BIBLIOGRAPHY

Ethical Guidelines:

• World Medical Association. Declaration Of Helsinki: Ethical Principles For Medical Research Involving Human Subjects

Research Regulations:

Food and Drug Administration Regulations:

• 21 CFR 11 Electronic Records; Electronic Signatures
• 21 CFR 50 Protection Of Human Subjects
• 21 CFR 54 Financial Disclosure By Clinical Investigators
• 21 CFR 56 Institutional Review Boards
• Categories Of Research That May Be Reviewed By The Institutional Review Board (IRB) Through An Expedited Review Procedure
• 21 CFR 312 Investigational New Drug Application
• 21 CFR 314 Applications For FDA Approval To Market A New Drug
• 21 CFR 812 Investigational Device Exemptions
• 21 CFR 814 Premarket Approval Of Medical Devices

Department of Health and Human Services Regulations:

• 45 CFR 46 Protection Of Human Subjects
• Categories Of Research That May Be Reviewed By The Institutional Review Board (IRB) Through An Expedited Review Procedure
• 45 CFR 46 Waiver Of Informed Consent Requirements In Certain Emergency Research
• 45 CFR 46 Protection Of Human Research Subjects Subpart B (Proposed Revision)

Comparison of regulations

• Significant Differences in FDA and HHS Regulations for Protection of Human Subjects
Research Guidelines:

- FDA Information Sheets
- OPRR Guidance on Approving Research Involving Prisoners. May 19, 2000
- OPRR Reports. Subject: Inclusion of Women and Minorities in Research. April 25, 1994

Other Readings: