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FDA GUIDANCE DOCUMENT CATEGORY: DRUG/BA/BE	CURRENT VERSION	STATUS OF REVISION
Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products (Real World Data/Real World Evidence	02.2023 - Draft	
Submitting documents using real-world data and real-world evidence to FDA for drug and biological products	09.2022 - Final	
Master Protocols: Efficient Clinical Trial Design Strategies to Expedite Development of Oncology Drugs and Biologics	03.2022 - Final	
Interpreting sameness of gene therapy products under orphan drug regulations	09.2021 - Final	
Adaptive Design Clinical Trials for Drugs and Biologics	09.2019 - Final	
Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products	03.2019 - Final	
Individual Patient Expanded Access Applications: Form FDA 3926	10.2017 - Final	
Emergency Use Authorization of Medical Products and Related Authorities Emergency Use Authorization of Medical Products and Related Authorities	01.2017 - Final	
Charging for Investigational Drugs under an IND Q&As	02.2024 - Final	
Expanded Access to Investigational Drugs for Treatment Use – Q&As	06.2016 - Final	
Investigational New Drug applications – determining whether human research studies can be conducted without an IND	09.2013 - Final	

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Safety reporting requirements for INDs and Bioavailability/Bioequivalence (BA/BE) studies – Small Entity Compliance Guide	12.2012 - Final	
Safety reporting requirements for INDs and Bioavailability/Bioequivalence (BA/BE) studies	12.2012 - Final	
Radioactive Drug Research Committee: Human Research without an IND application	08.2010 - Final	
FDA GUIDANCE DOCUMENT CATEGORY: DEVICES	**CURRENT VERSION**	**STATUS OF REVISION**
Digital Health Technologies for Remote Data Acquisition in Clinical Investigations	12.2023 - Final	
Humanitarian Device Exemption (HDE) Program	09.2019 - Final	
Humanitarian Use Device (HUD) Designations	09.2019 - Final	
Investigational IVDs used in clinical investigations of therapeutic products	12.2017 - Draft	
Acceptance of Clinical Data to Support Medical Device Applications and Submissions: FAQ	02.2018 - Final	
Evaluation and Reporting of Age, Race and Ethnicity-Specific Data in Medical Device Clinical Studies	09.2017 - Final	
Clinical considerations for investigational device exemptions (IDEs) for Neurological Devices targeting disease progression and clinical outcomes	11.2016 - Final	
Adaptive designs for medical device clinical studies	07.2016 - Final	

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Design considerations for pivotal clinical investigations for medical devices	11.2013 - Final	
Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies	10.2023 - Final	
Information Sheet: FAQs about Medical Devices	01.2006 - Final	
Information Sheet: Significant Risk and Nonsignificant Risk Medical Device Studies	01.2006 - Final	
FDA GUIDANCE DOCUMENT CATEGORY: GCP/CLINICAL TRIALS	**CURRENT VERSION**	**STATUS OF REVISION**
Diversity Action plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies	06.26.2024 - Draft	Closed for Comments on 09.26.2024
Standardized format for electronic submissions for marketing applications content for planning of bioresearch monitoring (BIMO) inspections for CBER submissions	06.05.2024 - Draft	Closed for Comments on 08.05.2024
Cancer Clinical Trial Eligibility Criteria: Laboratory Values	04.25.2024 - Draft	Closed for Comments on 06.25.2024
Cancer Clinical Trial Eligibility Criteria: Performance Status	04.25.2024 - Draft	Closed for Comments on 06.25.2024
Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant	04.25.2024 - Draft	Closed for Comments on 06.25.2024
Artificial Intelligence & Medical Products: How CBER, CDER, CDRH & OCP are Working Together	03.2024 - Draft	

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Real World Evidence: Considerations regarding non-interventional studies for drug and biological products	03.21.2024 - Draft	Closed for Comments on 06.18.2024
A risk-based approach to monitoring of clinical investigations questions and answers	04.12.2023 - Draft	
E6(R3) Good Clinical Practice (GCP)	06.06.2023 - Draft	Closed for Comments on 09.05.2023
Decentralized Clinical Trials for Drugs, Biological Products, and Devices	09.2024 - Final	
Considerations for the design and conduct of externally controlled trials for drug and biological products	02.01.2023 - Draft	Closed for Comments on 05.02.2023
Characterizing, Collecting, and Reporting Immune-Mediated Adverse Reactions in Cancer Immunotherapeutic Clinical Trials	10.17.2022 - Draft	
Investigator responsibilities – safety reporting for investigational drugs and devices	09.29.2021 - Draft	
Real-world data: Electronic Health Records and Medical Claims data to support regulatory decision-making for drug and biological products	07.2024	
Core Patient Reported Outcomes in Cancer Clinical Trials	06.2021 - Draft	
Sponsor responsibilities – safety reporting requirements and safety assessment for IND and Bioavailability/Bioequivalence studies guidance for Industry	06.25.2021 - Draft	
Information Sheet: Guidance for Sponsors, Clinical Investigators, and IRBs FAQs Form FDA 1572	05.2021 - Draft	

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Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trail Designs	09.2020 - Final	
Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank	08.2020 - Final	
Postmarketing Studies and Clinical Trials – Implementation of Section 505(o)(3) of the FD&C Act	09.2021 - Final	
Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials	03.2019 - Final	
Clinical Trial Imaging Endpoint Process Standards	04.2018 - Final	
Information Sheet: Payment and Reimbursement to Research Subjects	01.2018 - Final	
Form FDA 3674 – Certifications to accompany drug, biological product, and device applications/submissions	01.2017 - Final	
Collection of Race and Ethnicity Data in Clinical Trials	10.2016 - Final	
Financial Disclosure by Clinical Investigators	02.2013 - Final	
Oversight of clinical investigations – a risk-based approach to monitoring	08.2013 - Final	
FDA acceptance of foreign clinical studies not conducted under an IND FAQs	03.2012 - Final	
Statement of Investigator (Form FDA 1572) FAQs	06.2010 - Final	
Data retention when subjects withdraw from FDA-regulated clinical trials	10.2008 - Final	

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Establishment and Operation of Clinical Trial Data Monitoring Committees	03.2006 - Final	
Information Sheet: Sponsor-Investigator-IRB Interrelationship	01.1998 - Final	
Information Sheet: Recruiting Study Subjects	01.1998 - Final	
FDA GUIDANCE DOCUMENT CATEGORY: IRB/HSP	**CURRENT VERSION**	**STATUS OF REVISION**
Ethical considerations for clinical investigations of medical products involving children	09.2022 - Draft	
Certificates of Confidentiality	11.2020 - Final	
Impact of Certain Provisions of the Revised Common Rule on FDA Regulated Clinical Investigations	10.2018 - Final	
Institutional Review Board (IRB) Written Procedures	05.2018 - Final	
Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials	04.2018 - Draft	
Waiver of IRB requirements for Drug and biological product studies	10.2017 - Final	
Minutes of Institutional Review Board (IRB) meetings	09.2017 - Final	
Considerations when transferring clinical investigation oversight to another IRB	05.2014 - Final	
IRB responsibilities for reviewing the qualifications of investigators, adequacy of research sites and the determination of whether and IND/IDE is needed	08.2013 - Final	

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IRB continuing review after clinical investigation approval	02.2012 - Final	
Investigator responsibilities – protecting the rights, safety and welfare of study subjects	10.2009 - Final	
IRB registration FAQs	07.2009 - Final	
Adverse event reporting to IRBs – improving human subject protection	01.2009 - Final	
Process for handling referrals to FDA under 21 CFR 50.54 – Additional Safeguards for Children in Clinical Investigations	12.2006 - Final	
Using a Centralized IRB Review Process in Multicenter Clinical Trials	03.2006 - Final	
Information Sheet: Institutional Review Boards FAQ	01.1998 - Final	
FDA GUIDANCE DOCUMENT CATEGORY: CONSENT	**CURRENT VERSION**	**STATUS OF REVISION**
Key Information and facilitating understanding in informed consent guidance for sponsors, investigators and IRBs	03.2024 - Draft	Closed for Comments on 04.30.2024
Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors	08.2023 - Final	
Exception from Informed Consent Requirements for Emergency Research	04.2023 - Final	
Informed Consent Elements 21 CFR 50.25(c) Q&As	02.2012 - Final	
Exculpatory language in informed consent	08.2011 - Draft	

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FDA GUIDANCE DOCUMENT CATEGORY: COMPLIANCE	CURRENT VERSION	STATUS OF REVISION
Processes and Practices Applicable to Bioresearch Monitoring Inspections	06.2024 - Draft	Closed for Comments on 09.2024
Conducting remote regulatory assessments questions and answers	02.2024 - Draft	Closed for Comments on 04.24.2024
Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities	10.2023 - Draft	
Clinical Investigator administrative actions - disqualification	12.2022 - Final	
Information Sheet: FDA Inspections of Clinical Investigators	06.2010 - Final	
FDA GUIDANCE DOCUMENT CATEGORY: IN VITRO	**CURRENT VERSION**	**STATUS OF REVISION**
Sponsor responsibilities – safety reporting requirements and safety assessments for IND and Bioavailability	06.2021 - Draft	
Investigational IVDs used in clinical investigations of therapeutic products	12.2017 - Draft	
Distribution of In Vitro Diagnostic Products labeled for research use only or investigational use only	11.2013 - Final	
In vitro diagnostic (IVD) device studies FAQs	06.2010 - Final	
Informed consent for in vitro diagnostic device studies using leftover human specimens that are not individually identifiable	04.2006 - Final	

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FDA GUIDANCE DOCUMENT CATEGORY: 21 CFR PART 11	CURRENT VERSION	STATUS OF REVISION
Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers	10.2024 - Final	
Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using eCTD Specifications Guidance for Industry	09.2024 - Final	
Use of Electronic Records and Electronic Signatures in Clinical Investigations under 21 CFR part 11	10.2024 - Final	
Use of Electronic Informed Consent in Clinical Investigations – Q&A	12.2016 - Final	
Electronic Source Data in Clinical Investigations	09.2013 - Final	
Computerized systems used in clinical investigations	05.2007 - Final	
Guidance for Industry – Computerized Systems used in clinical trials	04.1999 - Final	

For the most accurate and up-to-date information related to clinical research guidelines and regulations, visit the ACRP Guidelines and Regulations Resource Center at acrpnet.org/insights/guidelines-and-regulations