

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Name of IRB guidance document	Date of current version	Version being superseded	Summary of Changes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"
Recruitment of Research Participants	May-13-2024	Aug-10-2022	Updated to expand social media section
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
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-14-2025	Mar-18-2025	Language added suggesting an information sheet at the time of recruitment, screening or determining eligibility
Privacy and Confidentiality	Aug-06-2025		Original publication date
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		
Research Noncompliance	Jun-17-2022		

Name of IRB guidance document	Date of current version	Version being superseded	Summary of Changes
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	Jun-28Oct-2025	May-12-2023	Added references; updated the title “Director of Research Integrity” to “Assistant Vice President for Research Integrity and Compliance”
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.
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
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	Mar-25-2025	Feb-02-2018	Odds of winning the raffle must be included in the consent form or information sheet.
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.