in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research and the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

Before being initiated, all human subjects research conducted within the LAC+USC Medical Center must be approved or deemed Exempt by the local Institutional Review Board (IRB), a registered IRB listed on the LAC+USC Medical Center Federal Wide Assurance (FWA) or an IRB designated on an IRB authorization agreement signed by the Chief Medical Officer.

The local IRB shall be appropriately established and constituted and its activities conducted in compliance with federal and State laws and regulations. Investigators and all key personnel in proposed research, including those individuals obtaining informed consent, must have completed a required educational program on the protection of human research participants.

IRB authority is granted by the Director, Los Angeles County Department of Health Services in accordance with the Los Angeles County contract and Attending Staff Association Bylaws. The responsibility of the IRB is to protect research participant safety, rights, and welfare. The IRB approves and monitors research in accordance with the Institution's FWA with Department of Health and Human Services (DHHS), regulations of the Food and Drug Administration (FDA) and the IRB Human Subjects Protection Program Policies and Procedures.

Clinical research involving human participants must be conducted in Medical Center-approved patient care settings. Exception requires approval of the Medical Center Chief Medical Officer and Chief Executive Officer, with concurrence of the IRB. Human subjects research in Comprehensive Health Centers requires the approval of the facility Medical Director. A list of IRB-approved research projects proposed for Medical Center facilities shall be maintained and distributed to the Medical Center Executive Council members.

PROCEDURE DOCUMENTATION

Institutional Review Board Policies and Procedure Manual

REFERENCES

Title 45 CFR 46 (Department of Health and Human Services, Protection of Human Subjects)
Title 21 CFR 50 (Food and Drug Administration, Protection of Human Subjects)
Title 21 CFR 56 (Food and Drug Administration, Institutional Review Boards)
Title 21 CFR 312, Subparts A, B, C (Food and Drug Administration, New Drug Application
Title 21 CFR 312, Subparts D, E (Food and Drug Administration, Responsibilities of Sponsors and Investigators)
Title 812 (Food and Drug Administration, Investigational Device Exemptions)
Title 34 CFR 99 (Family Educational Rights and Privacy Act (FERPA)
Public Law 103-403 (Research on Transplantation of Fetal Tissue)
National Institutes of Health (NIH) Guidance and Policy
Office for Human Research Protections (OHRP) Guidance
Food and Drug Administration (FDA) Guidance
45 Code of Federal Regulations, Parts 160 and l64; Section 164.512
California Health and Safety Code, Sections 24170-24179.5 (Protection of Human Subjects in Medical Experimentation Act)
California Code of Regulations, Title 22
Attending Staff Association Bylaws
Los Angeles County Contract, No. H-202522
Institutional Review Board Policies and Procedures
The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research
Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
Nuremberg Code
Declaration of Helsinki

REVISION DATES

February 11, 1999; April 9, 2002; January 27, 2004; June 10, 2008; September 29, 2008; February 10, 2015; July 30, 2018