

Subject:		Issued By:	
REFERENCES		IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA's President & CEO	
Policy #:	Issue Date:	Revised Date:	Effective Date:
2027	February 28, 2007		March 15, 2007

Reference: http://www.usc.edu/admin/provost/oprs/private/docs/oprs/Clinical_Trial_Regulations_2.pdf

PURPOSE

To provide a comprehensive listing of laws and regulations governing clinical research at USC/HRA.

FEDERAL REGULATIONS

OFFICE OF HUMAN RESEARCH PROTECTION (OHRP)

1. 45 CFR Part 46 (aka "The Common Rule")
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
2. 45 CFR Part 160 and 164 (164.512) <http://www.hhs.gov/ocr/hipaapre.html>

FOOD AND DRUG ADMINISTRATION (FDA)

1. 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
2. 21 CFR Part 56 Institutional Review Boards
http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr56_00.html
3. 21 CFR Part 312 Investigational New Drug Application (INDs)
http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr312_00.html
4. 21CFR Part 812 Investigational Device Exemptions (IDE)
http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr812_00.html

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HIPAA

CALIFORNIA (STATE) STATUTES:

1. Protection of Human Subjects in Medical Experimentation Act (HSC 24170-24179.5)
<http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=24001-25000&file=24170-24179.5>
2. Use of State Death Data Records (HSC 102231-102232) <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=102001-103000&file=102175-102249>
3. Consent for Minors Provision (HSC 111515-111545) <http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=111001-112000&file=111515-111545>
4. Confidentiality of Research Records involving AIDS Patients (HSC 121075-121125)
<http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=121001-122000&file=121075-121125>
5. Derivation and Use of Human Stem Cells (HSC 125119-125119.5)
<http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=125001-126000&file=125050-125119.5>
6. Pharmacist to be responsible for the proper labeling, storage and distribution of investigational drug (California Code of Regulations, Title 22, 70263 (o)) Please enter Title Number and Section Number after clicking on this hyperlink:
<http://government.westlaw.com/linkedslice/search/default.asp?tempinfo=find&RS=GVT1.0&VR=2.0&SP=CCR-1000>
7. Obtaining and using controlled substance for research (HSC 11212)
<http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=11001-12000&file=11210-11213> Also see: <http://www.health-research.org/files/pharmacy/Controlled.pdf>

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8. Labeling of investigational drugs (Business and Professions Code 4078 (1))
<http://www.leginfo.ca.gov/cgi-bin/displaycode?section=bpc&group=04001-05000&file=4070-4078> Also see: <http://www.health-research.org/files/pharmacy/DLIDS.pdf>

JCAHO

- Investigational drugs (Standard MM.7.40) -
<http://healthcare.infologixsys.com/products/Resources/Bar-code/JCAHO-Medication-Management-Standards/default.asp>
- Orders on investigational drugs (Standard MM.3.20) -
<http://healthcare.infologixsys.com/products/Resources/Bar-code/JCAHO-Medication-Management-Standards/default.asp>
- Hospital respects the rights of research subjects (Standard RI.2.180)
<http://www.jcrinc.com/10411/>
- Informed consent (Standard RI.2.40) - <http://www.jcrinc.com/10411/>

ETHICAL GUIDELINES

- Nuremberg Code <http://ohsr.od.nih.gov/guidelines/nuremberg.html>
- Declaration of Helsinki <http://ohsr.od.nih.gov/guidelines/helsinki.html>
- Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Belmont Report) <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.cms.hhs.gov/ClinicalTrialPolicies/Downloads/providerbulletin.pdf>



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P&P REFERENCES

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2. Unrelated business Income Tax (UBIT) on residual funds
<http://www.irs.gov/charities/article/0,,id=96104,00.html>
3. 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>
4. 48 CFR Part 31 (Cost Principles for For-Profits)
http://www.access.gpo.gov/nara/cfr/waisidx_02/48cfr31_02.html
5. Federal Office of Management and Budget (OMB) Circular A-122 (Cost Principles for Non-Profits) http://www.whitehouse.gov/omb/circulars/a122/a122_2004.html
6. 45 CFR Part 74, Appendix E (Contract Provisions – Cost Principles for Hospitals)
http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2002/ocfr/45cfr74.91.htm
7. OMB Circular A-21 (Cost Principles for Universities)
<http://clinton4.nara.gov/textonly/OMB/circulars/a021/a021.html>
8. 42 CFR section 405.205 (Medicare Coverage of an Investigational Device)
http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2002/ocfr/42cfr405.205.htm
9. 42 CFR section 411.15 (Exclusions & Limitations on Medicare Payments)
http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/cfr_2002/ocfr/42cfr411.15.htm

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FDA AND PHS ON CONFLICT OF INTEREST

1. 21CFR Part 54 (Financial Disclosure by Clinical Investigators)
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54&showFR=1>
2. FDA Form 3455 (Disclosure Form on Financial Interests and Arrangements of Clinical Investigators) <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf>
3. 42 CFR Part 50 (f) (Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought)
http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm

IRB CONFLICT OF INTEREST

1. 45 CFR 46.107(e) HHS – IRB Member Conflict of Interest
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.107>
2. 21 CFR 56.107(e) FDA – IRB Member Conflict of Interest
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.107>

MEDICARE AND MEDICAID COVERAGE ON CLINICAL TRIALS

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