

1. Food and Drugs Act
2. Food and Drug Regulations: Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects
3. Natural Health Products Regulations: Part 4, Clinical Trials Involving Human Subjects
4. Medical Devices Regulations: Part 3, Medical Devices for Investigational Testing Involving Human Subjects
5. Personal Information Protection and Electronic Documents Act
6. United States Code of Federal Regulations: 21 CFR 50, 56, 312, 812 and 45 CFR 46
7. ICH GCP International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use – ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R2)
8. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, TCPS2 2022
9. World Medical Association (WMA). Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects
10. Guidance Document: Part C, Division 5 of the Food and Drug Regulations “Drugs for Clinical Trials Involving Human Subjects” (Gui-0100) –(August 20, 2019)
11. Canadian Association of Research Ethics Boards. Guidance on Reporting of Unanticipated Problems Including Adverse Events to Research Ethics Boards in Canada (July 2010)
12. U.S. Department of Health and Human Services, Office for Human Research Protections, and FDA Institutional Review Board Written Procedures Guidance for Institutions and IRBs (May 2018)
13. U.S. Department of Health and Human Services, Office for Human Research Protections. Guidance on Reporting Incidents to OHRP (May 2011).
14. U.S. Department of Health and Human Services, Office for Human Research Protections. Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events (January 2007)
15. U.S. Department of Health and Human Services, Office for Human Research Protections. Guidance on IRB Continuing Review of Research (November 2010)
16. U.S. Department of Health and Human Services, Office for Human Research Protections. Guidance on the Use of Expedited Review Procedures (August 2003)
17. U.S. Department of Health and Human Services, Office for Protection from Research Risks. Memorandum re: IRB Meetings Convened via Telephone Conference Call (March 2000)
18. U.S. Department of Health and Human Services, Office for Protection from Research Risks and Food and Drug Administration. Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure. Federal Registrar: November 9, 1998 (Volume 63, Number 216)

19. U.S. Department of Health and Human Services, Food and Drug Administration. A Guide to Informed Consent – Information Sheet; Guidance for Institutional Review Boards and Clinical Investigators
20. U.S. Department of Health and Human Services, Food and Drug Administration. Comparison of FDA and HHS Human Subject Protection Regulations
21. U.S. Department of Health and Human Services, Food and Drug Administration. Sponsor-Investigator-IRB Interrelationship – Information Sheet; Guidance for Institutional Review Boards and Clinical Investigators
22. U.S. Department of Health and Human Services, Food and Drug Administration. Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors; FDA Institutional Review Board Inspections (April 2019)
23. U.S. Department of Health and Human Services, Food and Drug Administration. Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research (April 2013)
24. U.S. Department of Health and Human Services, Food and Drug Administration. Guidance for Industry; Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects (October 2009)
25. U.S. Department of Health and Human Services, Food and Drug Administration. Guidance for Clinical Investigators, Sponsors, and IRBs; Adverse Event Reporting to IRBs – Improving Human Subject Protection (January 2009)
26. U.S. Department of Health and Human Services, Food and Drug Administration. Guidance for IRBs, Clinical Investigators, and Sponsors; IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed (August 2013)
27. U.S. Department of Health and Human Services, Food and Drug Administration. Guidance for IRBs, Clinical Investigators, and Sponsors; IRB Continuing Review after Clinical Investigation Approval (February 2012)
28. U.S. Department of Health and Human Services, Food and Drug Administration. Institutional Review Boards Frequently Asked Questions – Information Sheet; Information Sheet – Guidance for Institutional Review Boards and Clinical Investigators
29. U.S. Department of Health and Human Services. Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subjects Protection (May 2004)
30. U.S. Department of Health and Human Services, National Institutes of Health. NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research (November 2017)
31. U.S. Department of Health and Human Services, National Institutes of Health. Guidance on NIH Office of Extramural Research (OER) on-line tutorial Protecting Human Research Participants (PHRP) (February 2008)

References

32. U.S. Department of Health and Human Services, National Institutes of Health. Frequently Asked Questions; Human Subjects Research – Requirement for Education
33. Canadian Institutes for Health Research. Best Practices for Protecting Privacy in Health Research (September 2005)