

Laws and Regulations Governing Clinical Research

Federal Regulations:

Office of Human Research Protection (OHRP)

- 45 CFR Part 46 (aka "The Common Rule") - <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
- 45 CFR Part 160 and 164 (164.512) - <http://www.hhs.gov/ocr/hipaapre.html>

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
- 21CFR Part 56 Institutional Review Boards - 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
- 21CFR Part 812 Investigational Device Exemptions (IDE) - 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&WAIAction=retrieve>
- Use of State Death Data Records (HSC 102231-102232) - <http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51791214415+0+0+0&WAIAction=retrieve>
- Consent for Minors Provision (HSC 111515-111545) - <http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51801614544+0+0+0&WAIAction=retrieve>
- Confidentiality of Research Records involving AIDS Patients (HSC 121075-121125) - <http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51803714571+0+0+0&WAIAction=retrieve>
- Derivation and Use of Human Stem Cells (HSC 125119-125119.5) - <http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=51808514655+0+0+0&WAIAction=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=

- Obtaining and using controlled substance for research (HSC 11212) - <http://www.leginfo.ca.gov/cgi-bin/waisgate?WAIISdocID=51813714724+0+0+0&WAIISaction=retrieve>
- Labeling of investigational drugs (Business and Professions Code 4078 (1)) - <http://www.leginfo.ca.gov/cgi-bin/waisgate?WAIISdocID=51815614743+0+0+0&WAIISaction=retrieve>

Institution Policies:

- Investigational drugs (LAC+USC Network Pharmacy Policy #250, #901) - http://www.health-research.org/files/drug_policy.pdf
- 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

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- Investigational drugs (Standard MM.7.40) - <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>
- Hospital respects the rights of research subjects (Standard 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>

Ethical Guidelines:

- Nuremberg Code - <http://ohsr.od.nih.gov/guidelines/nuremberg.html>
- Declaration of Helsinki - <http://ohsr.od.nih.gov/guidelines/helsinki.html>
- Belmont Report - <http://ohsr.od.nih.gov/guidelines/belmont.html>
- Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research - <http://ohsr.od.nih.gov/guidelines/belmont.html>

Financial Guidelines:

- Health Care Financing Administration, National coverage Decision (NCD), September 19, 2000, Medicare reimbursement for medical services related to clinical trials - <http://www.gamedicare.com/provider/cts.htm>
- Unrelated business Income Tax (UBIT) on residual funds - <http://www.irs.gov/charities/article/0,,id=96104,00.html>

- 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) - http://www.whitehouse.gov/omb/circulars/a122/a122_2004.html
- 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

- 21CFR Part 54 - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54&sho wFR=1>
- FDA Form 3455 - <http://forms.psc.gov/forms/FDA/fda3455.pdf>
- 42 CFR Part 50 (f) - http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm

IRB Conflict of interest

- 45 CFR 46.107(e) - <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.107>
- 21 CFR 56.107(e) - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.107>

Medicare and Medicaid Coverage on Clinical Trials

Submitting “routine costs” associated with “qualifying” clinical trials <http://www.cms.gov>