

LOS ANGELES COUNTY COLLEGE OF NURSING AND ALLIED HEALTH POLICY & PROCEDURE

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Subject: RESEARCH APPROVAL PROCESS	Original Issue Date: December 9, 2004	Policy #: 130
	Supersedes: April 12, 2012	Effective Date: April 9, 2015
Committees Consulted: Institutional Review Board College Administration Office of Risk Management	Reviewed & Approved by: College Institutional Effectiveness Committee College Planning	Approved by: Provost, College of Nursing & Allied Health (Signature on file)

PURPOSE:

To describe the process for obtaining approval to conduct research with Los Angeles County College of Nursing and Allied Health

To protect human subjects from harm or adverse outcomes related to their involvement in research

To ensure compliance with all regulatory agencies including (Health Insurance Portability and Accountability Act) HIPAA regulations

POLICY:

All research involving human subjects:

- Is approved by the Institutional Review Board (IRB) for the University of Southern California (USC) Health Sciences Campus, LAC+USC Medical Center, and Health Research Association.
- Abides by all regulatory agency requirements, HIPAA, DHS, and LAC+USC Medical Center policies.

The Provost/designee authorizes all research proposals prior to submission to IRB and prior to implementation.

Research proposals must include the following elements:

- Introduction
 - Problem statement
 - Explanation of how the study is grounded in research literature
 - Potential contribution to knowledge and practice
 - Hypotheses, questions, or objectives
- Literature review
- Research design
- Research methods detailing:
 - Selection of subjects
 - Interventions
 - Data collection
- Privacy and confidentiality
- Assessment of risks and benefits
- Any conflict of interest
- Data analysis

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- References
- Time line.

Public dissemination of research findings must be approved by the Provost
Copies of research documents are maintained by the college for seven years after research completion

A copy of the final Research Report will be submitted to the College library.

PROCEDURE:

Project Initiator:

- Submits Research Proposal, Research Approval Request form, and Curriculum Vitae to the Provost/designee and to the Director of Research
- Submits proposal to the IRB for review after approval by Provost
- Submits proposal to the Chief Nursing Officer for review and approval if research is to be conducted in the Nursing Department. (Refer to LAC+USC Medical Center Department of Nursing Services policy)
- Complies with all current directives from the IRB during the course of conducting approved research
- Informs Provost/designee and IRB of any unanticipated adverse events or changes in protocol within two days of occurrence
- Submits copies of all related documents and findings to the Provost/designee and Director of Research

Provost or designee:

- Reviews proposal
- Signs Research Approval Request form if authorization is granted
- Returns original form to project initiator
- Gives a copy of signed Research Approval Request to the Director of Research

Director of Research:

- Files copies of all documents
- Maintains records of research projects for a minimum of seven years.

PROCEDURE DOCUMENTATION:

Research Approval Request
Current IRB forms

REFERENCES:

Code of Federal Regulations Title 45, DHHS Policy Part 46 - Protection of Human Research Subjects
Institutional Review Board for USC Health Sciences Campus, LAC+USC Medical Center, and Health Research Association Policies and Procedures
LAC+USC Healthcare Network Department of Nursing Services Policy # 303: Nursing Research/Grants
LAC+USC Medical Center Policy #233: Research Approval and Consent

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DHS Policy # 361.27: Use and Disclosure of Protected Health Information for Research Purposes.

Title 34 C.F.R Part 99 Family Educational Rights and Privacy (FERPA)

REVISION DATES:

December 9, 2004

May 14, 2009

April 12, 2012

April 9, 2015