

List of IRB Guidance Documents

Name of IRB guidance document	Date of current version	Version being superseded	Summary of Changes
General Procedures Manual	Sept-09-2025	May-09-2023	Added language supporting IRB Administrators' role in determining studies as not constituting "human subject research"
Conflict of Interest	Apr-10-2022		No changes
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
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
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	Oct-09-2025	Sep-14-2023	Added flowchart from NIH website https://www.cc.nih.gov/orcs/ide/exemption-criteria-study-risk-determination
Research Involving Deception or Incomplete Disclosure	May-09-2023	Jun-29-2022	Added detailed description of deception vis a vis incomplete disclosure, including IRB requirements
Recruitment of Research Participants	May-13-2024	Aug-10-2022	Updated to expand social media section

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Participant Recruitment Pools	Oct-07-2024		Original publication date
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
Use of Raffles/Drawings in Research	Mar-25-2025	Feb-02-2018	Odds of winning the raffle must be included in the consent form or information sheet.

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Informed Consent	Dec-15-2025	Nov-10-2025	Dec-15-2025 update: Added options in providing documentation of consent other than through a wet signature Nov-10-2025 update: Added details on consenting participants who cannot read, definition of impartial witness, and explicit mention of the short form process as not an allowable option for such participant population, as well as non-English speakers
Research Using Data Collection on Social Media and Online Communities	May-13-2024		13May2024 version was reposted on 01Jul2024 – hyperlink to recruitment guidelines on page 3 was corrected to point to the IRB webpage containing current copies of all IRB guidelines and policies.
Privacy and Confidentiality	Aug-06-2025		Original publication date
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
Audio, Video or Digital Recordings	Jul-16-2021		Original publication date
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
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
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.
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)
Incidents & Research Noncompliance Reports	Dec-11-2025		Consolidates and supersedes: <ul style="list-style-type: none">• Incident Reports, ver. Aug-09-2022• Research Noncompliance, ver. Jun-17-2022

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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	Oct-28-2025	May-12-2023	Added references; updated the title “Director of Research Integrity” to “Assistant Vice President for Research Integrity and Compliance”
Study Closure	Oct-04-2023	Jul-14-2022	Clarification on procedures when a PI leaves Chapman
Site permissions	Dec-08-2025		Initial version