HELPING RESEARCH PROFESSIONALS

Recent FDA Updates

FDA has recently released several updates - including new and updated guidance documents, technical amendments, and policy clarifications - that may be relevant to research oversight committees (such as IRBs and IACUCs), investigators, and research organizations. To help research professionals stay informed, HRP has compiled the following summary highlighting updates released between December 1, 2025 through January 27, 2026, that may affect research oversight, study design, and regulatory responsibilities. In keeping with our focus on *Helping Research Professionals*, this resource is intended to offer practical context and useful reference points as FDA guidelines continue to evolve.

Date	Title	Links	Brief Summary
Dec 3, 2025	**Draft Guidance:** Monoclonal Antibodies: Streamlined Nonclinical Safety Studies	FR Notice: https://www.federalregister.gov/documents/2025/12/03/2025-21864/monoclonal-antibodies-streamlined-nonclinical-safety-studies-draft-guidance-for-industry Draft Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/monoclonal-antibodies-streamlined-nonclinical-safety-studies Press Release: https://www.fda.gov/news-events/press-announcements/fda-releases-draft-guidance-reducing-testing-non-human-primates-monoclonal-antibodies	This draft guidance describes FDA's current thinking on streamlined, risk-based nonclinical safety programs for monoclonal antibodies, including This draft guidance describes FDA's current thinking on streamlined, risk-based nonclinical safety programs for monoclonal antibodies, including circumstances where certain animal studies (e.g., repeat-dose or NHP studies) may be reduced, replaced, or omitted when scientifically justified. The guidance emphasizes fit-for-purpose nonclinical packages and alignment with the 3Rs, and may inform IACUC deliberations by reinforcing the need for clear scientific rationale and documentation linking animal use decisions to both scientific objectives and downstream human safety considerations.

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Dec 4, 2025	**Technical Regulatory Updates:** Medical Devices; Quality Management System Regulation Technical Amendments	FR Notice: https://www.federalregister.gov/documents/2025/12/04/2025-21955/medical-devices-quality-management-system-regulation-technical-amendments Regulations.gov: https://www.regulations.gov/document/FDA-2025-N-4635-0001	Makes technical and conforming amendments across multiple device regulations (including 21 CFR 812) to align terminology and cross-references with the amended Quality Management System Regulation (21 CFR 820 – amended in 2024). The amendments are non-substantive and do not change underlying regulatory requirements for device research or IDE conduct. Note: Changes to part 812 may impact citations and quoted text in SOPs and other materials. References to § 820.30 are replaced with references to § 820.10(c) (or § 820.10(c) is newly inserted) at § 812.1(a) (Scope), § 812.35(a)(3)(iii)(A) (Definition of credible information), and § 812.35(a)(3)(iv)(A) (Notice of IDE change).
Dec 15, 2025	**Final Guidance:** Enhancing Participation in Clinical Trials — Eligibility Criteria, Enrollment Practices, and Trial Designs	Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-participation-clinical-trials-eligibility-criteria-enrollment-practices-and-trial-designs	Provides recommendations to improve clinical trial participation and representativeness through scientifically justified eligibility criteria, enrollment practices, and trial designs that better reflect the patients likely to use the product in clinical practice. Encourages minimizing unnecessary exclusions and prospective planning and monitoring to support

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			representative enrollment across clinically relevant patient characteristics. Diverges from the prior 2022 draft guidance "*Enhancing the Diversity of Clinical Trial Populations*" by shifting from a primary emphasis on demographic diversity to a broader framework of participation and representativeness, incorporating both demographic and non-demographic characteristics (e.g., comorbidities, organ dysfunction, functional status, and real-world access considerations) to support the generalizability and real-world applicability of trial results.
Dec 16, 2025	**Final Guidance:** Investigator Responsibilities – Safety Reporting for Investigational Drugs and Devices	FR Notice: https://www.federalregister.gov/documents/2025/12/16/2025-22869/investigator-responsibilities-safety-reporting-for-investigational-drugs-and-devices-guidance-for Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigator-responsibilities-safety-reporting-investigational-drugs-and-devices	Clarifies investigator responsibilities for identifying, evaluating, and reporting safety information in IND and IDE studies, including the relationship between FDA safety reporting requirements and reporting to sponsors and IRBs. Aims to reduce confusion and improve consistency in safety reporting. Compared to the November 2023 draft guidance, the final guidance more clearly delineates investigator versus sponsor responsibilities (e.g., confirming that investigators are responsible for identifying and reporting safety information to

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			sponsors, while sponsors are responsibe for aggregate safety assessment and FDA expedited reporting), clarifies the distinction between FDA and IRB safety reporting obligations (e.g., recognizing that compliance with IND/IDE safety reporting does not replace local IRB unanticipated problem reporting requirements), and emphasizes that the guidance is intended to clarify existing requirements rather than impose new safety reporting duties on investigators.
Dec 16, 2025	**Final Guidance:** Sponsor Responsibilities – Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies	FR Notice: https://www.federalregister.gov/documents/2025/12/16/2025-22870/sponsor-responsibilities-safety-reporting-requirements-and-safety-assessment-for-investigational-new Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/sponsor-responsibilities-safety-reporting-requirements-and-safety-assessment-ind-and	Describes sponsor responsibilities for safety assessment and expedited safety reporting under IND regulations, including evaluation of aggregate safety data and submission of IND safety reports. Clarifies expectations to improve signal detection and reduce over-reporting. Compared to the November 2023 draft, the final guidance more clearly emphasizes the sponsor's responsibility for aggregate safety assessment and clinical judgment, explicitly discourages over-reporting of expedited IND safety reports, clarifies proportional application to BA/BE studies, and reinforces that the guidance is intended to clarify existing safety reporting

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			requirements rather than impose new obligations.
Dec 18, 2025	**Final Guidance:** Use of Real-World Evidence To Support Regulatory Decision-Making for Medical Devices; Guidance for Industry and Food and Drug Administration Staff	FR Notice: https://www.federalregister.gov/documents/2025/12/18/2025-23252/use-of-real-world-evidence-to-support-regulatory-decision-making-for-medical-devices-guidance-for Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices	Outlines FDA's expectations for using real-world data and real-world evidence (e.g., registries, EHRs, claims data) to support regulatory decision-making for medical devices, including data relevance, quality, and transparency considerations. Compared to the September 2017 draft, the final guidance reflects FDA's increased experience with real-world evidence (RWE), shifting from a conceptual framework to a more operational approach that clarifies how RWE may support specific medical device regulatory decisions while emphasizing data quality, methodological rigor, and proportionality to device risk. The final guidance also provides clearer indications of factors relevant to IRB oversight determinations, including whether RWE involves retrospective or secondary data use, data identifiability, and prospective or interventional activities.
Dec 19, 2025	**Final Guidance:** Processes and Practices Applicable to Bioresearch Monitoring	FR Notice: https://www.federalregister.gov/documents/2025/12/19/2025-23404/processes-and-practices-	The Dec 2025 final guidance consolidates and modernizes FDA's description of BIMO inspection processes. Compared to earlier information sheets which are now

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	Inspections; Guidance for Industry	applicable-to-bioresearch-monitoring-inspections-guidance-for-industry Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/processes-and-practices-applicable-bioresearch-monitoring-inspections	withdrawn (clinical investigator inspections; IRB inspections), the final guidance is broader in scope (clinical and nonclinical), more explicit about statutory authority and access to records/systems and adds structured "best practices" for communication before, during, and after inspections including concepts tied to remote regulatory assessments (RRAs) and electronic system access.
Dec 29, 2025	**New Resource:** CDER/Office of New Drugs Streamlined Nonclinical Studies and Acceptable New Approach Methodologies (NAMs)	FDA Webpage: https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cderoffice-new-drugs-streamlined-nonclinical-studies-and-acceptable-new-approach-methodologies-nams	This new resource describes CDER's current thinking on streamlined nonclinical approaches, including the use of New Approach Methodologies (NAMs), to support drug development while reducing or replacing traditional animal testing where scientifically justified. It outlines drug development contexts in which these approaches may be acceptable based on principles of scientific justification and regulatory decision-making and is intended as a living resource that will be updated over time. The resource may be informative to IACUCs by highlighting considerations that can help evaluate proposed reductions or alternatives to animal use, particularly

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			where sponsors seek to align nonclinical programs with evolving FDA expectations.
Jan 6, 2026	**Final (Updated) Guidance:** Clinical Decision Support Software	Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software	The final (updated) guidance clarifies FDA's interpretation of when clinical decision support software functions are excluded from the device definition or subject to oversight, focusing on factors such as user type (e.g., health care professionals vs. patients), transparency of the software logic, and the ability for clinicians to independently review the basis for recommendations.
Jan 6, 2026	**Final (Updated) Guidance:** General Wellness: Policy for Low Risk Devices	Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices	Describes FDA's enforcement discretion policy for low-risk general wellness products, including fitness trackers and wellness apps, and clarifies the boundary between general wellness functions and regulated medical device claims—important when such tools are used in research or as exploratory endpoints. The final (updated) guidance clarifies FDA's enforcement discretion approach for low-risk general wellness products, refining how the FDA distinguishes general wellness functions from regulated medical device claims based on intended use, claims, and risk to users. The update reflects FDA's experience with the

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			expanded use of modern consumer-facing digital health tools and wearables, providing clearer examples and boundaries to help stakeholders determine when wellness products remain outside of FDA oversight and when their use or claims may trigger oversight, including in research settings or when used to generate exploratory endpoints.
Jan 7, 2026	**Draft Guidance:** Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products	FR Notice: https://www.federalregister.gov/documents/2025/01/07/2024-31542/considerations-for-the-use-of-artificial-intelligence-to-support-regulatory-decision-making-for-drug Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological	This draft guidance outlines FDA's proposed risk-based framework for assessing the credibility of artificial intelligence (AI) models used to generate data supporting regulatory decision-making for drug safety, effectiveness, or quality, based on a defined context of use across the drug lifecycle. The guidance is directed to sponsors and "other interested parties" and excludes AI used solely for discovery or internal operational efficiencies. Although not directed to IRBs or investigators, the guidance may be indirectly relevant when AI tools are incorporated into clinical research in ways that influence participant risk stratification, safety monitoring, or protocol-driven clinical decisions. In such cases, IRBs and

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			investigators may wish to consider how AI outputs are used within the study, whether appropriate human oversight is maintained, and whether the AI's context of use affects risk assessment or human subject protections.
Jan 12, 2026	**Draft Guidance:** Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products	FR Notice: https://www.federalregister.gov/documents/2026/01/12/2026-00325/use-of-bayesian-methodology-in-clinical-trials-of-drug-and-biological-products-draft-guidance-for Draft Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-bayesian-methodology-clinical-trials-drug-and-biological-products	This draft guidance provides recommendations on the appropriate use of Bayesian statistical methods in clinical trials to support regulatory decision-making, including design, evaluation, prior justification, success criteria, and reporting expectations. While directed to industry, the guidance may prompt IRBs to look more closely at how studies using Bayesian designs describe data and safety monitoring, including interim reviews, stopping criteria, and oversight roles, and to consider how these features may affect ongoing assessments of participant risk and potential benefit as the study progresses.