HUMAN RESEARCH PROTECTION

Regulatory and external guidance references

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Resource type GUIDANCE

FDA

1. Title 21 - 21 CFR 56	*Institutional Review Boards*
2. Part 312 - Investigational New Drug Application - 21 CFR 312	*Drug, Investigational New Drug applications*
3. PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS - 21 CFR 812	*Device, Investigational device exemptions*
4. Applicability - §812.2(b)(1)	*SR/NSR devices*
5. PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES - 21 CFR 814	*Premarket approval, Postapproval requirements, Humanitarian Use Devices (HUD)*
6. 50.24 Exception from informed consent requirements for emergency research - 21 CFR 50.24	*Exception from Informed Consent (EFIC)*
7. FDA Guidance Document - EFIC	
8. Information Sheet Guidance for Institutional Review Boards (IRBs), Clinical Investigators, and Sponsors *IRB Information Sheets* *Non-local IRB Review* *Sponsor-Investigator-IRB Relationship* *Charging for Investigational Products* *Recruiting Study Subjects* *Payment and Reimbursement to Research Subjects* *Screening Tests Prior to Study Enrollment* *A Guide to Informed Consent* *Use of Investigational Products when Subjects enter a Second Institution* *Exception from Informed Consent for Emergency Research* *Off-Label and Investigational Use of Marketed Drugs, Biologics, and Medical Devices* *IRB Continuing Review After Clinical Investigation Approval* *+ Drugs and Biologics* *+ Medical Devices* *+ FDA Operations* *Categories of Research that May be Reviewed by the IRB through an Expedited Review Procedure*	
9. Categories of Research That May be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure	*Expedited review categories*
10. 21CFR 56.110	
11. Emergency use of an Investigational Drug or Biologic- Information Sheet (Guidance for Institutional Review Boards and Clinical Investigators)	*Emergency INDs*
12. Humanitarian Device Exemption (HDE) Program	*HDE/HUDs*
13. IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More than Minimal Risk to Human Subjects/Guidance for Sponsors, Investigators, and Institutional Review Boards (July 2017)	*Waiver or alteration of informed consent*
14. Institutional Review Boards Frequently Asked Questions *IRB Organization, IRB Membership, IRB Procedures, IRB Records, Informed Consent Process, Informed Consent Document Content, Clinical Investigations, General Questions*	
15. Information Sheet Guidance for Institutional Review Boards (IRBs), Clinical Investigators, and Sponsors	
16. FDA Guidance - A Guide to Informed Consent *Consent Document Content, The Consent Process, IRB Standard Format, Documentation of Informed Consent - 21 CFR 50.27, Non-English Speaking Subjects, Illiterate English Speaking Subjects, Assent of Children Elements of Informed Consent*	*Explains: "*use of the wording, *I understand..."*

17. Significant Risk and Nonsignificant Risk Medical Device Studies	*Significant Risk (SR), Nonsignificant Risk (NSR) Medical Devices*
18. Continuing Review after Study Approval	*Continuing reviews*
19. Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations	*Software, Medical Devices*
HHS / OHRP	
1. 45 CFR 46 (Revised Common Rule) *Subpart A – Basic HHS Policy for Protection of Human Research Subjects* *Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research* *Subpart C – Additional Protection Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects* *Subpart D – Additional Protections for Children Involved as Subjects in Research* *Subpart E – Registration of Institutional Review Boards*	*Protection of Human Subjects*
2. 45 CFR 46.110 - Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research. 3. OHRP Guidance - Expedited Review Categories (1998) 4. OHRP Guidance - Expedited Review Procedures Guidance (2003) 5. Federal Register Guidance - Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board Through an Expedited Review Procedure	*Expedited reviews*
6. OHRP Guidance - Institutional Review Board Written Procedures: Guidance for Institutions and IRBs (2018) 7. OHRP IRB Registration Instructions: Step-by-Step Instructions on Registering an Institutional Review Board (IRB)	*IRB procedures, written procedures, IRB registrations*
8. OHRP Guidance - Prisoner Involvement in Research (2003) 9. OHRP Guidance - Prisoner Research FAQs	*Prisoners*
10. OHRP Guidance - Engagement of Institutions in Human Subjects Research	*Engagement*
11. OHRP Guidance - Informed Consent, Legally Effective and Prospectively Obtained (OPRR Letter, 1993)	*Informed consent*
12. OHRP Guidance - Informed Consent of Subjects Who Do Not Speak English (1995)	*Non-English speakers, short form consent*
13. OHRP Guidance - Special Protections for Children as Research Subjects	*Minors, children*
14. OHRP Guidance - Guidance on Reporting Incidents to OHRP (2011) 15. OHRP Guidance - Unanticipated Problems Involving Risks & Adverse Events Guidance (2007)-	*Reporting, Common Rule agency contacts, unanticipated problems, serious or continuing noncompliance, adverse events*
16. HIPAA 45 CFR 164 *Subpart E – Privacy of Individually Identifiable Health Information* Subpart E Part 164.512	*Security and Privacy* *HIPAA waiver*
DoJ	
1. 28 CFR Part 46	*Department of Justice (DoJ)*
2. Bureau of Prisons regulation	
3. PART 22—CONFIDENTIALITY OF IDENTIFIABLE RESEARCH AND STATISTICAL INFORMATION - 28 CFR 22	
4. 28 CFR 512	
DoD	
1. 32 CFR Part 219 2. DoD: Instruction 3216.02 3. Dual Compensation Act (5 U.S.C. 5531) 4. OPNAVINST 5300.8B 5. SECNAVINST 3900.39D 6. 10 USC 980	*Department of Defense (DoD)*

DoE	
10 CFR Part 745	*Department of Energy (DoE)*
ED	
34 CFR Part 97	*Department of Energy (ED)*
EPA	
40 CFR Part 26	*Environmental Protection Agency (EPA)*
NSF	
45 CFR Part 690	*National Science Foundation (NSF)*
NIH	
1. NIH Genomic Data Sharing policy	*Genomic Data Sharing (GDS)*
2. NIH Certificate of Confidentiality	*Certificates of Confidentiality (CoC)*
3. Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research 4. NOT-OD-16-094	*Single IRB (sIRB)*
5. NIH Requirements Regarding Human Fetal Tissue Research HHS currently prohibits transplantation of human fetal tissue into humans/ human fetal tissue obtained from elective abortion [**42 U.S.C. 289g-1 and 42 U.S.C. 289g-2 NOT-OD-19-128** and **NOT-OD-19-137].**	
Minnesota	
1. Incapacitated Adults, Minnesota Statutes a. 524.5-313 POWERS AND DUTIES OF GUARDIAN b. 144.291 MINNESOTA HEALTH RECORDS ACT. c. 13.384 MEDICAL DATA. d. 253B.095 RELEASE BEFORE COMMITMENT.	*Incapacitated adults*
2. Adult maltreatment through abuse, neglect, or financial exploitation, Minnesota Statutes a. 626.556 b. 626.557 REPORTING OF MALTREATMENT OF VULNERABLE ADULTS 3. Pregnant woman's use of controlled substances for a non-medical purpose or habitual or excessive alcohol use during pregnancy, Minnesota Statutes 260E.31 REPORTING OF PRENATAL EXPOSURE TO CONTROLLED SUBSTANCES 4. Testing for reportable diseases (HIV, Hepatitis, TB, etc.), Minnesota Statutes MN Rules, Chapter 4605	*Mandatory reporting*