

List of IRB Guidance Documents

Name of IRB guidance document	Date of current version	Version being superseded	Summary of Changes
General Procedures Manual	May-09-2023	Dec-12-2022	May 2023 updates: <ul style="list-style-type: none"> Deleted ambiguous statement in the section on appointing nonvoting members to the IRB. Clarification as to who are authorized to review exempt studies Reposted in July 2023 with broken hyperlinks already fixed
Recruitment of Research Participants	Aug-10-2022		Reposted in May 2023 with document version appearing more clearly in the footer; reposted in July 2023 with broken hyperlinks already fixed
Vulnerable Populations in Research	Jun-17-2022		Reposted in May 2023 with document version appearing more clearly in the footer; reposted in July 2023 with broken hyperlinks already fixed
Guidelines for Student Classroom Projects and Research Involving Human Subjects	Aug-22-2022		Reposted in May 2023 with document version appearing more clearly in the footer; reposted in July 2023 with broken hyperlinks already fixed
Informed Consent	Jul-14-2022		Reposted in May 2023 with document version appearing more clearly in the footer; reposted in July 2023 with broken hyperlinks already fixed
Initial Review of Human Subject Research	May-10-2023	Sep-12-2022	Minor editorial changes only in May 2023; reposted in July 2023 with broken hyperlinks already fixed
Renewals of Research Involving Human Participants	May-09-2023	Jun-28-2022	Minor administrative edits (e.g., correct link to federal regulations) in May 2023; reposted in July 2023 with broken hyperlinks already fixed
IRB Review of Modifications	Mar-04-2024	Oct-16-2023	Added change in wording as a possible modification eligible to be handled by IRB staff
Study Closure	04Oct2023	Jul-14-2022	Clarification on procedures when a PI leaves Chapman
Post-Approval Monitoring	May-09-2023	Jun-22-2022	Language broadened for greater flexibility as to who may conduct monitoring (e.g., Office of Research staff, consultants, IRB members)
Incident Reports	Aug-09-2022		Currently under revision
Research Noncompliance	Jun-17-2022		Currently under revision

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Suspension and Termination of Research	Jun-17-2022		Reposted in May 2023 with document version appearing more clearly in the footer; reposted in July 2023 with broken hyperlinks already fixed
Reporting to Regulatory Agencies and Sponsor Regarding Research Involving Human Participants	May-12-2023	Jul-14-2022	May 2023 updates: <ul style="list-style-type: none"> • Funding source and award number added as among recommended information to include in external reporting • Clarification on workflow • Updated the link to OHRP’s reporting guidance Reposted in July 2023 with broken hyperlinks already fixed
Guidance for Accessing Health Data Including Protected Health Information (PHI)	Apr-24-2024	Mar-18-2024	Removed language requiring annual IRB review for all expedited review and full board studies involving PHI
Data and Safety Monitoring Plan	May-15-2023	May 2021	Safeguards for use of Protected Health Information (PHI) added in May 2023. Reposted in July 2023 with broken hyperlinks already fixed.
Research Involving Deception or Incomplete Disclosure	May-09-2023	Aug-09-2022	Link added to debriefing template in May 2023; reposted in July 2023 with broken hyperlinks already fixed
Guidelines for International Research	May-09-2023	Sep-14-2022	Clarified that there must be a means to communicate with non-English speakers throughout the research and not only at the time of recruitment and consenting; reposted in July 2023 with broken hyperlinks already fixed
Medical Devices	Sep-14-2023		Original publication date in Sept. 2023; reposted in March 2024 to include a revision history at end of document
Audio, Video or Digital Recordings	Jul-16-2021		Original publication date
Conflict of Interest	Apr-10-2022		No changes
Use of Raffles/Drawings in Research	Feb-02-2018		Reposted in Oct2023; no changes in content.