Laws and Regulations Governing Clinical Research

Federal Regulations:

Office of Human Research Protection (OHRP)

Food and Drug Administration (FDA)
- 21 CFR Part 50 Human Subjects Protections (Informed Consent) and Additional Safeguards for Children in Clinical Investigations - [http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr50_00.html](http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr50_00.html)
- 21 CFR Part 56 Institutional Review Boards - [http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr56_00.html](http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr56_00.html)
- 21 CFR Part 312 Investigational New Drug Application (INDs) - [http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr312_00.html](http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr312_00.html)
- 21 CFR Part 812 Investigational Device Exemptions (IDE) - [http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr812_00.html](http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr812_00.html)

HIPAA

California (State) Statutes:
- Protection of Human Subjects in Medical Experimentation Act (HSC 24170-24179.5) - [http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51797614502+3+0+0&WAISaction=retrieve](http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51797614502+3+0+0&WAISaction=retrieve)
- Use of State Death Data Records (HSC 102231-102232) - [http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51791214415+0+0&WAISaction=retrieve](http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51791214415+0+0&WAISaction=retrieve)
- Consent for Minors Provision (HSC 111515-111545) - [http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51801614544+0+0&WAISaction=retrieve](http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51801614544+0+0&WAISaction=retrieve)
- Confidentiality of Research Records involving AIDS Patients (HSC 121075-121125) - [http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51803714571+0+0&WAISaction=retrieve](http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51803714571+0+0&WAISaction=retrieve)
- Derivation and Use of Human Stem Cells (HSC 125119-125119.5) - [http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51808514655+0+0&WAISaction=retrieve](http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51808514655+0+0&WAISaction=retrieve)
- Pharmacist to be responsible for the proper labeling, storage and distribution of investigational drug (California Code of Regulations, Title 22, 70263 (o)) - [http://ccr.oal.ca.gov/cgi-bin/om_isapi.dll?clientID=181788&advquery=70263&hitsperheading=on&infobase=ccr&record=629CE&softpage=Document42&x=48&y=7&zz=](http://ccr.oal.ca.gov/cgi-bin/om_isapi.dll?clientID=181788&advquery=70263&hitsperheading=on&infobase=ccr&record=629CE&softpage=Document42&x=48&y=7&zz=)
- Obtaining and using controlled substance for research (HSC 11212) -
  [http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51813714724+0+0+0&WAISaction=retrieve](http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51813714724+0+0+0&WAISaction=retrieve)
- Labeling of investigational drugs (Business and Professions Code 4078 (1)) -
  [http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51815614743+0+0+0&WAISaction=retrieve](http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51815614743+0+0+0&WAISaction=retrieve)

**Institution Policies:**
- Investigational drugs (LAC + USC Network Pharmacy Policy #250, #901) -
- Investigational Drug Service (LAC + USC Network Pharmacy Policy #119)
- RN to administer investigational drugs (LAC + USC Network Nursing Policy #908)
- Nursing research, grants and project collaboration (LAC + USC Network Nursing Policy # 300-B)
- Research Approval and Consent and IRB responsibilities ((LAC + USC Network Policy# 233)
- IRB Policies and Procedures

**JCAHO**
- Investigational drugs (Standard MM.7.40) -
  [http://www.intra.ccgh.com/AutomatedCAMH/mm.html#MM.7.10](http://www.intra.ccgh.com/AutomatedCAMH/mm.html#MM.7.10)
- Orders on investigational drugs (Standard MM.3.20) -
  [http://www.intra.ccgh.com/AutomatedCAMH/mm.html#MM.3.20](http://www.intra.ccgh.com/AutomatedCAMH/mm.html#MM.3.20)
- Hospital respects the rights of research subjects (Standard RI.2.180) -
  [http://www.intra.ccgh.com/AutomatedCAMH/ri.html#RI.2.180](http://www.intra.ccgh.com/AutomatedCAMH/ri.html#RI.2.180)
- Informed consent (Standard RI.2.40) -
  [http://www.intra.ccgh.com/AutomatedCAMH/ri.html#RI.2.40](http://www.intra.ccgh.com/AutomatedCAMH/ri.html#RI.2.40)

**Ethical Guidelines:**

**Financial Guidelines:**
- Health Care Financing Administration, National coverage Decision (NCD), September 19, 2000, Medicare reimbursement for medical services related to clinical trials -
- Unrelated business income tax (UBIT) on residual funds -
• Department of Health and Human Services (DHHS)-“Financial Relationships in Research Involving Human Subjects: Guidance for Human Subject Protection” (Federal Register May 12, 2004) -
   http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2004/04-10849.htm

• 48 CFR Part 31 (For-Profits) - http://www.access.gpo.gov/nara/cfr/waisidx_02/48cfr31_02.html

• Federal Office of Management and Budget (OMB) Circular A-122 (Non-profits) -

• 45 CFR Part 74, Appendix E (Hospitals on Effort Report) -
   http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2002/octqtr/45cfr74.91.htm

• OMB Circular A-21 (Universities on Effort Report) -
   http://clinton4.nara.gov/textonly/OMB/circulars/a021/a021.html

• 42 CFR section 405.205 and 411.15
   http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2002/octqtr/42cfr405.205.htm
   http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2002/octqtr/42cfr411.15.htm

PHS and FDA on Conflict of Interest
• 21 CFR Part 54 -
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54&showFR=1
• FDA Form 3455 - http://forms.psc.gov/forms/FDA/fda3455.pdf

IRB Conflict of Interest
• 45 CFR 46.107(e) - http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.107

Medicare and Medicaid Coverage on Clinical Trials
Submitting “routine costs” associated with “qualifying” clinical trials http://www.cms.gov