University of Kentucky Office of Research Integrity Select Changes at the Federal Level Impacting Human Research			
Date	**Title**	**Web link**	**Comments**
Final Regulation/ Guidance 2024			
February 16, 2024	Food and Drug Administration Charging for Investigational Drugs Under an IND Questions and Answers Guidance for Industry	https://www.fda.gov/media/176308/download	This guidance addresses some questions/answers about when and how a sponsor may charge for an Investigational Drug under an IND. The guidance addresses what sponsors may charge for the drugs, how to be reimbursed for certain costs, and the time periods that sponsors may charge study participants for Investigational Drugs. The guidance addresses when sponsors must obtain authorization from the FDA to charge for their drugs, and the paperwork required for authorization. Also included are suggestions of when to contact the FDA to renew projects, and estimations of when the FDA may respond to sponsor outreach.
Final Regulation/ Guidance 2023			
December 22, 2023	Food and Drug Administration Digital Health Technologies (DHTs) for Remote Data Acquisition in Clinical Investigations	https://www.fda.gov/media/155022/download	Compared to intermittent trial visits, the use of DHTs to remotely collect data from trial participants may allow for continuous or more-frequent data collection. Includes guidance on selection of DHTs that are suitable for use in clinical investigations; verification and validation of DHTs for use in clinical investigations; identification and management of risks; what information to include in the Informed Consent. Some DHTs used in drug/biologic/companion device trials, may meet the definition of investigational device and require a Investigational Device Exemption determination (IDE exempt, Significant Risk, Nonsignfiicant Risk). If SR, an additional IDE may not be required, IF all information is included in the Investigational New Drug (IND) application.

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December 21, 2023	Food and Drug Administration (FDA) Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations	https://www.federalregister.gov/documents/2023/12/21/2023-27935/institutional-review-board-waiver-or-alteration-of-informed-consent-for-minimal-risk-clinical	final rule allows an exception from the requirement to obtain informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. The final rule permits an institutional review board (IRB) to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent for certain FDA-regulated minimal risk clinical investigations, if the IRB finds and documents five criteria that are consistent with the revised Common Rule. FDA interprets the term "practicably" to mean, for example, that the research is not unduly delayed by restricting it to consenting subject (e.g.,would cause ethical concern or compromise scientific validity). If scientifically sound research can practicably be carried out using only consenting subjects, FDA believes it should be carried out without involving nonconsenting subjects.
September 26, 2023	Food and Drug Administration (FDA) Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions	https://www.fda.gov/media/119933/download	This guidance provides recommendations on medical device cybersecurity considerations and what information to include in premarket submissions. The guidance replaces the FDA's guidance *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*
September 21, 2023	Food and Drug Administration (FDA) Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies	https://www.fda.gov/media/172258/download	Provides general considerations and FAQs to assist sponsors, institutional review boards (IRBs), and clinical investigators in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity during disasters and Public Health Emergencies that may lead to major disruption of clinical trial conduct and operations.

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September 8, 2023	Food and Drug Administration (FDA) Institutional Review Board (IRB) Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products	https://www.fda.gov/media/171902/download	Final guidance regarding the FDA Form 3926 to request review by the IRB Chair or designated member instead of full board. This streamlined alternative for submitting an IND is permitted for individual patient expanded access, including emergency use. Does not apply to other types of expanded access or device expanded access. Focus of review should be on individual patient. FDA does not expect that a protocol will be necessary to provide the IRB member with sufficient information to determine if they concur with treatment.
August 30, 2023	Food and Drug Administration (FDA) Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products	https://www.fda.gov/media/171667/download	Finalizes guidance on the applicability of FDA's investigational new drug (IND) application regulations under part 312 (21 CFR part 312) to various clinical study designs that utilize real-world data (RWD). Clarifies the Agency's expectation concerning clinical studies using RWD submitted to FDA in support of a regulatory decision regarding effectiveness and safety when such studies are not subject to part 312. Includes sponsor responsibilities including safety and study monitoring.
August 15, 2023	Food and Drug Administration (FDA) Informed Consent Information Sheet - Guidance for IRBs, Clinical Investigators, and Sponsors	https://www.fda.gov/media/88915/download	Provides FDA's expectations regarding informed consent process, roles of IRBs, clinical investigators, sponsors, and FDA , followed by a series of frequently asked questions. . Includes suggestions for enhancing the process without lengthening the form. Includes examples to illustrate concepts such as undue influence, coercion, and exculpatory language. Provides expectations regarding documentation and interpretation of required informed consent elements. Addresses when inclusion of risks and benefits of alternatives may be appropriate. Addresses language issues, delegation, alternative methods of obtaining consent, special populations and other considerations.

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June 21, 2023	Food and Drug Administration (FDA) Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program,	https://www.fda.gov/media/169616/download	FDA's voluntary pilot program for certain CDER-regulated oncology drug products used with certain corresponding in vitro diagnostic (IVD) tests needed to identify patient population, where no alternative treatment exists, benefits of drug outweigh risks, and validated assays can be used to support test accuracy.
May 16, 2023	Food and Drug Administration (FDA) Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products	https://www.fda.gov/media/167973/download	Artificial Intelligence (AI) and Machine Learning (ML) can be described as a branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions, and making predictions. ML is considered a subset of AI that allows models to be developed by training algorithms through analysis of data, without models being explicitly programmed. This white paper includes an overview of the current and potential future uses for AI/ML in therapeutic development. It also discusses the possible concerns and risks associated with these innovations and ways to address them. For instance, the paper describes the importance of having human involvement, which will vary depending on how the technologies will be used. The paper also emphasizes adopting a risk-based approach to evaluate and manage AI/ML in facilitating innovations and protecting public health.
April 12, 2023	Food and Drug Administration (FDA) A Risk-Based Approach to Monitoring of Clinical Investigations Questions and Answers	https://www.fda.gov/media/121479/download	Describes a risk-based approach to monitoring for participant safety and data integrity. Provides recommendations on planning a monitoring approach, developing the content of a monitoring plan, and addressing and communicating monitoring results. Describes use of centralized monitoring across multiple clinical sites to review study-wide data for inconsistencies, ensure that institutional review board and informed consent documents are current, and determine which clinical sites need on-site review.
February 16, 2023	U.S. Government Accountability Office Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness	https://www.gao.gov/products/gao-23-104721	GOA report recommended HHS optimize the use of inspections in the oversight of IRBs and protection of research participants, and examine and implement approaches for measuring IRB effectiveness.

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Draft Regulation/ Guidance 2024			
Draft Regulation/ Guidance 2023			
December 18, 2023	Food and Drug Administration (FDA) Draft: Use of Real-World Evidence (RWE) to Support Regulatory Decision-Making for Medical Devices	https://www.fda.gov/media/174819/download	Includes proposed revisions to 2017 RWE guidance; expands and updates recommendations to industry for assessing when real-world data is fit-for-purpose. Reiterates that IDE would not likely be needed if device is used in the normal course of medical practice, which could include off-label use, if administration is based on clinical care by health care practitioner. However, a registry study of a new intended use would likely be subject to IDE if physicians are instructed to treat specific patients in a prescribed way for purposes of data generation. Includes table of elements for documentation of relevance and reliability of Real World Data for FDA.
October 11, 2023	National Institutes of Health (NIH) Request for Information: Developing Consent Language for Research Using Digital Health Technologies	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-002.html	NIH is seeking input on gaps in providing digital health information in informed consent and the utility of a language resource for research with Digital Health Technologies including Points to Consider and Sample Language.
October 5, 2023	Public Health Service Policies on Research Misconduct	https://www.federalregister.gov/documents/2023/10/06/2023-21746/public-health-service-policies-on-research-misconduct	The Department of Health and Human Services (HHS), Office of the Secretary, Office of the Assistant Secretary for Health (OASH), Office of Research Integrity (ORI) have put forth a notice of proposed rulemaking (NPRM) to revise the Public Health Service (PHS) Policies on Research Misconduct (also known as the "2005 Final Rule"- 42 CFR part 93)." A number of changes to the regulations have been proposed to enhance clarity, efficiency and transparency in addressing research

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September 29, 2023	Food & Drug Administration (FDA) Proposed Rule Aimed at Helping to Ensure Safety and Effectiveness of Laboratory Developed Tests	https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202304&RIN=0910-AI85	Amends the FDA's regulations to make explicit that IVDs are devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory. Along with this amendment, the FDA is proposing a policy under which the agency intends to provide greater oversight of LDTs, through a phaseout of its general enforcement discretion approach to LDTs. FDA is seeking comment regarding varied approaches to enforcement including a different approach for academic medical center laboratories, and grandfathering some or all currently marketed LTDs with respect to premarket review and quality system requirements.
September 15, 2023	Food & Drug Administration (FDA) Digital health Frequently Asked Questions	https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-frequently-asked-questions-faqs?utm_medium=email&utm_source=govdelivery	Series of common and general questions hosted by the Center for Devices and Radiological Health's (CDRH) Digital Health Center of Excellence (DHCoE).
June 16, 2023	Office for Human Research Protections (OHRP) Frequently Asked Questions: Limited IRB Review and Related Exemptions	https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-frequently-asked-questions-limited-institutional-review-board-review-related-exemptions/index.html	Expands on the concept of limited review for exempt categories where information is recorded in identifiable manner and responses may place subject at risk;; discusses IRB and investigator responsibilities relative to privacy and confidentiality protections; states institution should have policy for evaluation of modifications to ensure exempt criteria remain met, including limited review; expedited procedures may be used for limited review.

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June 8, 2023	Food and Drug Administration (FDA) E6 (R3) Good Clinical Practice (GCP)	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r3-good-clinical-practice-gcp	As part of a modernization effort, the FDA has released draft guidance providing Good Clinical Practice (GCP) considerations to be utilized in the design and conduct of clinical trails with focus on efficiency, participant safety and data integrity. Investigator, Institutional Review Board (IRB) and sponsor responsibilities are further detailed.
May 1, 2023	Food and Drug Administration (FDA) Decentralized Clinical trials for Drugs, Biological Products, and Devices	https://www.fda.gov/media/167696/download	Describes DCT study design, use of remote facilities and telemedicine, and digital health technologies in conduct of DCTs. Outlines delegation of research tasks to remote study personnel and tracking of clinical providers limited to normal clinical activities. DCTs require plans for data collection and transmission from multiple sources. Remote consent may be involved. FDA recommends the use of a central IRB in DCTs to facilitate efficient review of the protocol, the informed consent documents, and other relevant trial-related information

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April 12, 2023	DHHS Office of Civil Rights NPRM to Bolster Patient-Provider Confidentiality Around Reproductive Health Care	https://www.federalregister.gov/public-inspection/current	Proposes to extend additional privacy protections for providers, insurers, patients, and others to safeguard PHI when that information otherwise would be disclosed or used to identify, investigate, sue, or prosecute someone for seeking, obtaining, providing, or facilitating lawful reproductive health care. Reproductive health care would be defined to include, but not be limited to, prenatal care, abortion, miscarriage management, infertility treatment, contraception use, and treatment for reproductive-related conditions such as ovarian cancer. As explained in OCR guidance, the existing Privacy Rule permits, but does not require, certain disclosures to law enforcement and others, subject to specific conditions.
March 31, 2023	Food & Drug Administration (FDA) Research Involving Children as Subjects and Not Otherwise Approvable by an IRB: Process for Referrals to FDA and OHRP	https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-research-involving-children-as-subjects/index.html	Guidance to assist institutional review boards (IRBs), institutions, investigators, and sponsors in understanding the processes used for review of research involving children as subjects that is not otherwise approvable by an IRB and has been referred to FDA, the Office for Human Research Protections (OHRP), or both, for review. Outlines how FDA and OHRP will collaborate on review. Includes an abbreviated process for research similar to protocols previously reviewed.
March 15, 2023	Food & Drug Administration (FDA) Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions and Answers	https://www.fda.gov/media/166215/download	Update provides additional recommendations on the risk-based approach to validation of electronic systems described in the September 2003 guidance for industry Part 11, Electronic Records; Electronic Signatures--Scope and Application." Facilitates the use of electronic systems, electronic records, and electronic signatures to improve the quality and efficiency of clinical investigations. In situations where electronic signatures cannot be placed in a specified signature block, a statement of testament (e.g., "I consent to participate") should be placed elsewhere in the document to state the meaning of the signature and link the signature to the electronic informed consent.

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February 1, 2023	(Draft) Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products	https://www.fda.gov/media/164960/download	The Food and Drug Administration (FDA) released draft guidance for industry, sponsors, and institutional review boards (IRBs) for the design and analysis of extrenally controlled trials; to include the selection of the type of control arm, such as a group of people who are treated or untreated, from an earlier time (historical control), or during the same time period (concurrent control) but in another setting. A summary of the focus of comparison (types of external control arms) along with considerations for the investigators, sponsors, and IRBs can be found on page 12 of the document.
Final Regulation/ Guidance 2022			
December 1, 2022	Food & Drug Administration (FDA) Clinical Investigator Administrative Actions - Disqualification	https://www.fda.gov/media/164561/download	Describes the administrative action of disqualifying a clinical investigator from participating in studies involving investigational new drugs (including biologics) or devices
November 1, 2022	Food & Drug Administration (FDA) Expanded Access to Investigational Drugs for Treatment Use Questions and Answers	https://www.fda.gov/media/162793/download	Includes the agency's recommendations for fulfilling new requirements of the 21st Century Cures Act and the FDA Reauthorization Act of 2017 that are related to expanded access.

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September 28, 2022	(Final) Clinical Decision Support Software, Guidance for Industry and Food and Drug Administration Staff	https://www.fda.gov/media/109618/download https://www.fda.gov/medical-devices/software-medical-device-samd/your-clinical-decision-support-software-it-medical-device?utm_medium=email&utm_source=govdelivery	The Food and Drug Administration (FDA) released final guidance which provides clarity on FDA's oversight of clinical decision support (CDS) software intended for health care professionals with the purpose of describing FDA's regulatory approach to CDS software functions. This guidance clarifies the types of CDS functions that do not meet the definition of a device as amended by the 21st Century Cures Act (Cures Act). The FDA has developed a graphic to provide a visual overview of certain policies described in the guidance and examples of non-device CDS functions and device software functions for illustrative purposes.
May 12, 2022	NIH Informed Consent for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing	Informed-Consent-Resource-for-Secondary-Research-with-Data-and-Biospecimens.pdf (nih.gov)	This document is intended to provide sample language to investigators and IRBs when developing informed consent documents for secondary use of data or biospecimens.
March 29, 2022	Office for Human Research Protections (OHRP) Clincial Trial Informed Consent Form Posting	https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/informed-consent-posting-guidance/index.html	Provides instructions for posting consent forms for clinical trials supported by common rule agencies.
February 25, 2022	Food and Drug Administration (FDA) Patient-Focused Drug Development: Methods to Identify What is Important to Patients	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-methods-identify-what-important-patients	Provides practical information and examples of qualitative research methods used to obtain patient input

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January 26, 2022	Food and Drug Administration (FDA) Patient Engagement in the Design and Conduct of Medical Device Clinical Studies	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-studies?utm_medium=email&utm_source=govdelivery	Describes how device developers, sponsors and industry can voluntarily use patient engagement to improve clinical study design and conduct. Activities with patient advisors involving interaction in a consultative or advisory capacity, does not generally constitute research or an activity subject to FDA's regulations regarding Institutional Review Boards (IRBs). Patient advisors refers to individuals who have experience living with a disease or condition, and can serve in an advisory or consultative capacity to improve clinical study design and conduct, but who are NOT study/research participants themselves.
Draft Regulation/Guidance 2022			
December 9, 2022	Food and Drug Administration Investigational New Drug Applications; Exemptions for Clinical Investigations To Evaluate a Drug Use of a Product Lawfully Marketed as a Conventional Food, Dietary Supplement, or Cosmetic	https://www.federalregister.gov/documents/2022/12/09/2022-26728/investigational-new-drug-applications-exemptions-for-clinical-investigations-to-evaluate-a-drug-use	Proposes to amend IND exemption regulations for certain clinical investigations of lawfully marketed foods, dietary supplements, and cosmetics being evaluated as a drug. Must not be intended to support a drug development plan (drug claim), labeling change, or present significant risk to health, safety, or welfare of subjects. Includes provision for self-determination or FDA-determined exemption. No timeline provided for final rule or effective date.
September 26, 2022	(Draft) Ethical Considerations for Clinical Investigations of Medical Products Involving Children	https://www.fda.gov/media/161740/download	The Food and Drug Administration (FDA) released draft guidance for industry, sponsors, and institutional review boards (IRBs) describing the FDA's current thinking regarding ethical considerations for clinical investigations of drugs, biological products, and medical devices (collectively referred to as "medical products") involving children and is intended to assist industry, sponsors, and IRBs when considering the enrollment of children in clinical investigations of medical products.

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August 25, 2022	(Draft) Food and Drug Administration (FDA) Charging for Investigational Drugs Under and IND Questions and Answers Guidance for Industry	https://fda.gov/media/161079/download	Reviews existing criteria for charging, costs that may be recovered, and FDA authorization process for the purpose of either clinical trials or expanded access for treatment use. The IND sponsors submits the request for FDA's authorization to charge for an investigational drug for use under the IND. FDA is providing this revised guidance, in a question and answer format, to address the most recently asked questions and provide additional questions and answers. When final, will replace 2016 Charging for Investigational Drugs under IND Q and A.
May 12, 2022	(Draft) Supplemental Information to the NIH Policy for Data Management and Sharing: Protecting Privacy When Sharing Human Research Participant Data	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-131.html	The NIH released draft supplemental information to the NIH Policy for Data Management and Sharing to address privacy considerations when sharing human research participant data. This information was developed to further clarify and provide direction about preferred practices and includes 1) operational principles for protecting participants' privacy when sharing scientific data, 2) best practices for implementing these principles, and 3) points to consider for designating scientific data for controlled access.
April 13, 2022	(Draft) Food and Drug Administration (FDA) Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials	https://www.fda.gov/media/157635/download	FDA recommends a Plan be submitted for medical products for which an IND or IDE submission is required, or for clinical studies are intended to support a marketing submission.
April 8, 2022	(Draft guidance) Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Draft Guidance for Industry and Food and Drug Administration Staff	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions	This guidance is intended to provide recommendations to industry regarding cybersecurity device design, labeling, and the documentation that FDA recommends be included in premarket submissions for devices with cybersecurity risk. These recommendations can facilitate an efficient premarket review process and help ensure that marketed medical devices are sufficiently resilient to cybersecurity threats.
Final Regulation/ Guidance 2021			

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October 12, 2021	NIH Implementation of the Revised Common Rule Provision Regarding Public Health Surveillance Activities Deemed Not to Be Research	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-001.html	The Revised Common Rule identifies certain public health surveillance activities as being excluded from applicability of the Common Rule. Acknowledging that such exclusions should be made cautiously, NIH, as a public health authority, will solely make all determinations as to whether an NIH-supported or -conducted study meets this exclusion criteria. Requests for such a determination should include a compelling justification and describe all activities for which the exclusion is being requested. NIH expects that NIH-supported or -conducted research will only be determined to be a public health surveillance activity in extremely rare cases.
September 27, 2022	Food and Drug Administration Digital Health Policy Navigator	https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-policy-navigator	Tool intended to help product developers understand whether a software function is potentially subject to or the focus of the FDA's regulatory oversight as a device, and if so, the considerations that may assist in determining the applicable FDA-specific legal and regulatory requirements and recommendations. The Navigator provides an interactive overview of digital health policies that may apply to your product's software functions
August 30, 2021	Food and Drug Administration (FDA) Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency - UPDATED	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency	Added questions - 1) confirmed that COVID vaccines or meds with an Emergency Use Authorization (EUA) would not be considered “investigational medical products”. Investigational products are typically exclusion criteria for clinical trials; but EUA products wouldn’t count. 2) recommends sponsors use a risk-based approach to decide regarding need for “re-monitoring” what was monitored remotely.
July 27, 2021	Office for Human Research Protections (OHRP) Incident Report Form and Instructions	https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html	New OHRP filliable Incident Reporting Form with submit function and Instructions.
March 1, 2021	National Human Genome Research Institute’s (NHGRI) Guidance for Third-Party Involvement in Extramural Research	https://www.genome.gov/about-nhgri/Policies-Guidance/Third-Party-Involvement-in-NHGRI-Supported-Extramural-Projects	Effective July 1, 2021, guidance applies to NHGRI-funded extramural investigators that are subject to NIH Data Sharing Policies, such as the NIH Data Sharing Policy or the NIH Genomic Data Sharing (GDS) Policy as well as their sub-recipients. Refer to guidance prior to seeking or receiving support or involvement from third parties in order to promote transparency regarding third-party support, prevent potential conflicts of interest, and preserve scientific objectivity.

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Draft Regulation Guidance 2021			
December 23, 2021	Food and Drug Administration (FDA) Digital Health Technologies for Remote Data Acquisition in Clinical Investigations, Availability	https://www.federalregister.gov/documents/2021/12/23/2021-27894/digital-health-technologies-for-remote-data-acquisition-in-clinical-investigations-draft-guidance?utm_source=federalregister.gov&utm_medium=email&utm_campaign=subscription+mailing+list	This guidance provides recommendations to sponsors, investigators, and other stakeholders on the use of digital health technologies (DHTs) to acquire data remotely from participants in clinical investigations evaluating medical products. DHTs may take the form of hardware and/or software and may be used to gather health-related information from study participants and transmit that information to study investigators and/or other authorized parties to evaluate the safety and effectiveness of medical products. Data may be obtained from sensors and include information on daily activities or measures from participants unable to report experiences (e.g., infants, cognitively impaired).
December 8, 2021	Food and Drug Administration (FDA) Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-real-world-data-and-real-world-evidence-support-regulatory-decision-making-drug?utm_medium=email&utm_source=govdelivery	Discusses the applicability of FDA's investigational new drug (IND) application regulations under part 312 (21 CFR part 312) to various clinical study designs that utilize real-world data (RWD). Clarifies the Agency's expectation concerning clinical studies using RWD submitted to FDA in support of a regulatory decision regarding effectiveness and safety when such studies are not subject to part 312.
November 30, 2021	Request for Information on Proposed Updates and Long-Term Considerations for the NIH Genomic Data Sharing Policy	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-029.html	Seeks input to keep pace with evolving developments such as use of information with potentially higher degree of identifiability; capability to link data from diverse datasets; and other novel data types (e.g., proteomic, metabolomic). Provides examples of data linkage challenges and considers whether data linkage should be addressed in informed consent. States intention to harmonize the GDS with the NIH Data Management and
November 29, 2021	Food and Drug Administration (FDA) Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/real-world-data-assessing-registries-support-regulatory-decision-making-drug-and-biological-products	Outlines FDA's recommendations for sponsors proposing to design a registry or to use real-world data (RWD) from existing registries to support regulatory decision-making.

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November 24, 2021	Food and Drug Administration (FDA) Investigational New Drug (IND) Application Requirements	https://www.federalregister.gov/documents/2021/11/24/2021-25615/agency-information-collection-activities-proposed-collection-comment-request-investigational-new?utm_medium=email&utm_campaign=subscription+mailing+list&utm_source=federalregister.gov	Applies to Investigator Initiated INDs, Emergency Use INDs, and Treatment INDs. General IND requirements include submitting an initial application as well as amendments to that application; submitting reports on significant revisions of clinical investigation plans; submitting information to the clinical trials data bank (https://clinicaltrials.gov); annual summary reporting to FDA; recordkeeping, drug accountability; subject case histories, and regulatory documentation. References completion of FDA Forms, 1571, 1572, and 3674, as well as guidance on clinical investigation oversight, pharmacogenomic data submissions, and adaptive trial designs.
October 18, 2021	Food and Drug Administration (FDA) Studies Using Leftover, Deidentified Human Specimens Require IRB Review – Letter to Industry	https://www.fda.gov/medical-devices/industry-medical-devices/studies-using-leftover-deidentified-human-specimens-require-irb-review-letter-industry?utm_medium=email&utm_source=govdelivery	The FDA believes it is possible in certain circumstances for IVD device investigations to be conducted using leftover specimens, which are remnants of specimens collected for routine clinical care or analysis that would otherwise have been discarded, that were obtained without informed consent; however, enforcement discretion does NOT apply to other requirements including IRB review and approval.
September 29, 2021	Food and Drug Administration (FDA) Investigator Responsibilities – Safety Reporting for Investigational Drugs and Devices	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigator-responsibilities-safety-reporting-investigational-drugs-and-devices	Provides guidance on how to identify safety information that raises an “unanticipated problem involving risk to human subjects or others” for investigational drugs or “unanticipated adverse device effects” and how that information should be reported. It applies to investigational new drug application (IND) studies and investigational device exemption (IDE) studies. Also outlines additional events that should be reported to the IRB by investigators including medication errors or breach of confidentiality.

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September 22, 2021	(Draft)Artificial Intelligence and Machine Learning in Software as a Medical Device	https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device#regulation	FDA's traditional paradigm of medical device regulation was not designed for adaptive artificial intelligence and machine learning technologies. Under the FDA's current approach to software modifications, the FDA anticipates that many AI/ML driven software changes to a device may need a premarket review. Includes the 2019 discussion paper "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML) Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback" that describes the FDA's foundation for a potential risk-based approach to premarket review Does not address a framework for research regulations.
July 1, 2021	National Institutes of Health (NIH) Request for Information: Developing Consent Language for Future Use of Data and Biospecimens	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-131.html	
June 28, 2021	FDA Sponsor Responsibilities— Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies Guidance for Industry	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/sponsor-responsibilities-safety-reporting-requirements-and-safety-assessment-ind-and	Includes the 2019 discussion paper "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML) Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback" that describes the FDA's foundation for a potential risk-based approach to premarket review
June 24, 2021	Food and Drug Administration (FDA) Cancer Clinical Trial Eligibility Criteria: Available Therapy in Non-Curative Settings	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cancer-clinical-trial-eligibility-criteria-available-therapy-non-curative-settings	
May 26, 2021	Food and Drug Administration (FDA) Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-surveillance-under-section-522-federal-food-drug-and-cosmetic-act-0	Does not address a framework for research regulations.

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Date	**Title**	**Web link**	**Comments**
May 19, 2021	Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions Statement of Investigator (Form FDA 1572)	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/information-sheet-guidance-sponsors-clinical-investigators-and-irbs-frequently-asked-questions	Provides updated FAQ 10,11,13 with information regarding waiver of investigator signature requirement, particularly where prohibited by international regulation or local laws.
May 17, 2021	Food and Drug Administration (FDA) COVID-19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention	https://www.fda.gov/media/148739/download	Master protocols can accelerate drug development by maximizing the amount of information obtained and leveraging infrastructure to increase trial efficiency. A master protocol is defined as a protocol designed with multiple sub-studies, which may have different objectives and involve coordinated efforts to evaluate one or more investigational drugs in one or more disease subtypes within the overall trial structure. Types of master protocols include umbrella trials, platform trials, and basket trials. FDA recommends the use of a central institutional review board to review the master protocol
April 14, 2021 (*comments due 5/14/21)*	Department of Health and Human Services (HHS) The Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form	https://www.federalregister.gov/documents/2021/04/14/2021-07620/agency-information-collection-request-30-day-public-comment-request?utm_medium=email&utm_campaign=subscription+mailing+list&utm_source=federalregister.gov	**The Office for Human Research Protections is requesting a three-year extension of the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form, OMB No. 0990-0263.**
January 13, 2021 (*comments due 2/12/21*)	Department of Health and Human Services (HHS) Establishment of Safeguards and Program Integrity Requirements for Health and Human Services-Funded Extramural Research Involving Human Fetal Tissue	https://www.federalregister.gov/documents/2021/01/13/2020-29107/establishment-of-safeguards-and-program-integrity-requirements-for-health-and-human-services-funded	**Amends Subpart B- defines human fetal tissue; includes model informed consent language for donation of fetal tissue for research; prohibits use of fetal tissue from "elective abortions" if acquired from select entities; and grants authorized agency representatives access to documents, consent records, personnel to establish that fetal tissue was not obtained from elective abortions.**
Final Regulation/ Guidance 2020			

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December 4, 2020	Food and Drug Administration (FDA) Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency - UPDATED	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency	**The updated guidance includes question and answers on a clinical trial investigator's responsibility to review all investigational new drug application safety reports, including reports that will not result in a change to the investigator brochure, informed consent, or protocol and considerations for electronic signatures on clinical trial records, including consent documents, during the public health emergency. Adds information on safety reporting and flexibility with Part 11 compliance with electronic signatures in remote consent.**
November 16, 2020	Food and Drug Administration (FDA) Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/certificates-confidentiality	**FDA will continue to issue discretionary CoCs related to the study of products subject to FDA jurisdiction. Guidance provides instruction for requesting CoC.**
November 9, 2020	Food and Drug Administration (FDA) Enhancing the Diversity of Clinical Trial Populations - Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial	**This guidance recommends approaches that sponsors of clinical trials intended to support a new drug application or a biologics license application can take to increase enrollment of underrepresented populations in their clinical trials.**
October 29, 2020	NIH Policy for Data Management and Sharing	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html	**Policy establishes the expectation for maximizing the appropriate sharing of scientific data generated from NIH-funded or conducted research, with justified limitations or exceptions. Effective January 2023, expects the development of Data Management and Sharing Plans**
October 9, 2020	Food and Drug Administration (FDA) Emergency Use Authorization for Vaccines to Prevent COVID-19	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19	**FDA is issuing this guidance to provide sponsors of requests for Emergency Use Authorization (EUA) for COVID-19 vaccines with recommendations regarding the data and information needed to support the issuance of an EUA under section 564 of the FD&C Act (21 U.S.C. 360bbb-3) for an investigational vaccine to prevent COVID-19 for the duration of the COVID-19 public health emergency.**

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October 8, 2020	Office for Human Research Protections (OHRP) Exception to the Single IRB Review Requirements for Certain HHS-Conducted or -Supported Cooperative Research Activities Subject to the 2018 Requirements During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-exception-determinations/october-2020-exception-determination/index.html	**OHRP provided an exception determination (as permitted by 45 CFR 46.114(b)(2)(ii)) stating that certain categories of cooperative research supported or conducted by HHS and subject to the 2018 Requirements are not required to comply with the 2018 Requirements' single IRB mandate.**
September 14, 2020	Food and Drug Administration (FDA) Assessing COVID-19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-covid-19-related-symptoms-outpatient-adult-and-adolescent-subjects-clinical-trials-drugs	**The guidance provides a common set of COVID-19 related symptoms and approach to measurement since daily assessments of all symptoms may not be feasible in clinical trials evaluating drugs to prevent or treat COVID-19.**
October 2, 2020	Office for Civil Rights (OCR) FAQs on Telehealth and HIPAA during the COVID-19 nationwide public health emergency	https://www.hhs.gov/guidance/document/faqs-telehealth-and-hipaa-during-covid-19-nationwide-public-health-emergency	**OCR will exercise its enforcement discretion & will not pursue otherwise applicable penalties for breaches that result from the good faith provision of telehealth services during the COVID-19 Nationwide Public Health Emergency**

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August 19, 2020	US Department of Health and Human Services (DHHS) Recission of Guidances and Other Informal issuances Concerning Premarket Review of Laboratory Developed Tests (LDT)	https://www.hhs.gov/coronavirus/testing/recission-guidances-informal-issuances-premarket-review-lab-tests/index.html	**The Food and Drug Administration (FDA) will not require premarket review of laboratory developed tests absent formal rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances. Those seeking approval or clearance of, or an emergency use authorization (EUA) for an LDT may nonetheless voluntarily submit a premarket approval application, which if approved triggers PREP Act coverage which immunizes laboratories from suits for loss related to the test. FAQs on Laboratory Developed Tests -** https://www.hhs.gov/sites/default/files/laboratory-developed-tests-faqs.pdf
August 17, 2020	Food and Drug Administration (FDA)Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank; Guidance for Responsible Parties, Submitters of Certain Applications and Submissions to the Food and Drug Administration, and Food and Drug Administration Staff; Availability	https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-17909.pdf	**Provides current FDA thinking regarding civil money penalties that may be assessed under the FD&C Act for violations of the requirement to submit clinical trial registration and results information to the clinicaltrials.gov data bank.**
July 21, 2020	Food and Drug Administration (FDA) Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal	**Provides guidance on minimal manipulation and homologus use criteria for determining if product qualifies for regulation solely under section 361 of the PHS Act (and not FDA). FDA intends to extend enforcement discretion under limited conditions with respect to the investigational new drug (IND) application and premarket approval (biologics license application (BLA)) requirements, for certain HCT/Ps, through May 2021.**
July 10, 2020	Food and Drug Administration (FDA) Cancer Clinical Trial Eligibility Criteria: Patients with HIV, Hepatitis B Virus, or Hepatitis C Virus Infections	https://www.fda.gov/media/121319/download	**Provides recommendations regarding eligibility criteria for clinical trials of drugs or biological products for the treatment of cancer.**

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July 10, 2020	Food and Drug Administration (FDA) Cancer Clinical Trial Eligibility Criteria: Patients with Organ Dysfunction or Prior or Concurrent Malignancies	https://www.fda.gov/media/123745/download	**Provides recommendations regarding eligibility criteria for clinical trials of drugs or biological products for the treatment of cancer.**
July 10, 2020	Food and Drug Administration (FDA) Cancer Clinical Trial Eligibility Criteria: Brain Metastases	https://www.fda.gov/media/121317/download	**Provides recommendations regarding eligibility criteria for clinical trials of drugs or biological products for the treatment of cancer.**
July 10, 2020	Food and Drug Administration (FDA)Cancer Clinical Trial Eligibility Criteria: Minimum Age Considerations for Inclusion of Pediatric Patients	https://www.fda.gov/media/121318/download	**Recommendations regarding eligibility criteria for clinical trials of drugs or biological projects for treatment of cancer. FDA provides guidance regarding the inclusion of pediatric patients, when appropriate.**
June 1, 2020	Food and Drug Administration (FDA) Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID-19 Public Health Emergency	https://www.fda.gov/media/138496/download	**FDA seeks to provide clarity regarding the key factors and procedures IRBs should consider when reviewing individual patient expanded access submissions.**
April 15, 2020	Department of Defense: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research	https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf	**DoD Instruction 3216.02 replaces DoD Directive 3216.02. There is no longer the requirement of a research monitor for greater than minimal risk research.**
April 8, 2020	Office for Human Research Protections (OHRP) Guidance on COVID-19	https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html	**Clarifies regulatory requirements and flexibility of 45 CFR 46; outlines Public Health Surveillance Activities which do not fall under IRB Purview; indicates agreement with FDA-issued Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic.**
January 22, 2020	National Institutes of Health (NIH), Additional Guidance on the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-058.html	**The purpose of this Notice is to inform the research community of the NIH requirement to adhere to the Revised Common Rule to use a single IRB for NIH-supported multi-site studies conducting research at more than one domestic site.**

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Draft Regulation Guidance 2020			
November 4, 2020	U.S. Department of Health and Human Services (HHS), HHS Proposes Unprecedented Regulatory Reform through Retrospective Review	https://www.hhs.gov/about/news/2020/11/04/hhs-proposes-unprecedented-regulatory-reform-through-retrospective-review.html?utm_source=news-releases-email&utm_medium=email&utm_campaign=november-08-2020	**HHS is proposes the department assess its regulations every ten years to determine whether they are subject to review under the Regulatory Flexibility Act (RFA), which requires regular review of certain significant regulations. PRO instruments have been qualified under the Medical Device Development Tools (MDDT) [https://www.fda.gov/medical-devices/science-and-research-medical-devices/medical-device-development-tools-mddt program] as tools that medical device sponsors can use in the development and evaluation of medical devices**
August 28, 2020	Food and Drug Administration (FDA) Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation	https://www.fda.gov/media/141565/download	**Patient-reported outcome (PRO) instruments facilitate the systematic collection of how patients feel, function, and survive as valid scientific evidence to support the regulatory and healthcare decision-making.**
April 8, 2020	Office for Human Research Protections (OHRP) Guidance on Coronavirus	https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html	**Clarifies public health activities that are excluded from the revised common rule; allows research modifications without prior IRB review to eliminate immediate hazards; Certificate of Confidentiality does not prohibit investigator's ability to comply with federal, state, local COVID-19 test reporting of research participants, states views consistent with FDA Guidance on Conduct of Clinical trials of Medical products during COVID-19 Pandemic**
March 18, 2020	Food and Drug Administration (FDA) Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency	**Addresses challenges to clinical trial conduct and offers guidance and flexibilities including enforcement discretion to facilitate research while ensuring participant and public health and safety. Provides questions/answers on when to pause or modify study conduct, recruitment, follow-up while balancing safety of subjects & staff with integrity of the research. Includes discussion of alternative secure delivery of study product; remote monitoring; contingency measures; modifications and missing data documentation; remote informed consent, etc.**
January 30, 2020	Food and Drug Administration (FDA) Cellular and Gene Therapy Guidances	https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/recently-issued-guidance-documents	**Multi-guidance website includes several newly released guidance documents**

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Final Regulation/ Guidance 2019			
November 29, 2019	Food and Drug Administration (FDA) Adaptive Designs for Clinical Trials of Drugs and Biologics	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/adaptive-design-clinical-trials-drugs-and-biologics-guidance-industry	**An adaptive design is defined as a clinical trial design that allows for prospectively planned modifications to one or more aspects of the design based on accumulating data from subjects in the trial. Describes potential ethical advantages such as stopping a trial due to lack of effectiveness. Provides examples to illustrate advantages.**
November 22, 2019	Office for Human Research Protections (OHRP), Determination of Exception to the Required Use of a Single IRB for Certain HHS Cooperative Research that is Subject to the 2018 Requirements	https://www.hhs.gov/ohrp/exception-determination-required-sirb-use-certain-research.html	**Grants an exception from the collaborative research provision for projects approved by an IRB before January 20, 2020 to use multiple IRBs in the following specific circumstances:** **1. Cooperative research conducted or supported by HHS agencies other than the National Institutes of Health (NIH), if an IRB initially approved the research before January 20, 2020, or** **2. Cooperative research conducted or supported by NIH if either:** **1. The NIH single IRB policy does not apply, and the research was initially approved by an IRB before January 20, 2020, or** **2. NIH excepted the research from its single IRB policy before January 20, 2020**
September 27, 2019	Food and Drug Administration (FDA) Policy for Device Software Functions and Mobile Medical Applications	https://www.fda.gov/media/80958/download	**Provides guidance on software on mobile or other computing platforms to clarify the subset to which FDA intends to apply authority. Provides examples of mobile medical apps for which FDA intends to exercise enforcement discretion.**
September 26, 2019	(Final) General Wellness: Policy for Low Risk Devices	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices	**CDRH does not intend to evaluate General Wellness Products (GWP) to determine if meet device definition. CDRH defines GWPs as products that: (1) are intended for only general wellness use (encourage general state of health, reduce risk of disease, aid living well with condition) and (2) present a low risk to the safety of users and other persons.**
September 6, 2019	Food and Drug Administration (FDA)Humanitarian Device Exemption (HDE) Program Guidance for Industry and Food and Drug Administration Staff	https://www.fda.gov/media/74307/download	**FDA provides additional guidance for the HDE program. The guidance provides recommendations to industry and FDA staff about operational aspects of the HDE program and also explains the principal criteria that FDA considers when determining if probable benefit to health have been demonstrated for a HUD that is being reviewed through the HDE program.**

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August 29, 2019	Food and Drug Administration (FDA) Placebos and Blinding in Randomized Controlled Cancer Clinical Trials for Drug and Biological Products	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/placebos-and-blinding-randomized-controlled-cancer-clinical-trials-drug-and-biological-products	**Provides recommendations to industry about the use of placebos and blinding in randomized controlled clinical trials in development programs for drug or biological products to treat hematologic malignancies and oncologic diseases. Due to practical and ethical concerns, a placebo-controlled study design should be limited to studies involving maintenance therapy, add-on trial designs, adjuvant therapies, or for indications where no treatment is available (e.g., supportive care).**
July 26, 2019	Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-128.html?utm_source=dlvr.it&utm_medium=twitter	**NIH requires informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained. The informed consent for donation of human fetal tissue (HFT) from elective abortions for use in research requires language that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not affect the method of abortion; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and to be signed by both the woman and the person who obtains the informed consent.**
July 11, 2019	Food and Drug Administration (FDA) Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials Guidance for Institutional Review Boards, Industry, Clinical Investigators, and Food and Drug Administration Staff	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/live-case-presentations-during-investigational-device-exemption-ide-clinical-trials?utm_campaign=2019-07-10%20Final%20Guidance%20on%20Live%20Case%20Presentations%20During%20IDE%20Clinical%20Trials&utm_medium=email&utm_source=Eloqua	**IDE protocols requesting to conduct a live case presentation must obtain IRB approval and FDA approval as an IDE supplement. The potential subject must provide informed consent to be featured. The live case presentations can be used to recruit investigators or subjects. They may not be appropriate where risk profile unknown or high-risk procedure or population.**

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January 2, 2019	National Institutes of Health (NIH) Implementation of the Final Rule on the Federal Policy for the Protection of Human Subjects (Common Rule)	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-050.html	**For studies approved under new common rule, NH will no longer require IRB review and approval of the entire grant application or contract proposal. For NIH-Funded clinical trials, informed consent document must be posted according to the revised rule requirements. Revised exemptions apply and NIH will not require annual IRB review unless required by the revised rule or other policy.**
Draft Regulation Guidance 2019			
November 22, 2019	Food and Drug Administration (FDA) Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/certificates-confidentiality	FDA will continue to issue discretionary CoCs related to the study of products subject to FDA jurisdiction. Guidance provides instruction for requesting CoC.
November 8, 2019	NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance	https://www.federalregister.gov/documents/2019/11/08/2019-24529/request-for-public-comments-on-a-draft-nih-policy-for-data-management-and-sharing-and-supplemental	**NIH is seeking public comments to facilitate the update of their responsible data management and sharing.**
September 23, 2019	Food and Drug Administration (FDA) Interacting with the FDA on Complex Innovative Trial Designs for Drugs and Biological Products	https://www.fda.gov/media/130897/download	**Recommends early interaction between sponsors and FDA regarding Complex Innovative Design (CID) such as those with non-traditional controls, sequential multiple assignment randomized trials (SMART), master protocols, and simulations.**
July 31, 2019	E8(R1) General Considerations For Clinical Studies	https://www.fda.gov/media/129527/download	**Guidance focuses on designing quality into clinical studies, considering the diversity of clinical study designs and data sources used to support regulatory and other health policy decisions throughout the product life cycle.**
June 5, 2019	Food and Drug Administration (FDA) Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial	**Provides recommendations for sponsors of clinical trials in broadening eligibility criteria to increase enrollment of underrepresented populations.**

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June 1, 2019	Food and Drug Administration (FDA) Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-inclusion-adolescent-patients-adult-oncology-clinical-trials	**Adolescent patients are not often included in adult cancer trials, resulting in delayed access to potentially effective therapies. This guidance outlines the appropriateness and considerations involved for including pediatric patients in adult cancer trials.**
March 15, 2019	Food and Drug Administration (FDA) Cancer Clinical Trial Eligibility Criteria: Patients with HIV, Hepatitis B Virus, or Hepatitis C Virus Infections	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cancer-clinical-trial-eligibility-criteria-patients-hiv-hepatitis-b-virus-or-hepatitis-c-virus	**Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients' access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug. This guidance discusses the potential inclusion of patients infected with HIV, HBV, or HCV in cancer trials.**
March 15, 2019	Food and Drug Administration (FDA) Cancer Clinical Trial Eligibility Criteria: Brain Metastases Guidance for Industry	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cancer-clinical-trial-eligibility-criteria-brain-metastases	**Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients' access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug. This guidance provides recommendations for broadening cancer trial eligibility criteria to include individuals with brain metastases, when appropriate.**
March 13, 2019	Food and Drug Administration (FDA) Cancer Clinical Trial Eligibility Criteria: Minimum Age for Pediatric Patients Guidance for Industry	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cancer-clinical-trial-eligibility-criteria-minimum-age-pediatric-patients	**Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients' access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug. This guidance discusses considerations for sponsors and institutional review boards regarding minimum age eligibility criteria for pediatric patients in cancer clinical trials.**
March 5, 2019	Food and Drug Administration (FDA) Comment Request; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable	https://www.federalregister.gov/documents/2019/03/05/2019-03901/agency-information-collection-activities-proposed-collection-comment-request-guidance-on-informed	**This notice solicits comments on the information collection associated with the guidance on informed consent for in vitro diagnostic (IVD) device studies using leftover human specimens that are not individually identifiable. 2006 FDA guidance on Informed Consent for IVD studies using leftover human specimens not individually identifiable, outlines circumstances in which FDA will exercise enforcement discretion regarding the informed consent requirement.**
February 21, 2019	Food and Drug (FDA) Use of Investigational Tobacco Products: Guidance for Industry and Investigators	https://www.fda.gov/media/94052/download	**Represents current thinking of the FDA regarding investigational tobacco products. The FDA intends to propose regulations establishing conditions for exempting investigational tobacco products from certain FD&C Act requirements. Until then, investigational tobacco products are not exempt from FD&C Act requirements.**

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February 15, 2019	Office for Human Research Protections (OHRP) Clinical Trial Informed Consent Form Posting	https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html	**Provides instruction for posting consent forms for clinical trials supported by common rule agencies.**
February 14, 2019	Office for civil Rights (OCR)Request for Information on Modifying HIPAA Rules To Improve Coordinated Care	https://www.federalregister.gov/documents/2018/12/14/2018-27162/request-for-information-on-modifying-hipaa-rules-to-improve-coordinated-care	**OCR seeks information on the provisions of the HIPAA Rules that may present obstacles to, or place unnecessary burdens on, the ability of covered entities and business associates to conduct care coordination and/or case management. PRIM&R is using the opportunity to recommend OCR consider how HIPAA rules could be harmonized with common rule regulations and to revise rules to facilitate vital research while continuing to protect privacy interests.**
Final Regulation/ Guidance 2018			
November 27, 2018	Food and Drug Administration (FDA) Certificates of Confidentiality Terms and Conditions on all FDA Funding Opportunity Announcements and Grant Awards	https://grants.nih.gov/grants/guide/notice-files/NOT-FD-19-002.html	Effective October 1, 2018 FDA-funded research will be deemed to be issued a “Certificate of Confidentiality” . Certificates issued in this manner will not be issued as a separate document. Awardees are expected to ensure that any investigator or institution not funded by FDA who receives a copy of identifiable, sensitive information protected by these requirements, abide by these measures.
November 1, 2018	National Institutes of Health (NIH) Update to NIH Management of Genomic Summary Results Access	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-023.html	Updates GDS policy to provide access to genomic summary results (GSR). GSR are defined to include those provided by a study’s investigator, if any, as well as summary statistics that may be computed by relevant NIH-designated data repository across all non-"sensitive" studies with data included in that repository. Provides a data access model that is proportional to the risks and benefits posed by broad access to this type of information, and takes into account any study-specific elements that might increase privacy risks or potential for harm within a study population. Unless otherwise indicated, the policy will allow unrestricted access to GSR for in order to advance health or further research purposes.

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October 11, 2018	Food and Drug Administration (FDA) Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/impact-certain-provisions-revised-common-rule-fda-regulated-clinical-investigations	Until FDA revises human subject protection regulations, this guidance provides clarification to reduce confusion and burden associated with complying with FDA and Common Rule regulations scheduled to go into effect 2019. The Common Rule informed consent provisions related to the content, organization, and presentation as well as the basic and additional elements are not inconsistent with FDA's current policies and guidance. This may avoid the need for sponsors or investigators to develop, and IRBs to review, two separate informed consent forms. FDA regulated expedited protocols must be found by the IRB reviewer to be no greater than minimal risk. The IRB must continue to conduct continuing review of FDA regulated expedited protocols.
July 30, 2018	Food and Drug Administration (FDA) Use of Electronic Health Record Data in Clinical Investigations: Guidance for Industry	https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM501068.pdf	Encourages the interoperability of electronic medical records (EHRs) and electronic data capture (EDC) to improve data integrity and limit errors in transcription. Consideration surrounding security, study design, and informed consent are discussed as well as FDA audit requirements for clinical data access. FDA also recommends informing participants regarding the extent of EHR access sponsor or sponsor representatives will have. Does not apply to postmarketing observational pharmacoepidemiologic studies or EHR as a recruitment tool.
July 20, 2018	National Institutes of Health (NIH) Delayed Enforcement and Short-Term Flexibilities for Some Requirements Affecting Prospective Basic Science Studies Involving Human Participants	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-212.html	interim policy (through 9-24-19), offers flexibilities and delayed enforcement for a NIH-funded prospective basic science studies involving human subjects that meet the NIH definition of a "clinical trial". NIH will exercise leniency with inaccurate funding opportunity announcement submissions and registration/reporting on Clinicaltrials.gov. Other requirements such as GCP training and use of the clinical trial information form remain.
July 10, 2018	National Academies of Sciences, Engineering, and Medicine (NASEM) Returning Individual Research Results to Participants: Guidance for a New Research Paradigm	http://nationalacademies.org/hmd/reports/2018/returning-individual-research-results-to-participants.aspx	Encourages return of individual results using a process-oriented approach that considers value to the participant, risks and feasibility of return, and quality of the research laboratory. Calls for development of a certification system for research labs to allow certain genetic results and other information to participants who want them.

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June 18, 2018	U.S. Department of Health and Human Services (HHS) and 16 other federal departments Final Rule Delay	https://www.federalregister.gov/documents/2018/06/19/2018-13187/federal-policy-for-the-protection-of-human-subjects-six-month-delay-of-the-general-compliance-date	Notice of Proposed Rulemaking (NPRM) was published on April 20, 2018 (83 FR 17595), which proposed an additional 6-month delay for the general compliance date for the 2018 Requirements and a flexibility that would allow regulated entities to take advantage of three burden-reducing provisions of the 2018 Requirements during the delay period. May apply to all or specific studies. Must adopt all three provisions (cannot choose). Once adopted, study must comply with new common rule on January 21, 2019.
May 14, 2018	Office for Human Research Protections (OHRP) Effects of Disasters on Human Research Protections Programs Guidance	https://www.hhs.gov/ohrp/regulations-and-policy/guidance/effects-of-disasters-on-human-research-protections-programs-guidance/index.html	Provides guidance on flexibility and the oversight of ongoing human research protections programs in affected areas after disasters (e.g., hurricanes, tornados, earthquakes). Provides options for institutions in the affected areas that are unable to function, including reliance with IRB authorization agreements. Acknowledges that expiration of approval could occur and research may continue if in the best interest of enrolled subjects.
May 1, 2018	Joint Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) guidance: Institutional Review Board Written Procedures: Guidance for Institutions and IRBs	https://www.fda.gov/RegulatoryInformation/Guidances/ucm512760.htm	Final guidance is to assist IRB administrators, IRB chairpersons, and other institutional officials responsible for preparing and maintaining written IRB procedures. In order to provide clarification on scope and content of IRB procedures, while taking into account local variation, the Agencies have created an IRB Written Procedures Checklist which incorporates HHS and FDA regulatory requirements. The tool was created as part of the Agencies' efforts to harmonize regulatory requirements.
March 1, 2018	Food and Drug Administration (FDA) E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)	https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf	Captures addendum to ICH GCP guidelines including sponsor, investigator, and IRB responsibilities. Also addresses investigator supervision, quality management, and risk-based monitoring.

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March 1, 2018	Food and Drug Administration (FDA)10/25/2018 E18 Genomic Sampling and Management of Genomic Data Guidance for Industry	https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM504556.pdf	Provides harmonized principles of genomic sampling and management of genomic data in clinical studies. Intends to increase awareness and provide a reminder regarding subjects' privacy, protection of the data generated, the need to obtain suitable informed consent, and transparency in reporting findings. Recommends single for genomic samples and data, but as anonymization, as defined in ICH E15, does not allow for subjects to be re-identified as the coding keys have been deleted. Suggests informed consent practices allow for broad use of the samples, such as assay development, disease research, drug response, or pharmacovigilance.
February 21, 2018	Food and Drug Administration (FDA):Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices	https://www.federalregister.gov/documents/2018/02/21/2018-03244/human-subject-protection-acceptance-of-data-from-clinical-investigations-for-medical-devices	FDA submissions and applications that include clinical investigations conducted outside the United States and submitted to support an Investigational Device Exemption (IDE) or device marketing application must provide statements and information regarding how the investigations conform with Good Clinical Practice (GCP) standards. This includes review and approval by an independent ethics committee (IEC) and freely given informed consent of subjects. Investigations conducted in the United States must include a statement regarding compliance with human subject protection, institutional review board (IRB), and IDE regulations.

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January 25, 2018	Food and Drug Administration (FDA) Payment and Reimbursement to Research Subjects - Information Sheet	https://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm	Acknowledges that payment for participation is generally acceptable. Determination of payment for time, inconvenience, discomfort should be just and fair. FDA does not consider reimbursement for travel and associated costs to raise issues regarding undue influence. IRB reviews both payment and proposed method/schedule for consideration of undue influence. Any completion payment should not be so large as to unduly induce subject's continued participation.
Draft Regulation Guidance 2018			
November 15, 2018 *(comments due by March 7, 2019)*	Food and Drug Administration (FDA) Proposed Rule: Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations	https://www.gpo.gov/fdsys/pkg/FR-2018-11-15/pdf/2018-24822.pdf	Proposal to amend regulations to implement section 3024 of the 21st Century Cures Act. This proposed rule, if finalized, would allow an exception from the requirement to obtain informed consent when a clinical investigation poses no more than minimal risk to human subjects and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects and would permit an IRB to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain FDA-regulated minimal risk clinical investigations.
November 7, 2018	Office for Human Research Protections (OHRP) Activities Deemed Not to Be Research: Public Health Surveillance 2018 Requirements	https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-activities-deemed-not-be-research-public-health-surveillance/index.html	Delineates public health surveillance from public health research. The direct link to decision making and action by a public health authority is a hallmark of public health surveillance. In the context of public health surveillance, the collection, management, analysis, and interpretation of surveillance information or biospecimens is designed to inform a public health authority, and generally is followed by public health action or by the dissemination of information to public health programs and others to stimulate public health action. OHRP views surveillance activities that are not undertaken for the purpose of directly informing public health decision making or action generally not to be public health surveillance, even if they might be considered surveillance for other purposes. Guidance provides examples of surveillance activities that OHRP considers NOT to be research under the revised common rule.

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September 20, 2018 (*comments due by November 19, 2018)*	Food and Drug Administration (FDA) Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank	https://www.fdanews.com/ext/resources/files/2018/09-20-18-CivilMoneyPenalties.pdf?1537467154	FDA intends to enforce clinical trial registration and results submission requirements beginning with a warning letter with a 30 day period to comply and avoid civil fines. Priority will be on high-risk trials, noncompliance history or repeat offenders. Civil money penalties may be assessed for (1) failing to submit required clinical trial registration and/or results information to the ClinicalTrials.gov data bank, (2) submitting false or misleading information to the ClinicalTrials.gov data bank, (3) failing to submit the required certification to FDA, or (4) knowingly submitting a false certification to FDA.
August 17, 2018 *(comments due by October 16, 2018)*	National Institutes of Health (NIH) Office of Science Policy (OSP) Recombinant or Synthetic Nucleic Acid Research: Proposed Changes to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)	https://www.gpo.gov/fdsys/pkg/FR-2018-08-17/pdf/2018-17760.pdf	Works to streamline human gene transfer (HGT) clinical research protocols by eliminating redundancies between FDA and NIH review , specifically limiting the scope of the NIH's Recombinant DNA Advisory Committee (RAC). Institutional biosafety committees (IBCs) will still provide oversight in partnership with the IRB; however, research involving recombinant or synthetic nucleic acid will no longer require special review.
August 17, 2018 *(comments due by October 16, 2018)*	National Institutes of Health (NIH) Office of Science Policy (OSP) Recombinant or Synthetic Nucleic Acid Research: Proposed Changes to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)	https://www.gpo.gov/fdsys/pkg/FR-2018-08-17/pdf/2018-17760.pdf	Works to streamline human gene transfer (HGT) clinical research protocols by eliminating redundancies between FDA and NIH review , specifically limiting the scope of the NIH's Recombinant DNA Advisory Committee (RAC). Institutional biosafety committees (IBCs) will still provide oversight in partnership with the IRB; however, research involving recombinant or synthetic nucleic acid will no longer require special review.
August 13, 2018 (*comments due by October 12, 2018)*	Food and Drug Administration (FDA) Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics Guidance for Industry	https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM616325.pdf	Aims to establish an infrastructure to create a more efficient process for drug approvals without compromising safety. Multiple expansion clinical trials assess different aspects of the drug's safety and efficacy with an increase in safety monitoring, and reporting. A central IRB is recommended and the informed consent document must to be updated as the protocol is modified and more information about patient safety is made available.

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July 27, 2018	Food and Drug Administration (FDA) Long Term Follow-up (LTFU) After Administration of Human Gene Therapy Products	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/long-term-follow-after-administration-human-gene-therapy-products	human gene therapy products mediate their effects by transcription or translation of transferred genetic material or by specifically altering host (human) genetic sequences. The products achieve therapeutic effect through permanent or long-acting changes in the human body, there may be an increased risk of delayed adverse events. As a result, subjects in GT trials may be monitored for a “long term follow-up” (LTFU) period lasting as long as 15 years. Guidance provides criteria and a series of questions for determining potential of delayed risks in trials that warrant LTFU.
July 19, 2018	Office for Human Research Protections (OHRP) Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements	https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-scholarly-and-journalistic-activities-deemed-not-to-be-research/index.html	1 of 3 burden reducing provisions available during delay period: Addresses the 2018 Requirements that explicitly clarify that a category consisting of certain scholarly and journalistic undertakings are not included in the definition of "research", and do not fall within the scope of the regulations. This category concerns scholarly and journalistic activities often conducted in various fields that focus directly on the specific individuals about whom information is collected and used, without extending that information to draw generalizations about other individuals or groups.
July 19, 2018	Office for Human Research Protections (OHRP) When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements	https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-when-continuing-review-is-not-required-during-the-6-month-delay-period/index.html	1 of 3 burden reducing provisions available during delay period: During the 6-month delay period, continuing review is not required for studies that are eligible for expedited review in accordance with 45 CFR 46.110 under the pre-2018 Requirements. However, during the delay period, the IRB reviewer(s) will still be required to determine that the research involves no more than minimal risk, and meets current expedited review categories. This guidance only applies during the 6-month delay period.
July 19, 2018	Office for Human Research Protections (OHRP) Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements	https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-elimination-of-irb-review-of-research-applications-and-proposals/index.html	1 of 3 burden reducing provisions available during delay period: Eliminates requirement for grant applications or proposals to undergo IRB review and approval for the purpose of certification. Experience suggests that review and approval of the application or proposal is not a productive use of IRB time. Elimination of that requirement is not expected to reduce protections for human subjects because the research study (e.g. a research protocol) would remain subject to the requirement for IRB review and approval, assuming that an HHS component funds the research.

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June 20, 2018	Food and Drug Administration (FDA) Major Depressive Disorder: Developing Drugs for Treatment	https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM611259.pdf	Guidance for industry regarding trial design for anti-depressant drugs which allows for inclusion of patients with a history of suicidal thoughts or behavior. Encourages broad inclusion with appropriate safety monitoring.
June 13, 2018	Food and Drug Administration (FDA) Humanitarian Device Exemption (HDE) Program	https://www.federalregister.gov/documents/2018/06/13/2018-12633/humanitarian-device-exemption-program-draft-guidance-for-industry-and-food-and-drug-administration	Provides answers to common questions about the HDE program including FDA actions on HDE applications, post-approval requirements, and special considerations for devices marketed under the HDE Program. Explains criteria that the FDA considers when determining if "probable benefit(s)" to health have been demonstrated for a humanitarian use device (HUD)that is being reviewed through the HDE Program. 21st Century Cures increased the population estimate from 4,000 to 8,000 annually.
June 12, 2018	Food and Drug Administration (FDA) Patient-Focused Drug Development: Collecting Comprehensive and Representative Input	https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM610442.pdf	Addresses how stakeholders can collect and submit patient experience data to the product development and regulatory decision making process.
April 9, 2018 (*comments due by 6/8/18)*	Food and Drug Administration (FDA) Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials	https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM603873.pdf	Addresses the complex ethical issue of balancing maternal and fetal safety with need for clinical data on treatments for chronic disease or acute illness during pregnancy. FDA recommends compliance with 45 CFR 46 Subpart B requirements for FDA-regulated clinical research. IRB should include representative capacity for review of research involving pregnant women. The IRB considers risks and benefits from the research itself, (not clinical therapies received independent of the research), and safeguards. Provides guidelines for sponsors (or investigators) in designing trials that minimize risks. When adequate nonclinical studies have been completed; and limits pre-clinical participation to those trials that hold out the prospect of direct benefit to the pregnant woman and/or fetus that is not otherwise available outside the research setting or cannot be obtained by any other means.

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April 30, 2018	Environmental Protection Agency (EPA)Strengthening Transparency in Regulatory Science	https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science	For pivotal research that will contribute to EPA regulatory policy decisions, EPA will ensure that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis. Pivotal regulatory science" is the studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point-of-departure from which a reference value is calculated. In other words, they are critical to the calculation of a final regulatory standard or level, or to the quantified costs, benefits, risks and other impacts on which a final regulation is based.
April 1, 2018	Food and Drug Administration (FDA) Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination	https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM604441.pdf	Describes an optional streamlined submission process for determining whether use of an investigational in vitro diagnostic (IVD) in a clinical trial for an oncology therapeutic is considered significant risk (SR), nonsignificant risk (NSR), or exempt. Applies to trials involving codevelopment of an investigational IVD with an oncology investigational drug.

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Final Regulation/ Guidance 2017			
December 18, 2017	Office for Civil Rights (OCR) 21st Century Cures Act Mandate	https://public3.pagefreezer.com/browse/HHS.gov/31-12-2020T08:51/https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html	Guidance in response to the Cures Act, explains how the HIPAA Privacy Rule applies to research, including when protected health information can be shared without first obtaining authorization from patients. OCR explains that HIPAA-covered entities are always permitted to disclose PHI for research purposes if it has been de-identified in accordance with 45 CFR 164.502(d), and 164.514(a)-(c).If PHI is not de-identified, authorization from patients is required unless the covered entity has obtained Documented Institutional Review Board (IRB) or Privacy Board Approval.
December 8, 2017	Food and Drug Administration (FDA) Software as a Medical Device (SAMD): Clinical Evaluation	https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM524904.pdf	A SaMD (software as a Medical Device) is described as software that utilizes an algorithm (logic, set of rules, or model) that operates on data input (digitized content) to produce an output that is intended for medical purposes. Describes a converged approach for planning the process for clinical evaluation of a SaMD . Considers 1) Valid Clinical Association, 2) Analytical Validation, and 3) Clinical Validation.
December 1, 2017	Food and Drug Administration (FDA) Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue Based Products (HCT/Ps): Minimal Manipulation and Homologous Use	https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM585403.pdf	HCT/Ps are defined in 21 CFR 1271.3(d) as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Guidance provides criteria and a flow chart for determining which HCT/Ps will not require FDA pre-market approval, but will be regulated solely under section 361 of the Public Health Service Act (PHS Act) (e.g., minimally manipulated; homologous use; limited additional agents; no systemic effect; not dependent on metabolic activity of living cells or dependency is for autologous, allogenic, or reproductive use). Guidance provides interpretation of minimal manipulation and homologous use. FDA indicates that it intends to exercise enforcement discretion for the next 36 months with respect to select investigational new drug (IND) applications for certain HCT/Ps.

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December 18, 2017	Food and Drug Administration (FDA) Investigational In Vitro Diagnostics (IVDs) Used in Clinical Investigations of Therapeutic Products	https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM589083.pdf	Provides guidance for In-vitro investigational devices (IVD) used to guide management of subjects in therapeutic product trials. For instance, useof an uncleared or novel device to assess eligibility, assign participants to a treatment arm, select a dose level for a particular group of participants, monitor for side effects. If so, IRB must consider characteristics for studies that are significant risk, non-significant risk, or exempt from Investigational Device Exemption (IDE) requirements.
October 3, 2017	Food and Drug Administration (FDA) Expanded Access to Investigational Drugs for Treatment Use — Questions and Answers	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM351261.pdf	Describes how individual patients under expanded access can now be treated with investigational drugs without getting the full review of the IRB. Physicians/PI now only need the approval of one IRB member to treat individual subjects. Rather than the full IRB review board, only the IRB Chair or an appropriate member is required to grant approval for the use of an investigational drug on an individual patient under expanded access.
September 25, 2017	Food and Drug Administration (FDA) & Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) Minutes of Institutional Review Board Meetings - Draft Guidance for Institutions and IRBs	https://www.hhs.gov/ohrp/ohrp-and-fda-issue-joint-guidance-minutes-irb-meetings.html	Joint guidance issued to assist institutions and IRBs in preparing and maintaining minutes of IRB meetings that meet the regulatory requirements for minutes set forth in FDA and HHS regulations. The guidance also provides general recommendations on the type and amount of information to be included in the minutes.
September 7, 2017	Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html	NIH will now provide Certificates of Confidentiality automatically to any NIH funded recipients that are covered by this policy. This automatic certification applies to research in which identifiable, sensitive information or biospecimens are collected or used. The policy defines identifiable information as any research that the individual's identity is known or could reasonably discovered based on current science and statistical methods. The policy also defines the generation of individual level, human genomic data or the use of such data as being covered regardless of identifiably.

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August 31, 2017	Food and Drug Administration (FDA) Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices	http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM513027.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery	Describes how the FDA determines that real-world data, which are collected from sources outside of traditional clinical trials, may be sufficient for use in premarket and postmarket regulatory decisions. Also clarifies when an Investigational Device Exemption (IDE) may be needed to prospectively collect and use real-world data for purposes of determining the safety and effectiveness of a device. If so, FDA will work with the sponsor to develop the least burdensome approach.
August 11, 2017	National Institutes of Health New Human Subjects and Clinical Trial Information Form	https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm	For application due dates of January 25, 2018, and beyond, grant applicants will be required to use an updated application forms package (FORMS-E), which includes the new human subject and clinical trial form. This form consolidates human subjects, inclusion enrollment, and clinical trial information previously collected across multiple agency forms. The form requests human subject and clinical trials information at the study level using discrete form fields, which is a change from current practice.
July 24, 2017	Food and Drug Administration (FDA) IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects	https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM566948.pdf	The 21st Century Cures Act amended the Federal Food, Drug, and Cosmetic Act to provide authority for FDA to permit an exception from informed consent requirements when the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject. FDA intends to issue regulations to reflect this statutory change. Until FDA issues these regulations, this guidance informs sponsors, investigators, IRBs and other interested parties that FDA does not intend to object to an IRB waiving or altering informed consent requirements for certain minimal risk clinical investigations. In addition, this guidance explains that FDA does not intend to object to a sponsor initiating, or an investigator conducting, a minimal risk clinical investigation for which an IRB waives or alters the informed consent requirements as described in the guidance.

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June 1, 2017	Food and Drug Administration (FDA) Humanitarian Use Devices; 21st Century Cures Act; Technical Amendment	https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-11816.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery	The 21st Century Cures Act became law on December 13, 2016. The Act amends the Food, Drug, and Cosmetic Act (FD&C Act) by removing the requirement for local Institutional Review Board (IRB) review for Investigational Device Exemption (IDE) studies and for the use of Humanitarian Device Exemption (HDE) devices by striking the references to the term "local." This means that medical device investigators, sponsors, and clinical sites can choose to rely on a central IRB rather than an institution's local IRB for these activities. This includes IRB review for multi-site studies.
February 17, 2017	Substance Abuse and Mental Health Services Administration (SAMSHA) 42 CFR Part 2	https://www.gpo.gov/fdsys/pkg/FR-2017-01-18/pdf/2017-00719.pdf Frequently Asked Questions - https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs	Revisions allow the release of patient identifying information to "qualified personnel" to conduct scientific research, if the researcher provides documentation that research meets HIPAA and/or Common Rule requirements. Researches receiving protected information under these provisions are fully bound by the rule, and may include program data in their research reports only in aggregate, non-identifiable form. Includes provisions for researchers holding protected data to obtain linkages to federal and non-federal data repositories that include patient identifying information if the data linkage is reviewed and approved by an IRB.
January 19, 2017	Department for Health and Human Services (DHHS) & 15 Federal Agencies, Federal Policy for the Protection of Human Subjects	https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-protection-of-human-subjects	Revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was originally promulgated as a Common Rule in 1991. This final rule is intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. These revisions are an effort to modernize, simplify, and enhance the current system of oversight.

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January 13, 2017	Food and Drug Administration (FDA) Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions	http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM451440.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery	Provides a framework for benefit-risk assessment for sponsors including hypothetical assessments of examples. Enhances the predictability, consistency and transparency of the IDE review process; Provides a common understanding between the FDA staff and clinical trials sponsors on what information informs the benefit-risk assessment of an IDE submission; and Facilitates the incorporation of evidence and knowledge from different domains—clinical, nonclinical and patient—to support a comprehensive, balanced decision-making approach.

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Draft Regulation Guidance 2017			
December 8, 2017	Food and Drug Administration (FDA) Clinical and Patient Decision Support Software	https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587819.pdf	Excludes select Clinical Decision Support (CDS) software from, the definition of a device, if four criteria are met- 1) Not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system; 2) Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information; 3)Intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and 4)Enables independent review by a clinician, of the basis for treatment recommendations.
December 8, 2017	Food and Drug Administration (FDA) Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act	https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820.pdf	Outlines draft changes that will be made to existing guidance based on the curs act. Includes various software examples and indicates applicable regulatory requirements.
August 31, 2017	Food and Drug Administration (FDA) Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices	http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM513027.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery	Describes how the FDA determines that real-world data, which are collected from sources outside of traditional clinical trials, may be sufficient for use in premarket and postmarket regulatory decisions. Also clarifies when an Investigational Device Exemption (IDE) may be needed to prospectively collect and use real-world data for purposes of determining the safety and effectiveness of a device.
June 20, 2017	Food and Drug Administration (FDA) Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers	https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm563785.pdf	The goals of the draft guidance are to clarify and update reA1:D16commendations for applying and implementing part 11 requirements in the current environment of electronic systems used in clinical investigations and to encourage and facilitates the use of electronic records and systems to improve the quality and efficiency of clinical investigations. Discusses procedures that may be followed to help ensure that electronic records and electronic signatures meet FDA requirements and are considered to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

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Date	**Title**	**Web link**	**Comments**
Final Regulation/ Guidance 2016			
December 15, 2016	Food and Drug Administration (FDA) Use of Electronic Informed Consent in Clinical Investigations Questions and Answers	http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm436811.pdf	Provides guidance when using electronic informed consent (eIC) on site or remotely, questions and answers focus on ensuring protection of subject rights and welfare, enhancing subject comprehension; obtaining E-signatures; maintaining adequate documentation, confidentiality, and archiving; ongoing provision of information, and providing subject copies. Includes considerations for pediatric subjects, IRB responsibilities, allowance for combined consent/HIPAA documents, and FDA expectations for inclusion of eIC materials in research submissions and document availability at inspections.
December 13, 2016	21st Century Cures Act	https://www.congress.gov/114/bills/hr6/BILLS-114hr6rfs.pdf	Impacts research in the US, particularly federally funded projects. Promotes innovation, advancement in biomedical sciences and eliminates barriers and duplicate regulations. Harmonizes Conflict of Interest reporting. Calls for development of FDA guidance on use of real world evidence and alternative ways to conduct post-approval research. Reevaluates OHRP and FDA regulations to allow for FDA waivers of consent for research of no more than minimal risk, assure adequate protections of vulnerable populations, and assure ability of single central IRB review for multicenter studies.
November 9, 2016	INTEGRATED ADDENDUM TO International Conference on Harmonization (ICH) E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2) Step 5 Implementation	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r2-good-clinical-practice-integrated-addendum-ich-e6r1	Aims to encourage sponsors to implement improved oversight and efficient management of clinical trials (e.g., centralized risk-based monitoring), while continuing to ensure protection of human subjects participating in trials and clinical trial data integrity.
September 16, 2016	Department of Health and Human Services (DHHS) National Institutes of Health (NIH) Clinical Trials Registration and Results Information Submission	https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-22129.pdf	Rule expands the legal requirements for submitting registration and results information for clinical trials involving U.S. Food and Drug Administration-regulated drug, biological and device products. Does not apply to phase 1 trials or small feasibility device studies. Applies to public and private sector sponsors and other entities who meet the definition of a responsible party. Rule outlines the timeframe for registration and results submission. Effective date is January 18, 2017

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September 16, 2016	National Institutes of Health (NIH) Policy on the Dissemination of NIH-Funded Clinical Trial Information	https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-22379.pdf	The policy establishes the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH will ensure that these trials are registered at ClinicalTrials.gov, and that results information of these trials is submitted to ClinicalTrials.gov. Includes phase 1 clinical trials and trials that do not involve any FDA regulated product such as trials involving only behavioral interventions. Effective date is January 18, 2017
September 16, 2016	National Institutes of Health (NIH) Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html	Establishes the expectation that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6. Applies to NIH-funded investigators and clinical trial site staff who are responsible for the conduct, management and oversight of NIH-funded clinical trials. This policy is effective as of January 1, 2017
July 27, 2016	Food and Drug Administration (FDA) Adaptive Designs for Medical Device Clinical Studies	http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm446729.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery	Adaptive design allows for planned, anticipated modifications to a clinical study based on accumulating data, while maintaining the trial's integrity and validity. The guidance intends to encourage companies to use adaptive design in an effort to reduce resource requirements and/or increase the chance of study success. Changes to study design based on unblinded outcomes would not be considered adaptive as such modifications could result in invalid or false positive rates. Sponsors are encouraged to clearly articulate the circumstances under which protocol amendments will be submitted to the IRB for review. Pre-specified adaptations should be disclosed to the IRB during the initial approval process.

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June 21, 2016	National Institutes of Health (NIH) National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html	Establishes the expectation that all sites participating in multi-site, human research studies funded by the NIH will use a single Institutional Review Board (sIRB) for review, relative to DHHS IRB regulations. Applies to NIH-Funded, multi-site human research studies conducted at US domestic sites, where each site will conduct the same protocol. The effective date for the policy is May 25, 2017. It will apply to all competing grant applications (new, renewal, revision, or resubmission) with receipt dates on or after May 25, 2017. Ongoing, non-competing awards will not be expected to comply until the grantee submits a competing renewal application. Compliance date extended September 2017.
June 21, 2016	Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html	Delineates between IRB review activities that should be charged as indirect costs (Primary Activities) and those that may be charged as direct costs with appropriate budget justification (Secondary Activities). Includes 12 scenarios to assist investigators in developing budgets and in making decisions whether or not IRB cost can be "direct costs" on the NIH Grant/Contract Application.
June 2, 2016	Food and Drug Administration (FDA) Expanded Access to Investigational Drugs for Treatment Use — Questions and Answers	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM351261.pdf	Finalizes 2009 Guidance in Q & A format. Outlines process for FDA approval of expanded access use (individual, intermediate size population, emergency, and treatment IND). Includes requirements (convened IRB review, informed consent) and timelines for when treatment may begin.
June 2, 2016	Food and Drug Administration (FDA) Individual Patient Expanded Access Applications: Form FDA 3926	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM432717.pdf	Guidance regarding the FDA Form 3926 which is a streamlined alternative for submitting an IND for use in cases of individual patient expanded access, including emergency use. Does not apply to other types of expanded access or device expanded access.
June 2, 2016	Food and Drug Administration (FDA) Charging for Investigational Drugs Under an IND	http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm351264.pdf	Outlines criteria for charging for investigational drugs made available under the expanded access program and specifies cost that may be recovered when charging for an investigational drug under an IND.

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May 23, 2016	National Institutes of Health (NIH) Points to Consider for Institutions and Institutional Review Boards in Submission and Secondary Use of Human Genomic Data under the NIH Genomic Data Sharing (GDS) Policy	https://osp.od.nih.gov/	Details the essential role of Institutional Officials and IRBs in implementing the GDS Policy. Provides guidance regarding development and review of Data Sharing Plans, Institutional Certification which includes IRB review assurance, and points to consider regarding informed consent. Under the GDS Policy, NIH expects explicit consent will have been obtained to use research and clinical specimens and cells lines and strongly encourages investigators seeking consent to include consent for future research use and broad sharing of genomic and phenotypic data generated from such specimens. Further resources are available on the GDS website including links to consent tools from the NIH National Human Genome Research Institute (NHGRI).
April 15, 2016	NIH Guidelines For Research Involving Recombinant or Synthetic Nucleic Acid Molecules	https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf	Streamlines the review process for human gene transfer protocols subject to the NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules. The NIH Recombinant DNA Advisory Committee (RAC) review of individual human gene transfer protocols will be performed only in exceptional cases in which an oversight body (e.g., Institutional Biosafety Committee or IRB) determines RAC review would be significantly beneficial.
April 4, 2016	Food and Drug Administration (FDA) Regulatory amendment on Administrative Actions for IRB Noncompliance	https://federalregister.gov/a/2016-07523	Clarifies that FDA may require the IRB to withhold approval of new FDA-regulated studies, stop the enrollment of new subjects in ongoing studies, and terminate ongoing studies until noncompliance is corrected. Clarifies that it is not FDA taking action on studies directly. Rather, FDA directs the IRB to take such actions until the IRB takes appropriate action to correct the noncompliance. Also, FDA has authority inform other organizations of the IRB noncompliance as needed.
February 11, 2016	NIH Policy on Informed Consent for Human Fetal Tissue Research	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-033.html	NIH expects funded grantees and contractors to comply with all applicable federal, state, and local laws and regulations related to human fetal tissue research. NIH expects grantees and contractors to maintain appropriate documentation, such as an attestation from the health care provider or a third party supplier, that informed consent was obtained at the time of tissue collection.

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Draft or Pending Documents 2016			
August 2, 2016 *(comments due by October 3, 2016)*	Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP) joint guidance "Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs."	http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm512761.pdf	The purpose of this draft guidance is to assist IRB administrators, IRB chairpersons, and other institutional officials responsible for preparing and maintaining written IRB procedures. In order to provide clarification on scope and content of IRB procedures, while taking into account local variation, the Agencies have created an IRB Written Procedures Checklist which incorporates HHS and FDA regulatory requirements. The tool was created as part of the Agencies' efforts to harmonize regulatory requirements.
July 27, 2016 (comments due by October 22, 2016)	Food and Drug Administration (FDA) Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices	http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM513027.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery	Describes how the FDA determines that real-world data, which are collected from sources outside of traditional clinical trials, may be sufficient for use in premarket and postmarket regulatory decisions. Also clarifies when an Investigational Device Exemption (IDE) may be needed to prospectively collect and use real-world data for purposes of determining the safety and effectiveness of a device
June 1, 2016 *(comments due by July 31, 2016*)	Food and Drug Administration (FDA) Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions	http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm504091.pdf	This categorization assists CMS in determining whether or not an IDE device should be covered (reimbursed by CMS). Currently, devices with an approved Investigational Device Exemption (IDE) are categorized into one of two categories by FDA Experimental/Investigational (Category A) devices or Non-experimental/Investigational (Category B) devices based on our understanding of the risks and benefits of the device. The guidance further explains the framework that FDA intends to use to help determine appropriate categorization for an IDE in which the device will be studied

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May 17, 2016 (*comments due by July 18, 2016*)	Food and Drug Administration (FDA) Use of Electronic Health Record Data in Clinical Investigations.	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM501068.pdf	Provides sponsors, investigators, CROs, IRBs, and others recommendations and clarification on use of Electronic Health Records (EHRs)in prospective clinical investigations used by clinical investigators to collect source data in prospective clinical investigations. Sponsors are responsible for assessing the validity, reliability, and integrity of clinical trial source data. EHRs have the advantage of providing study personnel efficient access to real-time data from many sources. Sponsors are encouraged to consider the technical aspects, privacy, and security of EHRs in site qualification. FDA also recommends informing participants regarding the extent of EHR access sponsor or sponsor representatives will have access, as well as associated risks or safeguards in place to protect privacy and confidentiality. Also provides FDA's inspection, recordkeeping, and record retention requirements for EHR data. Does not apply to postmarketing observational pharmacoepidemiologic studies or EHR as a recruitment tool.
May 16, 2016 (comments due by July 15, 2016)	National Science Foundation (NSF) Proposal and Award Policies and Procedures Guide - Draft Guide available for review at https://www.nsf.gov/bfa/dias/policy/papp/pappg17_1/draftpappg_may2016.pdf	https://federalregister.gov/a/2016-11466	Clarifies IRB documentation that NSF must have in order to make an award when proposals involve human subjects. NSF cannot accept any IRB document that qualifies conditions that must be met before human subjects work can be carried out, such as "in concept" or other limited approvals that require continued monitoring of the award activities involving human subjects activities by NSF. For projects lacking definite plans for the use of human subjects pursuant to 45 CFR 690.118, NSF can accept a preliminary approval from an IRB that establishes a limited approval period, requires the PI to submit an amendment or new IRB application prior to the expiration date, and stipulates that no work with human subjects, including recruitment, may be conducted until full IRB approval is obtained.

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March 17, 2016 (*comments due by April 17, 2016*)	National Institutes of Health (NIH) and Food and Drug Administration (FDA) Request for Public Comment on Draft Clinical Trial Protocol Template for Phase 2 and 3 IND/IDE Studies	https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-043.html	The NIH and FDA are developing a template with instructional and sample text for NIH funded investigators to use in writing protocols for phase 2 or 3 clinical trials that require Investigational New Drug application (IND) or Investigational Device Exemption (IDE) applications. The agencies are seeking feedback from investigators, investigator-sponsors, and institutional review board members, etc. regarding the utility and clarity of the instructions and sample text. Based on comments, NIH may consider developing an online, step-by-step protocol template tool to dynamically guide users through steps to write a clinical trial protocol.
March 1, 2016 *(comments due by July 18, 2016)*	Food and Drug Administration (FDA) Draft Guidance for Industry Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat Clostridium difficile Infection Not Responsive to Standard Therapies	http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/UCM488223.pdf	FDA plans to continue to exercise enforcement discretion if Fecal Microbiota for Transplantation (FMT) is used to treat C. difficile infection not responding to other therapies, provided that: A licensed healthcare provider obtains consent; donor and stool are qualified by screening; and FMT product is not obtained from a stool bank. The federal register notice added that FDA wants comments on the requirement for IRB review when the FMT is provided by a stool bank (*https://www.federalregister.gov/articles/2016/03/01/2016-04372/enforcement-policy-regarding-investigational-new-drug-requirements-for-use-of-fecal-microbiota-for*)
January 26, 2016 *(comments due by April 18, 2016)*	International Committee of Medical Journal Editors (ICMJE) Proposed Clinical Trial Data Sharing Requirements	http://www.icmje.org/news-and-editorials/M15-2928-PAP.pdf	The ICMJE is seeking feedback on its proposed requirements for sharing clinical trial data. Data Sharing has implications for informed consent as may be a condition of participation or tracked as a yes/no option. Details are available in the editorial, "Sharing Clinical Trial Data: A Proposal From the International Committee of Medical Journal Editors" at http://icmje.org/news-and-editorials/M15-2928-PAP.pdf.

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Final Regulation/ Guidance 2015			
October 9, 2015	National Human Genome Research Institute (NHGRI) Notice of Plans for NHGRI Implementation of NIH Genomic Data Sharing (GDS) Policy	http://grants.nih.gov/grants/guide/notice-files/NOT-HG-15-038.html	Per the NIH GDS Policy informed consent documents for prospective data collection after January 25, 2015 should state what data types will be shared, for what purposes, and whether sharing will occur through open (unrestricted) or controlled access databases. Research involving samples collected prior to January 25, 2015, NHGRI recognizes that informed consent processes may not have explicitly anticipated future broad data sharing or research use. The NHGRI expectation goes beyond the basic NIH expectation with regard to grandfathered data sources. NHGRI expects that by January 25, 2020, all human data used by NHGRI-funded or -supported research will be generated from specimens or cell lines for which explicit consent for future research use and broad data sharing can be documented.
September 25, 2015	Food and Drug Administration (FDA) Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products	https://www.gpo.gov/fdsys/pkg/FR-2015-09-25/pdf/2015-24313.pdf	According to FDA's Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products, the requirement for an Investigational New Drug (IND) depends on the intended use. If the study is examining a potential therapeutic purpose, then an IND is required. For instance, an IND would be required if the intent of the study was to evaluate a product's effect on smoking cessation or the ability to cure nicotine addiction, prevent relapse, or mitigate withdrawal symptoms. Studies not assessing a therapeutic purpose would not require an IND.
September 24, 2015	United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern	http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf	Purpose of policy is to strengthen ongoing institutional review and oversight of certain life sciences research with high-consequence pathogens and toxins in order to identify potential Dual use research of concern (DURC) and mitigate risks where appropriate. DURC is a subset of dual use research defined as: "life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security."

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July 30, 2015	National Institutes of Health (NIH) Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards): Updated Notice	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-129.html	This notice provides additional clarification related to prior NIH approval of human subjects research plans for awards during the period of support, but for which definitive plans could not be described in the grant application. The guidance outlines the human subjects documentation requirements for delayed onset awards (e.g., awards pending pre-clinical results; multi-project awards with plans to add new protocols; or awards with funding mechanisms to stimulate new research areas or support pilot projects for junior faculty).
July 30, 2015	National Institutes of Health (NIH) Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval: Updated Notice	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-128.html	This notice provides detailed guidance on the types of changes in human subjects research awards that will require prior NIH approval. Changes in research procedures in an active award that would result in an increased risk to human subjects will require prior NIH approval before implementation.
February 9, 2015	Food and Drug Administration (FDA) Mobile Medical Applications (MMA)	http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm263366.pdf	Supersedes September 2013 version. Defines the narrow scope of MMAs that FDA intends to apply oversight authority to which is only those that are an accessory to a regulated device or transform a mobile platform into a regulated device and functionality could pose a risk to a patient's safety if the app were to not function as intended. Research using mobile medical apps involving human subjects may be subject to investigational device exemption (IDE) regulations. Specific examples are provided as guidance and MMA creators are encouraged to engage in early collaboration meetings with FDA to receive recommendations for those that require clinical investigations to support marketing.
February 9, 2015	Food and Drug Administration (FDA) Mobile Medical Applications (MMA)	http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm263366.pdf	Supersedes September 2013 version. Defines the narrow scope of MMAs that FDA intends to apply oversight authority to which is only those that are an accessory to a regulated device or transform a mobile platform into a regulated device and functionality could pose a risk to a patient's safety if the app were to not function as intended. Research using mobile medical apps involving human subjects may be subject to investigational device exemption (IDE) regulations. Specific examples are provided as guidance and MMA creators are encouraged to engage in early collaboration meetings with FDA to receive recommendations for those that require clinical investigations to support marketing.

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February 9, 2015	Food and Drug Administration (FDA) Medical Device Data Systems (MDDS), Medical Image Storage Devices, and Medical Image Communications Devices	http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm401996.pdf	FDA does not intend to enforce compliance with regulatory controls, premarket review, and post-market reporting for MDDS, and devices that display, store, or transmit data or images. FDA does not intend to enforce compliance with regulatory controls for a MDDS that is an in vitro device that is intended for assessing the risk of cardiovascular diseases (21 CFR 880.9(c)(4)) or for use in diabetes management (21 CFR 880.9(c)(5)). FDA does intend to enforce requirements for active patient monitors which are used to make medical decisions, and systems that modify or analyze medical data, and those that control a connected medical device. This scope applies to MMA's as well.

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Date	**Title**	**Web link**	**Comments**
Draft or Pending Documents 2015			
December 17, 2015 (*comments due by February 16, 201* 6)	Food and Drug Administration (FDA) Safety Assessment for Investigational New Drug Application Safety Reporting; Draft Guidance for Industry	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM477584.pdf	Provides recommendations to sponsors on developing a systematic approach to IND safety reporting. Includes the following recommendations to identify and evaluate important safety information that must be submitted to FDA and all participating investigators: (1) The composition and role of a safety assessment committee, (2) aggregate analyses for comparison of adverse event rates across treatment groups, (3) planned unblinding of safety data, (4) reporting thresholds for IND safety reporting, and (5) the development of a safety surveillance plan.
December 4, 2015 (*comments due by February 1, 201* 6)	Food and Drug Administration (FDA) Best Practices for Communication Between IND Sponsors and FDA During Drug Development	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM475586.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery	Jointly published by the drug and biologic branches, this guidance describes best practices and procedures for timely, transparent, and effective communications between investigational new drug (IND) application sponsors and FDA. Includes the types of advice appropriate for sponsors to seek and general expectations for FDA responses.

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November 5, 2015 (*comments due by February 3, 2016*)	Food and Drug Administration (FDA) & Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) Minutes of Institutional Review Board Meetings - Draft Guidance for Institutions and IRBs	http://www.fda.gov/RegulatoryInformation/Guidances/ucm470046.htm	Provides joint guidance regarding the preparation and maintenance of meeting minutes to show attendance; actions; votes; basis for change or disapproval; and controverted issues with resolution. Details documentation of regulatory findings/determinations and review responsibilities either in the minutes or elsewhere in the IRB records with inclusion of protocol-specific information justifying the finding or determination.
October 30, 2015	Food and Drug Administration (FDA) A stay is in effect for parts of subsection VI.D of Investigational New Drug Applications (INDs)-Determining Whether Human Research Studies Can Be Conducted Without an IND [http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf]	https://www.federalregister.gov/articles/2015/10/30/2015-27729/investigational-new-drug-applications-determining-whether-human-research-studies-can-be-conducted	FDA is staying part of the final guidance to allow for further consideration of controversial sections including: Clinical studies designed to evaluate non-nutritional structure-function effects of conventional foods; clinical studies designed to support a health claim for dietary supplements or conventional food; Structure-Function or Disease Related Effects of Live Organisms; and Clinical Studies Designed to Evaluate Structure-Function or Disease Related Effects of Cosmetics. The stay does not apply to clinical investigations intended to evaluate whether a food substance may reduce the risk of a disease in individuals less than 12 months of age, those with altered immune systems, and those with serious or life-threatening medical conditions.
October 29, 2015 (*comments due by December 28, 2015*)	Food and Drug Administration (FDA) Using Technologies and Innovative Methods To Conduct FDA-Regulated Clinical Investigations of Investigational Drugs	https://www.federalregister.gov/articles/2015/10/29/2015-27581/using-technologies-and-innovative-methods-to-conduct-food-and-drug-administration-regulated-clinical?et_rid=49295945&et_cid=78003	Seeks specific input from stakeholders regarding use of new technologies and innovative methods of communication and data collection that may enhance the efficiency and effectiveness of clinical trials. FDA requests feedback on experience with implementation of technology including successes, barriers, and lessons learned.

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Date	**Title**	**Web link**	**Comments**
September 28, 2015	The Food and Drug Administration (FDA) International Conference on Harmonization- E6(R2) Good Clinical Practice Guideline.	https://www.federalregister.gov/articles/2015/09/29/2015-24623/e6r2-good-clinical-practice-international-conference-on-harmonisation-draft-guidance-for-industry	The guideline has been amended in effort to increase efficiency and respond to increased clinical trial complexity and cost, technological advances, electronic records and document standards. Addendum sections are designed to encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording, and reporting while continuing to ensure human subject protection and data integrity.
September 8, 2015 *(comments due by January 7, 2016)*	Health and Human Services (HHS) Notice Of Proposed Rulemaking (NPRM) Federal Policy for the Protection of Human Subjects	https://www.federalregister.gov/articles/2015/09/08/2015-21756/federal-policy-for-the-protection-of-human-subjects	The goals of the NPRM are to increase human subjects' ability and opportunity to make informed decisions; reduce potential for harm and increase justice by increasing the uniformity of human subject protections in areas such as information disclosure risk, coverage of clinical trials, and coverage of IRBs; and facilitate current and evolving types of research that offer promising approaches to treating and preventing medical and societal problems through reduced ambiguity in interpretation of the regulations, increased efficiencies in the performance of the review system, and reduced burdens on researchers that do not appear to provide commensurate protections to human subjects.
July 23, 2015	National Institutes of Health (NIH) Preliminary Guidance Related to Informed Consent for Research on Dried Blood Spots Obtained Through Newborn Screening - See more at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-127.html#sthash.DUumKRBc.dpuf	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-127.html	Describes implications of legislation on NIH-funded research involving newborn dried blood spots. Such research using specimens collected on or after 3/18/15 will require IRB approval under HHS 45 CFR 46 and parental permission. Waiver of parental permission is not permitted under this legislation. Non-identifiable newborn dried blood spots collected prior to 3/18/15, may continue to be used without parental permission as this activity would continue to be considered research that does not involve human subjects under the current hhs regulations. Research funded by state and private entities is not subject to these provisions of the law.

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Date	**Title**	**Web link**	**Comments**
6/18/2015 *(comments due by September 16th, 2015)*	Food & Drug Administration (FDA) Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (IDE)	http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM451440.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery	Guidance for FDA staff, sponsors, and sponsor-investigators which explains the framework for FDA's assessment of benefits and risks, (including risk control and mitigation measures), which impacts the IDE decision. Framework facilitates the incorporation of evidence and knowledge from different domains—clinical, nonclinical and patient—to support a comprehensive, balanced decision-making approach. Provides examples of design features and protective measures that may be applied to IDE studies. Provides hypothetical examples of benefit-risk assessments.
5/29/15 (*comments due by July 30, 2015*)	Food and Drug Administration (FDA) Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM446695.pdf	Provides guidance to sponsor-investigators in preparing and submitting complete IND applications. Describes seeking a cross-reference authorization to reference sections of a commercial sponsor's IND. Outlines required portions of Chemistry, Manufacturing, and Control (CMC) information as well as requests for waiver for complete CMC when not available. Describes pharmacology and toxicology data needed for various study types. Previous human experience includes reference list, copies of literature and a consolidated assessment of available information. Provides a flow chart of the IND review process including attempts to resolve any deficiencies prior to issuing a clinical hold. Also addresses IND amendments, import-export requirements, and sponsor-investigator responsibilities.
3/6/2015 (*comments due by May 8th, 2015*)	Food and Drug Administration (FDA) Use of Electronic Informed Consent in Clinical Investigations Questions and Answers	http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm436811.pdf	Provides guidance when using electronic informed consent (eIC) on site or remotely, questions and answers focus on ensuring protection of subject rights and welfare, enhancing subject comprehension; obtaining E-signatures; maintaining adequate documentation, confidentiality, and archiving; ongoing provision of information, and providing subject copies. Includes considerations for pediatric subjects, IRB responsibilities, allowance for combined consent/HIPAA documents, and FDA expectations for inclusion of eIC materials in research submissions and document availability at inspections.

University of Kentucky Office of Research Integrity Select Changes at the Federal Level Impacting Human Research			
Date	**Title**	**Web link**	**Comments**
3/6/2015 (comments due by May 7th, 2015)	Office for Human Research Protections (OHRP) Draft Guidance for Industry, Clinical Investigators, and Institutional Review Boards—Use of an Electronic Informed Consent in Clinical Investigations—Questions and Answers	http://www.gpo.gov/fdsys/pkg/FR-2015-03-09/pdf/2015-05301.pdf	OHRP is considering whether to adopt the positions and recommendations proposed in the FDA Use of Electronic Informed Consent In Clinical Investigations guidance for research regulated under the HHS protection of human subjects regulations, 45 CFR part 46, and to issue a joint OHRP and FDA guidance document on this topic when the final guidance document is developed. OHRP requests comments to determine if OHRP guidance should differ or if FDA guidance is appropriate for social, behavioral, and other non-FDA regulated research.
Final Regulation/ Guidance 2014			
December 18, 2014	Newborn Screening Saves Lives Reauthorization Act	https://www.congress.gov/bill/113th-congress/house-bill/1281	The law includes two significant changes to the human subjects regulations as they apply to research with newborn dried blood spots. First, the law requires that all research funded pursuant to the Public Health Service Act using newborn dried spots be considered human subjects research regardless of whether the specimens are identifiable. Second, the law eliminates the ability of the IRB to waive informed consent under 45 CFR 46.116(c) and 116(d) for research involving newborn dried blood spots. According to OHRP, this law applies only to HHS-funded research that specifically involves the use of newborn dried blood spots and not to research funded by other entities that is conducted at institutions that have extended their FWA to cover all research, regardless of funding.
October 23, 2014	National Institutes of Health -Notice of Revised NIH Definition of “Clinical Trial”	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html	New definition of a clinical trial is -A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. - The revised definition is designed to make the distinction between clinical trials and clinical research studies which is a broad category including epidemiological and outcomes research. It is not intended to expand the scope of the category of clinical trials. Effective date January 25, 2015. Additional information, case studies, and question & answers are available at http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials

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Date	**Title**	**Web link**	**Comments**
August 27, 2014	National Institutes of Health NIH Genomic Data Sharing Policy (effective date January 25, 2015)	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html	Sets forth expectations that ensure the broad and responsible sharing of genomic research data. IRB reviews protocols for collection of genomic and phenotypic data to ensure sharing is consistent with the informed consent from whom the data were obtained; risks to individuals, families, groups, and populations associated with data are considered, and investigator's plan for de-identifying datasets is consistent with standards outlined in the policy. For studies initiated after effective date, NIH expects informed consent process and document to state participant's genomic and phenotypic data may be shared broadly for future research and explain whether it will be shared through open or closed access. For studies proposing to use cell lines or clinical specimens, NIH expects that informed consent for future research use and broad data sharing will have been obtained even if the cell lines or clinical specimens are de-identified.
August 19, 2014	Food and Drug Administration (FDA) FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations	http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279107.pdf	Finalizes June 2013 draft guidance. Describes three actions on IDE applications: 1. Approved 2. Approval with Conditions 3. Disapproved. In the case of approval with conditions, approval is granted and the study may be initiated upon IRB approval on the condition that, within 45 days the sponsor submits information addressing the issues identified in FDA's decision letter. Also describes process of "staged approval' or "staged approval with conditions" which permits a portion of the planned study to commence while outstanding issues are addressed (i.e., approve enrollment of first cohort of subjects to confirm safety profile before permitting testing of entire subject cohort). Includes process and examples of FDA's voluntary Pre-Decisional IDE review process allowing sponsors to obtain timely feedback from FDA review staff on a near-final IDE application.
June 20, 2014	Food and Drug Administration (FDA) Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices	http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072688.pdf	Supersedes 2003 guidance. Applies to narrow scope of MRI investigations. Provides operating conditions such as specific absorption rate (SAR) levels that FDA may consider as meeting the regulatory definition of Significant Risk (SR) device study.

University of Kentucky Office of Research Integrity Select Changes at the Federal Level Impacting Human Research			
Date	**Title**	**Web link**	**Comments**
May 22, 2014	Food and Drug Administration (FDA) Guidance for IRBs, Clinical Investigators, and Sponsors Considerations When Transferring Clinical Investigation Oversight to Another IRB	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM307779.pdf	Presents responsibilities of institutional review boards (IRBs), clinical investigators, and sponsors when oversight of a previously approved, ongoing clinical investigation under FDA's jurisdiction is transferred from one IRB to another IRB. Outlines an eight step process for transferring oversight to another IRB. Change from 2012 draft notes IRBs are to notify the sponsor of any decisions to suspend or terminate study approval and recommends use of a letter to provide currently enrolled subjects with changes in contact information (e.g., for reporting injuries, complaints, subject rights, etc.).
February 20, 2014	U.S. Department of Health and Human Services (HHS) HIPAA Guidance on Sharing Information Related to Mental Health	http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/mhguidance.html	FAQs about when it is appropriate under for a health care provider to share the protected health information of a patient who is being treated for a mental health condition. Clarifies when HIPAA permits providers to: communicate with a patient's family members, friends, or others depending on whether the patient is an adult or a minor; and capacity to agree or object. Clarifies how providers may communicate with family members, law enforcement, or others when the patient presents a serious and imminent threat of harm to themselves or others. Presents heightened protections afforded to psychotherapy notes by the Privacy Rule, a parent's right to access the protected health information of a minor, the potential applicability of Federal alcohol and drug abuse confidentiality regulations or state laws that may provide more stringent protections than HIPAA, and the intersection of HIPAA and FERPA in a school setting.
February 18, 2014	Food and Drug Administration (FDA) Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff	http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery	In addition to guidance on pre-submissions for marketing applications, the guidance provides instructions on submitting a Pre-Sub for SR, NSR, or Exempt from IDE determinations and Pre-Sub for an IDE application. Includes examples of questions that are and are not conducive to productive discussion. Pre-Sub timeframe is 75-90 days.

University of Kentucky Office of Research Integrity Select Changes at the Federal Level Impacting Human Research			
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February 3, 2014	Department of Health and Human Services (DHHS) CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports Jointly released by Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the Office for Civil Rights (OCR)	https://www.federalregister.gov/documents/2014/02/06/2014-02280/clia-program-and-hipaa-privacy-rule-patients-access-to-test-reports	Strengthens patients' right to access lab tests. Amends the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to allow laboratories to give a patient, or a person designated by the patient, his or her "personal representative," access to the patient's completed test reports on the patient's or patient's personal representative's request. At the same time, the final rule eliminates the exception under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to an individual's right to access his or her protected health information when it is held by a CLIA-certified or CLIA-exempt laboratory. While patients can continue to get access to their laboratory test reports from their doctors, these changes give patients a new option to obtain their test reports directly from the laboratory.

University of Kentucky Office of Research Integrity Select Changes at the Federal Level Impacting Human Research			
Date	**Title**	**Web link**	**Comments**
Draft or Pending Documents 2014			
December 3, 2014	National Institutes of Health (NIH) Request for Comments on the Draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-026.html	Proposes that NIH funded institutions will be expected to use a single IRB of record for domestic sites of multi-site studies unless there is justification for an exception if local IRB review is needed to meet the needs of specific populations or where it is required by federal, state or tribal laws or regulations. Advises handling local contextual issues relevant to most studies through mechanisms other than local IRB review, such as the involvement of ad hoc members or consultants with the necessary specialized knowledge or expertise or by submission of information by the individual site(s). Calls for IRB Authorization Agreements to document the delegation of responsibilities.
November 19, 2014	Department of Health and Human Services and the National Institutes of Health (NIH) Notice of Proposed Rulemaking (NPRM) for Clinical Trials Registration and Results Submission under FDAAA	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-018.html (comment re NPRM at www.regulations.gov docket number NIH-2011-0003)	NPRM describes proposed interpretations of, and in some cases modifications to, requirements and practices for submitting registration and results information to ClinicalTrials.gov. Proposes an approach for determining which trials are subject to rule and adds required data elements. Applicable clinical trials include controlled, intervention studies of drugs, biologics, and devices (excluding phase 1 studies of drugs/biologics and feasibility studies of devices). Proposes to require submission of summary results for applicable clinical trials regardless of whether the product is approved or cleared for marketing. Input is requested regarding format (technical or non-technical) and other requirements for result summaries to assist in interpreting result information. Full summary available at http://www.nih.gov/news/health/nov2014/od-19_summary.htm
November 19, 2014	National Institutes of Health (NIH) Draft NIH Policy on Dissemination of NIH-Funded Clinical Trial Information	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-019.html (comment on proposed NIH policy vie email at clinicaltrials.disseminationpolicy@mail.nih.gov)	Released in conjunction with NPRM above is a draft NIH policy that would apply to all NIH-funded awardees and investigators conducting clinical trials, funded in whole or in part by NIH, regardless of study phase, type of intervention, or whether they are subject to the rules proposed in the NPRM. Proposed scope includes NIH funded phase 1 trials of drugs and biological products, small feasibility studies of devices, and clinical trials of behavioral, surgical, and other types of health and medical interventions. Full summary available at http://www.nih.gov/news/health/nov2014/od-19_summary.htm

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Date	**Title**	**Web link**	**Comments**
October 24, 2014 (comments due by December 23, 2014)	Office for Human Research Protections (OHRP), Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care	http://www.hhs.gov/ohrp/newsroom/rfc/comstdofcare.html	The draft guidance explains how to apply 45 CFR Part 46 to studies that are designed to evaluate one or more standards of care. It discusses whether risks are considered risks of research when one of the purposes of the research is the evaluation or comparison of risks associated with standards of care. It also discusses disclosing certain reasonably foreseeable risks to prospective subjects when seeking their informed consent to participate in such research activities. It explains OHRP's position that in general the reasonably foreseeable risks of research in a study include the already identified risks of the standards of care being evaluated as a purpose of the research when the risks being evaluated are different from the risks some of the subjects would be exposed to outside of the study. Reasonably foreseeable risks must be described to prospective subjects when seeking their informed consent in accordance with 45 CFR 46.116(a)(2). The draft guidance addresses the following topics: 1. What are "standards of care"? 2. What are "risks of research" in studies evaluating risks associated with standards of care?
7/15/2014 (comments due by September 15, 2014)	Food and Drug Administration (FDA) Informed Consent Information Sheet - Guidance for IRBs, Clinical Investigators, and Sponsors	http://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery#about	Draft guidance provides FDA's expectations regarding informed consent process. Includes suggestions for enhancing the process without lengthening the form. Includes examples to illustrate concepts such as undue influence, coercion, and exculpatory language. Provides expectations regarding documentation and interpretation of required informed consent elements. Addresses when inclusion of risks and benefits of alternatives may be appropriate. Addresses language issues, delegation, alternative methods of obtaining consent, special populations and other considerations.
March 18, 2014 (comments due by June 19, 2014)	Food and Drug Administration (FDA) Humanitarian Device Exemption (HDE): Questions and Answers - Draft Guidance for HDE Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm389154.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery#role	Draft guidance answers common questions regarding Humanitarian Use Devices and HDEs. Reflects changes in HDE program resulting from Food and Drug Administration Safety and Innovation Act (FDASIA) relative to eligibility criteria to be sold for profit. Many of the FAQs relative to IRB review and approval are duplicated from the July 8, 2010 FDA HDE FAQ.

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Date	**Title**	**Web link**	**Comments**
February 6, 2014 (*comments due 4/7/14*)	Food and Drug Administration (FDA) Reopening of Comment Period for Guidance on Investigational New Drug Applications-Determining Whether Human Research Studies can be Conducted Without an IND Application	https://www.federalregister.gov/articles/2014/02/06/2014-02550/guidance-for-clinical-investigators-sponsors-and-institutional-review-boards-on-investigational-new	Following publication of the September 10, 2013, FDA reopening for applicability of the IND regulations to clinical research studies involving cosmetics and foods (including dietary supplements). This action was in response to requests for more time to review the guidance and consider its effect on researchers and health care providers, among others.

University of Kentucky Office of Research Integrity Select Changes at the Federal Level Impacting Human Research			
Date	**Title**	**Web link**	**Comments**
Final Regulation/Guidance 2013			
December 12, 2013	Presidential Commission for the Study of Bioethical Issues Recommendations on Incidental Findings: Anticipate and Communicate	https://bioethicsarchive.georgetown.edu/pcsbi/node/3567.html	Includes five broad recommendations. 1. Informing recipients regarding the possibility of and the plan for disclosure of incidental or secondary findings. 2. Call for diagnostic evidence-based practice guidelines from professional groups . 3. Call for federal support of empirical research on incidental and secondary findings. 4. Public education of all stakeholders regarding ethical, practical, and legal considerations. 5. Equal access to guidance to make informed choices regarding how to respond to and care for findings.
October 19, 2013	World Medical Association Declaration of Helsinki (DOH)	https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm513027.pdf	Seventh revision addresses compensation and treatment for subjects harmed as a result of research participation; obligations in regard to publication and dissemination of research results; states medical research only justified in vulnerable groups when benefits group and cannot be carried out in a non-vulnerable group; calls for registration of every human research study in a publicly accessible database prior to recruitment.
October 1, 2013	Food and Drug Administration (FDA) Draft Guidance for Industry and Food and Drug Administration Staff - Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies	http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279103.pdf	Provides industry and clinical innovators with guidance regarding IDE applications for early feasibility studies of significant risk devices including proof in principle, first in human, basic functionality, and initial clinical safety. IRB oversight may require more frequent continuation review.

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September 25, 2013	Food and Drug Administration (FDA) Mobile Medical Applications	http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf	SUPERSEDED by March 2015 version. Finalizes 2011 guidance outlining mobile applications that meet the definition of device, (used as an accessory to a regulated medical device or to transform a mobile platform (e.g., smart phone, tablet, computer), into a regulated medical device. FDA intends to apply oversight authority to only those mobile apps whose functionality could pose a risk to a patient's safety if the app were to not function as intended. Research using mobile medical apps involving human subjects may be subject to investigational device exemption (IDE) regulations. Mobile medical app creators are encouraged to engage in early collaboration meetings with FDA to receive recommendations for testing and development of devices requiring clinical investigations to support marketing.
September 23, 2013	Office for Human Research Protection (OHRP) FAQ "When does compensating subjects undermine informed consent or parental permission?"	http://www.hhs.gov/ohrp/policy/consentfaqsmar2011.pdf	FAQ revised to remove sentences that reference the IRB's view of remuneration as FAQ is designed to focus on potential undue influence in the consent process. OHRP continues to assert that IRBs should not consider remuneration as a way of offsetting risk however that subject does not fit within context of this informed consent FAQ. Remuneration to subjects may include compensation for risks associated with their participation in research and that compensation may be an acceptable motive for agreeing to participate in research. IRBs may need to request a plan from the investigator, for monitoring subject recruitment to ensure that such inducements do not result in inequitable subject recruitment (e.g., recruiting only economically disadvantaged individuals).
September 17, 2013	Food and Drug Administration (FDA) Final Electronic Source Data in Clinical Trials Guidance	http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm328691.pdf	Addresses source data used to fill predefined fields in electronic case report forms (eCRF). Discusses identification of authorized source data originators (person, equipment, system), data element identifiers to facilitate inspections, manual and electronic source data capture, investigator responsibilities for review and retention of e data, and use of computerized systems in clinical investigations. Includes instructions for modifications and corrections as well as use of electronic prompts, flags, and data quality checks in the eCRF. Outlines expectations regarding retention of e records. Includes a glossary of terms.

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September 10, 2013	Food and Drug Administration (FDA) Investigational New Drug Applications (INDs)-Determining Whether Human Research Studies Can Be Conducted Without an IND	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf	Final represents FDA's current thinking regarding when an Investigational New Drug (IND) application is needed. Includes information on (1) clinical investigations using marketed drugs, (2) bioequivalence/ bioavailability studies, (3) studies using radio labeled or cold isotopes, (4) studies using dietary supplements, foods, cosmetics (5) studies using endogenous compounds, (6) pathogenesis studies using modified organisms, (7) studies using wild-type organisms in challenge models, and (8) studies that do not have a commercial purpose. Also provides information on IND exempt studies and a process for seeking advice from FDA.
August 27, 2013	Food and Drug Administration (FDA) IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM328855.pdf	Finalizes draft guidance issued November 2012. Clarifies that IRBs, sponsors, and clinical investigators all have responsibility for ensuring research complies with applicable regulations and risks to subjects are minimized. Reminds IRB of long-standing role in assessment of 1) the qualifications of the clinical investigator, 2) the adequacy of the facility in which the research will take place, and 3) whether an investigational new drug application (IND) or investigational device exemption (IDE) application is necessary for the proposed clinical investigation. Clarifies that that role may be fulfilled by local or central IRB.
August 8, 2013	Food and Drug Administration (FDA) Guidance for Industry: Oversight of Clinical Investigations- A Risk-Based Approach to Monitoring	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf?source=govdelivery	Finalizes draft guidance from August 2011 with a goal to enhance human subject protection and the quality of clinical trial data by focusing sponsor oversight on the most important aspects of study conduct and reporting. The guidance describes strategies for monitoring activities that reflect a modern, risk-based approach that focuses on critical study parameters and relies on a combination of monitoring activities to oversee a study effectively. The guidance specifically encourages greater use of centralized monitoring methods where appropriate.

University of Kentucky Office of Research Integrity Select Changes at the Federal Level Impacting Human Research			
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April 1, 2013	Food and Drug Administration (FDA) Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors on Exception from Informed Consent Requirements for Emergency Research	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM249673.pdf	Clarification updates to guidance finalized March 2011 - In Question #18, the phrase "unless a waiver from FDA is prospectively applied for and granted" was deleted. FDA made this change to clarify that there are no waiver provisions applicable for 21 CFR 50.24. In Section XI and various other places, FDA made minor changes to clarify the provision regarding the "establishment" of an independent data safety monitoring committee (DMC). FDA interprets this regulatory provision to permit a sponsor to either establish an independent DMC or to secure the services of an already established DMC to exercise oversight of the clinical investigation. FDA is making this clarification to provide flexibility to sponsors in meeting the regulatory requirements.
February 26, 2013	Food and Drug Administration (FDA) Additional Safeguards for Children in Clinical Investigations of Food and Drug Administration-Regulated Products	http://www.gpo.gov/fdsys/pkg/FR-2013-02-26/pdf/2013-04387.pdf	Finalizes 2001 interim rule. Effective March 28, 2013. Adopts safeguards described in HHS subpart D. Four changes to final rule are: (1) The definition of guardian has been modified, (2) the definition of permission has been modified, (3) paragraph (a) has been added to § 50.51 to require, consistent with § 46.404 of HHS subpart D, that IRBs assess the level of risk to children in clinical investigations subject to § 50.51, and (4) a phrase has been added to § 50.55(e) to make it clear that the exception for emergency research described in § 50.24 applies to research in children. Concludes that while investigational arm of a study may be considered to have direct benefit, the placebo arm does not meet the requirements of direct benefit if poses risks that are more than minimal.
February 26, 2013	Food and Drug Administration (FDA) Guidance for Clinical Investigators, Industry, and FDA Staff Financial Disclosure by clinical Investigators	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf?source=govdelivery	Final guidance outlines FDA's expectation for submission of financial disclosure of clinical investigators and those who are full or part time employees of the sponsor including any steps taken to minimize potential for bias. Requirement applies to covered clinical studies which includes most clinical trials with the exception of Phase I and expanded access. Guidance includes FAQs.

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February 14, 2013	Environmental Protection Agency (EPA) Protections for Subjects in Human Research Involving Pesticides	http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2010-0785-0037	Final amendment strengthens existing standards for human research involving pesticides submitted to EPA by third parties. Broadens the scope and applicability of the rule, further strengthening the standards for research to be considered in EPA decisions; clarifying the approach used in the EPA's science and ethics reviews of human research involving pesticides; and formally disallowing participation in testing by subjects who cannot consent for themselves.
January 17, 2013	Department of Health and Human Services (DHHS) Modifications to the HIPAA Privacy	https://s3.amazonaws.com/public-inspection.federalregister.gov/2013-01073.pdf	Modifies Privacy, Security, and Enforcement rules consistent with the Health Information Technology for Economic and Clinical Health (HITECH) Act and Genetic Information

University of Kentucky Office of Research Integrity Select Changes at the Federal Level Impacting Human Research			
Date	**Title**	**Web link**	**Comments**
Draft or Pending Documents 2013			
September 27, 2013	National Institutes of Health (NIH) Draft NIH Genomic Data Sharing (GDS) Policy	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-119.html	Draft policy apples to NIH-funded research involving large-scale human genomic data produced by array-based or high-throughput genomic technology and gene expression data, irrespective of funding source. Recommends researchers and institutions submitting large-scale genomic datasets to NIH-designated data repositories consider a Certificate of Confidentiality. Includes considerations for IRB review and informed consent including a tiered system of open-access and controlled-access data access mechanism; secondary research; and individual, family, and population risks. Provides guidance on other expectations for data submission and data release.
June 17, 2013	Food and Drug Administration (FDA) Important Information about IND Requirements for Use of Fecal Microbiota to Treat Clostridium difficile Infection Not Responsive to Standard Therapies	http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm357258.htm	Acknowledges concerns expressed regarding FDA requirement for IND submission for use of fecal Microbiota to treat Clostridium difficile infection not responsive to standard therapies. FDA intends to exercise enforcement discretion while the agency develops appropriate policies. However, compliance with IND regulations is strongly encouraged. Minimum expectations include informed consent stating that use of fecal products to treat C. difficile is investigational and including a discussion of potential risks.
March 12, 2013	DHHS Secretary's Advisory Committee on Human Research Protection Considerations and Recommendations Concerning Internet Research and Human Subjects Research Regulations	http://www.hhs.gov/ohrp/sachrp/mtgings/2013%20March%20Mtg/internet_research.pdf	Provides FAQs and review points to consider in the review and conduct of internet research. Addresses technical issues, scientific design, subject identity, consent comprehension and verification of data integrity.

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Date	**Title**	**Web link**	**Comments**
4/30/2013 *(comments due 06/24/2013)*	Food and Drug Administration (FDA) Agency Information Collection Activities; Proposed Collection; Comment Request; Protection of Human Subjects: Informed Consent; Institutional Review Boards	https://www.federalregister.gov/articles/2013/04/24/2013-09622/agency-information-collection-activities-proposed-collection-comment-request-protection-of-human	With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.
Final Regulation/ Guidance 2012			
December 19, 2012	Food and Drug Administration (FDA) Guidance for Industry and Investigators Safety Reporting Requirements for INDs and BA/BE Studies	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM227351.pdf?source=govdelivery	Provides guidance regarding FDA expectations for expedited safety reporting for drugs/biologics being investigated under an IND and bioavailability (BA)/bioequivalence (BE) studies conducted under an IND and BA/BE studies that are deemed IND exempt.
December 19, 2012	Food and Drug Administration (FDA) Guidance for Industry and Investigators Safety Reporting Requirements for INDs and BA/BE Studies-Small Entity Compliance Guide	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM332846.pdf?source=govdelivery	Complements IND and BA/BE safety reporting guidance. Provides answers to frequently asked questions applicable to sponsor-investigators.
August 2, 2012	National Institutes of Health (NIH) Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards): Notice Number: NOT-OD-12-130	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-130.html	Clarifies NIH requirements related to prior NIH approval of human subjects research plans for awards which were submitted with the intent to conduct human subjects research during the period of support, but for which definitive plans could not be described in the grant application.

University of Kentucky Office of Research Integrity Select Changes at the Federal Level Impacting Human Research			
Date	**Title**	**Web link**	**Comments**
August 2, 2012	National Institutes of Health (NIH) Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval NOT-OD-12-129	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-129.html	Provides detailed guidance on the types of changes in human subjects research awards that will require prior NIH approval and provides information on the process for submission of such requests. Focus on changes that may involve increased risks including change in study design, new vulnerable subject population, increased risk procedure, or other new information impacting risks.
May 30, 2012	Food and Drug Administration (FDA) Final Rule on Disqualification of a Clinical Investigator	http://www.gpo.gov/fdsys/pkg/FR-2012-04-30/pdf/2012-10292.pdf?source=govdelivery	Finalizes draft guidance released April 2011. Final rule expands the scope of clinical investigator disqualification. The Commissioner of Food and Drugs determines that an investigator is ineligible to receive one kind of test article (drugs, devices or new animal drugs), the investigator also will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for other kinds of products regulated by FDA. FDA also is amending the list of regulatory provisions under which an informal regulatory hearing is available by adding and changing the scope of certain provisions.
February 1, 2012	Food and Drug Administration (FDA) IRB Continuing Review after Clinical Investigation Approval	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf?source=govdelivery	Developed with OHRP to harmonize regulatory requirements, this provides guidance to institutional review boards (IRBs) in carrying out their continuing review responsibility under 21 CFR 56.108(a) and 56.109(f) by providing recommendations regarding the criteria, process, and frequency of continuing review to assure the protection of the rights and welfare of human subjects enrolled in clinical investigations.
February 9, 2012	Food and Drug Administration (FDA) Questions and Answers on Informed Consent Elements	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf	Guidance is intended to help sponsors, investigators and Institutional Review Boards better understand and implement the new informed consent requirement set forth in 21 CFR 50.25(c) for applicable clinical trials. Applicable clinical trials initiated on or after March 7, 2012, must be in compliance with the new requirement and include the new statement in all informed consent documents.
Draft or Pending Documents 2012			
Date	Title	Web link	**Comments**

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November 20, 2012 (*comments due January 22, 2013)*	Food and Drug Administration (FDA) IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM328855.pdf	Intended to remind IRBs of their longstanding role in the review of 1) the qualifications of the clinical investigator, 2) the adequacy of the facility in which the research will take place, and 3) the determination of whether an investigational new drug application (IND) or investigational device exemption (IDE) application is necessary for the proposed clinical investigation.
November 20, 2012 (*comments due February 22, 2013)*	Food and Drug Administration (FDA) Electronic Source Data in Clinical Investigations	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf	This draft guidance document provides recommendations to sponsors, Contract Research Organizations (CROs), data management centers, clinical investigators, and others involved in capturing, reviewing, and archiving electronic source data in FDA-regulated clinical investigations. This draft guidance document promotes capturing source data in electronic form, and it is intended to assist in ensuring the reliability, quality, integrity, and traceability of electronic source data.
August 14, 2012 *(comments due within 60 days of publication)*	Food and Drug Administration (FDA) Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials	http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm315156.htm	The purpose of this guidance is to assist sponsors in prospectively assessing the occurrence of treatment-emergent suicidal ideation and behavior in clinical trials of drug and biological products. Applies to clinical trials conducted under investigational new drug applications, or trials that are intended for submission in a new drug application or a biologics license application. Addresses concerns regarding burden and value of assessments and provides advice on evaluation of alternative instruments.

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Date	**Title**	**Web link**	**Comments**
June 12, 2012 *(comments due August 13, 2012)*	Food and Drug Administration (FDA) Guidance for IRBs, Clinical Investigators, and Sponsors, Considerations When Transferring Clinical Investigation Oversight to Another IRB	http://www.gpo.gov/fdsys/pkg/FR-2012-06-12/pdf/2012-14295.pdf	Simultaneously released with OHRP guidance below, this document discusses regulatory responsibilities of institutional review boards (IRBs), clinical investigators, and sponsors when oversight of a previously approved clinical investigation under FDA's jurisdiction is transferred from one IRB to another IRB. This guidance also addresses questions that have been previously raised concerning procedures and processes that are required and/or recommended by FDA when such oversight is transferred.
June 12, 2012 *(comments due August 13, 2012)*	Office for Human Research Protections (OHRP) Considerations in Transferring a Previously-Approved Research Project to a New IRB or Research Institution	http://www.gpo.gov/fdsys/pkg/FR-2012-06-12/html/2012-14287.htm	Draft guidance presents common scenarios for transfer of a previously-approved research project to another institutional review board (IRB) or to a new engaged research institution, and outlines the administrative actions to be considered by IRBs, engaged institution(s), and investigators. In particular, the guidance addresses the following questions: 1. What is the regulatory background for research project transfer? 2. What actions may apply when the research project remains at the same institution, but responsibility for IRB review is transferred either from an internal to an external IRB, or from an external IRB to another external IRB ? 3. What actions may apply when the research project remains at the same institution, but responsibility for IRB review is transferred from one internal to another internal IRB? 4. What actions may apply when the research project is transferred to a new engaged institution?
February 14, 2012	Food and Drug Administration (FDA) Investigational New Drug Applications for Positron Emission Tomography (PET) Drugs	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291573.pdf	Draft guidance differentiates regulatory and IND expectations between clinical use and investigational use of PET drugs. Research Use refers to administration of Pet drugs to human subjects typically under a Radioactive Drug Research Committee (RDRC). Guidance covers when an IND is needed for a PET drug, Expanded Access for Clinical Use of certain Pet Drugs and charging considerations.

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Final Regulation/ Guidance 2011			
Date	Title	Web link	**Comments**
November 8, 2011	Department of Defense (DoD) Instruction 3216.02 Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research	http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf	Outlines DoD policy relative to research involving human subjects conducted or supported by the DoD; additional protections afforded vulnerable populations; general prohibition on testing for chemical or biological warfare agents; human subject definition; compliance with foreign country requirements; and responsibilities.
September 22, 2011	Office for Human Research Protection (OHRP) Correspondence on "Non-engaged" Scenarios	http://www.hhs.gov/ohrp/policy/Correspondence/index.html	Outlines some exceptions from engagement that have been granted on a case-by-case basis in certain circumstances. Instructs investigators and institutions to contact OHRP with questions about whether involvement in a non-exempt research study would make them engaged. The scenarios of "not engaged" research described include Awardee Institution; Data Center; and Magnetic Resonance Imaging facility.
August 23, 2011	Department of Health and Human Services (HHS) Conflict of Interest (COI)	http://grants.nih.gov/grants/policy/coi/	Amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). Summary of Major Changes Table outlines scope, types, exclusions, and threshold for disclosure; requirements for sub recipients, initial and repeated training, public access to certain disclosure information; and retrospective review of certain non-compliance cases.
July 1, 2011	Office for Human Research Protection (OHRP) Updated Guidance on Written IRB Procedures	http://www.hhs.gov/ohrp/policy/irbgd107.html	Written procedures updated to include reference to the latest guidance documents including Guidance on Continuing Review of Research; Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others; Guidance on IRB Approval of Research with Conditions; and updated web links and contact information.
June 21, 2011	Office for Human Research Protection (OHRP) Federalwide Assurance Process FAQs	http://answers.hhs.gov/ohrp/categories/1563	Establishes the Federalwide Assurance (FWA) as the only type of assurance of compliance accepted and approved by OHRP. Provides guidance regarding the registration process; Authorization and Investigator Agreements; limits to OHRP involvement in research that is not HHS supported; and listing of "common rule" agencies.

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June 20, 2011	Office for Human Research Protection (OHRP) Guidance on Reporting Incidents to OHRP	http://www.hhs.gov/ohrp/compliance/reports/index.html	Clarifies what information regarding serious or continuing noncompliance by the institutional review board needs to be reported, and provides updated OHRP's contact information including email box for incident reports. The email address for sending incident reports is IRPT.OS@hhs.gov.
June 15, 2011	Food and Drug Administration (FDA) Medical Devices; Exception from General Requirements for Informed Consent Final Rule	http://www.gpo.gov/fdsys/pkg/FR-2011-06-24/pdf/2011-15816.pdf	Final rule confirms the establishment of a new exception from the general requirements for informed consent to permit the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents without informed consent in certain circumstances. FDA has created this exception to help ensure that individuals who may have been exposed to a chemical, biological, radiological, or nuclear agent are able to benefit from the timely use of the most appropriate diagnostic devices, including those that are investigational. This final rule adds a requirement that the investigator submit the required documentation to FDA, in addition to submitting it to the reviewing Institutional Review Board (IRB).
March 31, 2011	Food and Drug Administration (FDA) Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors on Exception from Informed Consent Requirements for Emergency Research	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM249673.pdf	Finalizes draft from August 2006. Guidance for sponsors, IRBs, and investigators for interpreting and complying with regulations and community consultation. Also provides information regarding other aspects of emergency research including concurrence of a licensed physician, use of data monitoring committees, use of independent IRBs, and documentation of efforts to contact a subject's LAR or family member regarding participation.
March 29, 2011	National Institutes of Health (NIH) Change in policy on the Submission of Plans for Instruction in the Responsible Conduct of Research for Individual and Institutional Career Development (K) Award	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-059.html	Required RCR plans for instruction will have page limits separate from the page limits for other combined components that are limited to 12 pages (Individual K) or 25 pages (Institutional K).

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January 4, 2011	Food and Drug Administration (FDA) Final Rule: Including Trial Registration as required basic element for informed consent for applicable trials	http://edocket.access.gpo.gov/2011/2010-33193.htm	Requires that consent documents and process for applicable drug, biologic, and device clinical investigations include a statement that clinical trial information for such trials has been submitted to the National Institutes of Health/ National Library of Medicine (NIH/NLM) for inclusion in the clinical trial registry databank per the FDA Amendments Act of 2007 (FDAAA) . Compliance date is March 7, 2012. Section III of guidance provides details about applying the compliance date.

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Draft or Pending Documents 2011			
Date	Title	Web link	**Comments**
December 19, 2011	Food and Drug Administration (FDA) Draft Guidance for Industry and FDA Staff - Evaluation of Sex Differences in Medical Device Clinical Studies	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283453.htm	Outlines CDRH's expectations regarding sex-specific patient enrollment, data analysis and reporting of study information. The specific objectives of this guidance are: 1) to provide recommendations for study design and conduct to encourage enrollment of women in proportions that are representative of the demographics of disease distribution; 2) to outline recommended statistical analyses of study data for sex differences, and to identify sex-specific questions for further study; 3) to encourage the consideration of sex and associated covariates (e.g., body size, plaque morphology, etc.) during the study design stage; and 4) to specify CDRH's expectations for reporting sex-specific information in summaries and labeling for approved devices.
November 10, 2011	Food and Drug Administration (FDA) Draft Guidance for Industry, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff - FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm277669.htm?utm_source=Customer+List&utm_campaign=355fe3b709-Draft_Guidance_Exculpatory_language9_20_2011&utm_medium=email	Provides clarification regarding the regulatory implications of the decisions that FDA may render based on review of an Investigational Device Exemption (IDE) and provides a general explanation of the reasons for those decisions. FDA has developed methods to allow a clinical investigation of a device to begin under certain circumstances, even when there are outstanding issues regarding the IDE submission. These mechanisms, including approval with conditions, staged approval, and communication of outstanding issues related to the IDE through future considerations.
September 7, 2011 *(comments due November 4, 2011*)	Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP) joint draft document - Guidance on Exculpatory Language in Informed Consent	http://www.hhs.gov/ohrp/newsroom/rfc/	Provides guidance on the regulatory prohibition on exculpatory language including examples of language that FDA and OHRP consider exculpatory along with examples of language considered acceptable. OHRP and FDA consider exculpatory language to be language which has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt. Guidance clarifies that language meant to inform subjects that they would give up legal rights to be compensated for use of biospecimens would not be considered exculpatory. When final, will supersede previous OHRP guidance and FDA FAQ Information Sheet.

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August 24, 2011 (*comments due November 28, 2011*)	Food and Drug Administration (FDA) Draft Guidance: Oversight of Clinical Investigations- A Risk-Based Approach to Monitoring	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf	Outlines a range of approaches to monitoring the conduct and progress of clinical investigations by sponsors or sponsor-investigators in order to ensure compliance with applicable regulations, assess data integrity, and correct practices that could result in inadequate human subject protection or poor data quality. Provides rationale for facilitating risk-based monitoring, various approaches and strategies for use in developing a monitoring plan and documenting monitoring activities.
July 26, 2011 (*comments due October 26, 2011)*	Office for Human Research Protection (OHRP) Advanced Notice of Proposed Rulemaking (ANPRM) for Revisions to the Common Rule	http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html	Proposed changes intended to strengthen protections; minimize burdensome bureaucratic procedures increasing overall effectiveness; harmonize unanticipated problem reporting; and provide uniform guidance. Proposed revisions impact the risk-benefit framework; duplicative review of multi-site research; secondary use of biospecimens and data; revised exemption and expedited review processes; proposed standards for data security; and informed consent.
May 24,2011 *(comments due July 24, 2011)*	Food and Drug Administration (FDA) Guidance for Clinical Investigators, Industry, and FDA Staff Financial Disclosure by Clinical Investigators	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM256525.pdf	Revision provides clarifications and FAQs regarding the inclusion of investigator financial disclosures in drug, biologic, and device marketing applications. Includes potential FDA actions to ensure reliability of data and FAQs regarding financial disclosure.
April 27, 2011 (*comments due by June 27, 2011*)	Food and Drug Administration (FDA) Periodic Review of Existing Regulations; Retrospective Review	http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0259-0001	In accordance with Executive Order 13563, ``Improving Regulation and Regulatory Review,'' FDA is conducting a review of its existing regulations to determine, in part, whether they can be made more effective in light of current public health needs and to take advantage of and support advances in innovation. The goal is to help ensure that FDA's regulatory program is more effective and less burdensome in achieving its regulatory objectives. FDA is requesting comment and supporting data on which, if any, of its existing rules are outmoded, ineffective, insufficient, or excessively burdensome and thus may be good candidates to be modified, streamlined, expanded, or repealed.

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April 11, 2011 *(comments due by July 12, 2011)*	Food and Drug Administration (FDA) Proposed rule on Disqualification of Clinical Investigators	http://www.gpo.gov/fdsys/pkg/FR-2011-04-13/pdf/2011-8786.pdf	Under this proposal, when an investigator is ineligible to receive certain test articles, he/she will also be ineligible to conduct any clinical investigation that supports an application for research or marketing permit for FDA regulated products. The reviewing IRB will be notified when the investigator is disqualified. Additional changes harmonize requirements among regulated products.
Final Regulation/ Guidance 2010			
Date	Title	Web link	**Comments**
November 10, 2010	Office for Human Research Protections (OHRP) Guidance on IRB Approval of Research with Conditions	http://www.hhs.gov/ohrp/policy/conditionalapproval2010.html	Includes illustrations of what conditions preclude and what conditions permit IRB approval with conditions. Conditional approval requires a process for review of responsive materials from PI by the chair or designee to determine whether the conditions of approval are satisfied. IRB's have flexibility regarding who is designated to verify that conditions have been satisfied depending on the nature of the required conditions. An IRB may approve some components of a proposed study and defer taking action on other components at initial review.
November 10, 2010	Office for Human Research Protections (OHRP) Guidance on IRB Continuing Review of Research	http://www.hhs.gov/ohrp/policy/continuingreview2010.html	Finalizes draft guidance and supersedes January 2007 guidance on continuation review. Provides recommendations regarding the approval criteria, process, and frequency for continuing review to assure the protection of the rights and welfare of human subjects participating in research.
September 29, 2010	Food and Drug Administration (FDA) Final Rule: Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans	http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm226358.htm	The final rule lays out clear, internationally harmonized definitions and standards so that critical safety information about investigational new drugs will be accurately and rapidly reported to the agency, minimizing uninformative reports and enhancing reporting of meaningful, interpretable information. FDA Q & A regarding final rule - http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm226358.htm Enforcement of Safety Reporting Requirements guidance indicates FDA plans to exercise enforcement discretion regarding the reporting requirements in the final rule until September 28, 2011. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM257976.pdf

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September 21, 2010	Office for Human Research Protections (OHRP) Guidance on Withdraw of Subjects from Research	http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html	Supersedes draft guidance released December 2008. Provides guidance regarding (1) whether the investigator may use, study, or analyze already collected data about the subject who withdraws from the research or whose participation is terminated by the investigator; and (2) whether the investigator can continue to obtain data about the subject and if so, under what circumstances. The guidance below addresses these and related questions. OHRP recommends that investigators plan for the possibility that subjects will withdraw from research and include a discussion of what withdrawal will mean and how it will be handled in their research protocols and informed consent documents.
August 2, 2010	Food and Drug Administration (FDA) Guidance for Industry and Researchers, The Radioactive Drug Research Committee: Human Research Without an Investigational New Drug Application	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM163892.pdf	Provides clarification regarding what research studies may be conducted under RDRC vs. IND process. Also provides info regarding membership, functions, reporting requirements of an RDRC.
July 8, 2010	Food and Drug Administration (FDA) Humanitarian Device Exemption (HDE) Regulation: FAQ	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110194.htm	Supersedes draft document Aug 5, 2008. Provides guidance and decision tree for IRB review. Delineates HUD "clinical use" according to approved labeling from "investigational use" which incur same requirements as other FDA regulated research including 21 CFR 50, 56. IRB approval is required for clinical use of a HUD to treat or diagnose patients and the IRB may require informed consent as part of such approval. Additional safeguards apply for clinical use of a HUD in children.
June 21, 2010	Food and Drug Administration (FDA) FDA Inspections of Clinical Investigators	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf	Supersedes January 2006 guidance. Provides the how, who, what, when information regarding FDA inspections of clinical investigators both in the United States and international sites conducting studies as part of a marketing application submitted to FDA.
June 25, 2010	Food and Drug Administration (FDA) In Vitro Diagnostic (IVD) Device Studies FAQ	http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071230.pdf	Supersedes December 1999 guidance. Outlines general regulatory issues and provides decision tree regarding exemption determinations for IVD.

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May 1, 2010	Food and Drug Administration (FDA) Clinical Investigator Administrative Actions	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214008.pdf	Outlines administrative action of disqualifying a clinical investigator from participating in studies. FDA may disqualify a clinical investigator from receiving investigational drugs, biologics, or devices if FDA determines that the investigator has repeatedly or deliberately violated the agency's regulations or has repeatedly or deliberately submitted false information to the sponsor or FDA.
May 1, 2010	Food and Drug Administration (FDA) Information Sheet Guidance for Sponsors, Clinical Investigators, and IRB Frequently Asked Questions - Statement of Investigator (Form FDA 1572)	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf	Replaces draft version of 2008 FAQ. Additions to section on conduct of foreign clinical studies under an IND in regard to 1572 commitments (specifically IRB membership) and FDA waiver to allow use of an Independent Ethics Committee (IEC) that is compliant with ICH Good Clinical Practice guidelines. Provides practical guidance for completing each section of the Form 1572.
April 30, 2010	Office for Human Research Protection (OHRP) correspondence regarding use of a central IRB	http://www.hhs.gov/ohrp/policy/Correspondence/cirb20100430.html	OHRP letter to a medical center regarding use of a central IRB clarifies that OHRP fully agrees with FDA's position regarding use of a single central IRB for multicenter research. States the advance notice of proposed rulemaking on IRB accountability issued March 5, 2009 was proposed to address concerns about regulatory liability which inhibit institutions from relying on the review of an IRB operated by another organization or institution.
March 30, 2010	Office for Human Research Protection (OHRP) revised set of Frequently Asked Questions and Answers (FAQs) on Institutional Review Board (IRB) Registration	http://answers.hhs.gov/ohrp/categories/1565	Revised version of FAQs originally effective on July 15, 2009.
January 8, 2010	Office for Human Research Protection (OHRP) correspondence regarding student subject pools and use of penalties for students who fail to show up for scheduled research appointments	http://www.hhs.gov/ohrp/policy/Correspondence/ohrp20100108.html	OHRP letter to a commercial company, which provides a web-based system for managing student subject pools. Letter clarifies that imposing penalty credits on students who fail to show up for scheduled appointments with investigators without cancelling by a specified deadline violates the requirement of Department of Health and Human Services (HHS) regulations at 45 CFR part 46.116(a)(8). Such penalties may not be implemented for non-exempt human subjects research conducted or supported by HHS or for non-federally supported research to which an OHRP approved Federalwide Assurance (FWA) applies.
Draft or Pending Documents 2010			
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December 1, 2010	Food and Drug Administration (FDA) Electronic Source Documentation in Clinical Investigations	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM239052.pdf	Provides guidance to sponsors, CROs, and investigators regarding use and archiving electronic data in FDA regulated trials. Reviews requirements for how data elements are transcribed manually and automatically from an instrument into the electronic case report form (eCRF). Sites must maintain a list of prospectively determined originators authorized to transmit data elements to the eCRF. Investigators review completed portions of an eCRF before data are archived or released to third parties.
October 14, 2010 *(comments due by January 11, 2011)*	Food and Drug Administration (FDA) Investigational New Drug Applications (INDs)-Determining Whether Human Research Studies Can Be Conducted Without an IND	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf	This draft guidance provides clarification regarding when an Investigational New Drug (IND) application is needed. Includes information on (1) clinical investigations using marketed drugs, (2) bioequivalence/bioavailability studies, (3) studies using radiolabeled or cold isotopes, (4) studies using dietary supplements, (5) studies using endogenous compounds, (6) pathogenesis studies using modified organisms, (7) studies using wild-type organisms in challenge models, and (8) studies that do not have a commercial purpose. Also provides information on IND exempt studies and a process for seeing advice from FDA.
September 28, 2010 *(comments due by December 28, 2010)*	Food and Drug Administration (FDA) Guidance for Industry and Investigators Safety Reporting Requirements for INDs and Bioavailability and Bioequivalence Studies	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM227351.pdf	This draft guidance is intended to help sponsors and investigators comply with the new requirements in the final rule entitled ‘‘Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans.
July 14, 2010 (*comments due by Sept13, 2010)*	Office of Civil Rights (OCR) and Office for Human Research Protection proposed modification to HIPAA Privacy, Security, and Enforcement Rules under the Health Information Technology for Economic and Clinical Health (HITECH) Act	http://edocket.access.gpo.gov/2010/2010-16718.htm	Two key research-related provisions in the HIPAA Privacy Rule relate to compound authorizations and authorizations for future use and disclosure.

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May 21, 2010 *(comments due by July 20, 2010)*	HHS and Public Health Service (PHS) proposal to amend regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is sought and Responsible Prospective Contractors	http://edocket.access.gpo.gov/2010/pdf/2010-11885.pdf	Since the promulgation of the regulations in 1995, biomedical and behavioral research and the resulting interactions among Government, research institutions, and the private sector have become increasingly complex. This complexity, as well as a need to strengthen accountability, have led to the proposal of amendments that would expand and add transparency to investigator disclosure of significant financial interests, enhance regulatory compliance and effective institutional oversight and management of investigators' financial conflicts of interests, as well as NIH's compliance oversight.
May 3, 2010 *(comments due by May 18, 2010)*	HHS Request for Information - HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health (HITECH) Act.	http://edocket.access.gpo.gov/2010/pdf/2010-10054.pdf	The HITECH Act provides that an individual has the right to receive information about disclosures made through a covered entity's electronic health record for purposes of carrying out treatment, payment and health care operations. The request for information seeks comments on the perceived burden on covered entities. The proposed rule will follow, providing further opportunity for comment.
February 19, 2010 *(comments due by May 20, 2010)*	FDA Proposed Rule on Reporting Information Regarding Falsification of Data	http://edocket.access.gpo.gov/2010/pdf/2010-3123.pdf	Proposed rule to require prompt reporting of data falsification by sponsors; no later than 45 days after a sponsor becomes aware of the information. FDA is seeking comments on the definition of "falsification of data", the proposed reporting time frame, whether the regulatory changes should extend to marketing applications, whether the proposed rule should provide evidentiary standards or thresholds, whether FDA should provide additional examples of what it considers "errors" that would not be required to be reported, and the type of information that should be reported to FDA when a sponsor reports possible falsification of data.
January 13, 2010	FDA Guidance for IRBs, Clinical Investigators, and Sponsors IRB Continuing Review after Clinical Investigation Approval	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM197347.pdf	Assist institutional review boards (IRBs) in carrying out their continuing review responsibility under 21 CFR 56.108(a) and 56.109(f) by providing recommendations regarding the criteria, process, and frequency of continuing review to assure the protection of the rights and welfare of subjects in clinical investigations. The draft guidance should also help clinical investigators and sponsors better understand their responsibilities related to continuing review. When finalized, this document will supersede the Information Sheet, *Continuing Review After Study Approval* (September 1998, Office of Health Affairs, Food and Drug Administration).

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Final Regulation/ Guidance 2009			
Date	Title	Web link	**Comments**
November 24, 2009	National Institutes of Health (NIH) Update on the Requirement for Instruction in the Responsible Conduct of Research	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html	Outlines best practices that have evolved in the research training community over the past two decades; provides access to additional information that may be useful to institutions and individuals in meeting obligations under NIH policy; specifies that on-line instruction may be a component of instruction in responsible conduct of research but is not sufficient to meet the NIH requirement for such instruction, except in special or unusual circumstances.
October 29, 2009	Food & Drug Administration (FDA) Guidance on Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf	Outlines FDA expectations concerning investigator's responsibilities and protection of rights, safety and welfare of study subjects. Also provides summary of investigator responsibilities for significant risk device investigations.
October 19, 2009	NIH Notice on Development of Data Sharing Policy for Sequence and Related Genomic Data	http://grants.nih.gov/grants/guide/notice-files/NOT-HG-10-006.html	Provides intent and considerations related to developing policy and process for IRB review and informed consent to allow broad sharing of large sequence and genomic datasets into centralized databases so that they are available as rapidly as possible to a wide range of scientific investigators.
October 15, 2009	Office for Human Research Protection (OHRP) FAQs regarding Exempt Research Determinations	http://answers.hhs.gov/ohrp/categories/1564	Provides guidance regarding who in an institution may make exempt determinations and suggested protections to ensure accurate determinations and compliance with reporting changes that could affect exempt status.
October 14, 2009	OHRP's Compliance Oversight Procedures for Evaluating Institutions	http://www.hhs.gov/ohrp/compliance/evaluation/	This document summarizes the procedures used by OHRP in performing compliance oversight evaluations of institutions and human subjects research that are under OHRP's jurisdiction. In particular, OHRP offers guidance on the following topics: •How OHRP conducts for-cause compliance oversight evaluations; •How OHRP conducts not-for-cause compliance oversight evaluations; •Possible outcomes of OHRP compliance oversight evaluations; •Public and governmental access to OHRP compliance oversight evaluation records; and •The Privacy Act is not applicable to OHRP compliance oversight evaluation records.

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Date	**Title**	**Web link**	**Comments**
August 20, 2009	National Science Foundation (NSF) Implementation of Section 7009 of the America COMPETES Act	http://edocket.access.gpo.gov/2009/E9-19930.htm	Effective January 4, 2010, NSF will require that, at the time of proposal submission to NSF, a proposing institution's Authorized Organizational Representative have certification available for review upon request that the institution has a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF.
August 13, 2009	FDA Expanded Access to Investigational Drugs for Treatment Use	http://edocket.access.gpo.gov/2009/pdf/E9-19005.pdf	Amends regulations on expanded access to investigational new drugs for treating patients. Expanded access to investigational drugs for treatment use will be available to: • individual patients, including in emergencies • intermediate-size patient populations • larger populations under a treatment protocol or treatment investigational new drug application (IND).
August 13, 2009	FDA Charging for Investigational Drugs Under an Investigational New Drug Application	http://edocket.access.gpo.gov/2009/pdf/E9-19004.pdf	Amends the IND regulation on charging patients for investigational drugs. The rule revises the charging regulation to clarify the circumstances under which charging for an investigational drug in a clinical trial is appropriate, • set forth criteria for charging for an investigational drug for the different types of expanded access for treatment use described in FDA's final rule on expanded access for treatment use of investigational drugs, and • clarify what costs can be recovered.
July 17, 2009	OHRP Updated Web-based Electronic Submission System for Submitting FWAs and IRB Registrations	http://ohrp.cit.nih.gov/efile	This system also allows an institution or organization (IORG) to submit documents for registering a new institutional review board (IRB) and to update or renew an existing IRB registration. Using the electronic system for registration of an IRB that reviews research conducted or supported by the Department of Health and Human Services (HHS) is required unless an institution or organization lacks the ability to register an IRB electronically via this system.
July 14, 2009	FDA IRB Registration FAQ	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM171256.pdf	Reviews process, procedures, timeline and requirements for IRB registration.
July 9, 2009	OHRP Guidance Registration of IRBs	http://www.hhs.gov/ohrp/assurances/index.html#registernew	IRB Registration Guidance Website

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March 24, 2009	OHRP Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards	http://www.hhs.gov/ohrp/policy/gina.html	Guidance provides background on protections provided by the Genetic Information Nondiscrimination Act of 2008 (GINA) and implications for investigators who conduct, and IRBs that review, genetic research involving human subjects that is conducted or supported by HHS.
February 4, 2009	OHRP Compliance Oversight Activities: Determinations of Noncompliance	http://www.hhs.gov/ohrp/compliance/findings/	This document provides a list of determinations of noncompliance by category that OHRP has made in compliance oversight determination letters over the last several years.
January 15, 2009	FDA IRB Registration Requirements - outlines registration requirements for IRBs reviewing FDA regulated research	http://www.fda.gov/OHRMS/DOCKETS/98fr/E9-682.pdf	Published simultaneously with OHRP Sub-E in effort to develop coordinated means of communication; assessing IRB performance and to identify and respond to emerging problems before they result in ''serious transgressions''.
January 14, 2009	FDA Guidance for Clinical Investigators, Sponsors, and IRBs Adverse Event Reporting to IRBs - Improving Human Subject Protection	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126572.pdf	Recommendations for sponsors and investigators conducting investigational new drug (IND) trials to help them differentiate between those AEs that are unanticipated problems that must be reported to an IRB and those that are not.
January 13, 2009	OHRP Correspondence regarding determining when institutions are engaged in research	http://www.hhs.gov/ohrp/policy/Correspondence/ohrp20090113.html	Correspondence (1) clarifying when a survey firm may be engaged in human subjects research; and (2) clarifying the relationship between engagement and the Federalwide Assurance (FWA).
January 1, 2009	OIG Report -THE FDA Oversight of Clinical Investigators' Financial Information	http://oig.hhs.gov/oei/reports/oei-05-07-00730.pdf	Presents 2007 data and findings regarding investigator disclosure of financial interest. Identifies deficiencies and recommendations.
Draft or Pending Documents 2009			
Date	Title	Web link	**Comments**
December 29, 2009 *(comments due by March 1, 2010)*	21 CFR Part 50 Informed Consent Elements FDA Proposed rule open for public comment	http://edocket.access.gpo.gov/2009/E9-30751.htm	[Finalized 2011]
May 8, 2009 *(comments due by July 7, 2009)*	NIH proposed rule regarding Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-099.html	Proposes more comprehensive guidelines to ensure objectivity of results by protecting federally funded research from compromise by financial conflict of interest. Potential for COI has increased as a result of accelerated multidisciplinary & translational research. Request input regarding inclusion of Phase I, dollar thresholds, potential management requirements, & assuring institutional compliance.

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March 5, 2009 *(comments due by June 3, 2009)*	OHRP advanced notice of proposed rulemaking; request for comments regarding holding IRBs & the institutions operating the IRBs accountable for adherence to 45 CFR 46.	http://edocket.access.gpo.gov/2009/E9-4628.htm	OHRP is contemplating this regulatory change to encourage institutions to rely on IRBs that are operated by another institution or organization, when appropriate and encourage cooperative review arrangements.
February 20, 2009 *(comments due by March 31, 2009) [FINAL RULE listed in Final Regulation/Guidance section- 8-20-09]*	NSF request for comment on requirement for students and postdoctoral researchers involved in NSF proposals to be educated in the responsible and ethical conduct of research (RCR)	http://www.thefederalregister.com/d.p/2009-02-26-E9-4100	Effective October 1, 2009, NSF proposes to require that at the time of proposal submission to NSF, a proposing institution's Authorized Organizational Representative must certify that the institution has a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduates, graduate students, and postdoctoral researchers.
Final Regulation/ Guidance 2008			
Date	Title	Web link	**Comments**
December 30, 2008	OHRP FAQ regarding Quality Assurance Research	http://answers.hhs.gov/ohrp/categories/1569	FAQ regarding OHRP current thinking regarding quality improvement activities; guidance to help identify when QI activities are considered human subject research.
December 1, 2008	Guidance for Sponsors, Clinical Investigators, and IRBs- Data Retention when Subjects Withdraw from FDA-Regulated Clinical Trials	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126489.pdf	Reiterates FDA's promotion of "intent-to-treat" analysis and the longstanding policy that all data collected up to a point of withdrawal must be maintained in the database and included in subsequent analysis.
October 16, 2008	OHRP Guidance on Engagement of Institutions in Human Subject Research	http://www.hhs.gov/ohrp/policy/engage08.html	Use to assess whether an assurance is needed in collaborative research.
October 16, 2008	OHRP Guidance on Research Involving Coded Private Information or Biological Specimens. This guidance has been updated to be consistent with OHRP'S OCTOBER 16, 2008 GUIDANCE ON ENGAGEMENT OF INSTITUTIONS IN HUMAN SUBJECTS RESEARCH (Replaces OHRP'S AUGUST 10, 2004 guidance)	http://www.hhs.gov/ohrp/policy/cdebiol.html	Eliminates one example from 2004 and adds minor clarification.

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September 1, 2008	Food & Drug Administration Amendments Act (FDAAA) summarizes first year accomplishments of act. Impacts FDA (responsibilities & authorities) and sponsors/investigators (registration of clinical trials).	http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/ucm083161.htm	Expands Clinical Trial Databases/ enhanced Post marketing Safety - Risk Evaluation & Mitigation Strategies (REMS).
September 29, 2008	OHRP correspondence Memo to National Cancer Institute re: Protocol Review and Consent Changes for NCI/CTEP sponsored trials [original memorandum March 2008 CTEP]	http://www.hhs.gov/ohrp/policy/Correspondence/nci200870929.html	Impacts Cooperative Group Studies; Action Letter dictates types of review and PI enrollment suspension.
February 15, 2008	OHRP Statement regarding Quality Assurance Research	http://www.hhs.gov/ohrp/policy/Correspondence/pronovost20080730.html	Conclusion regarding Johns Hopkins hospital infection research.
January 25, 2008	NIH Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)	http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html	Discusses sensitive data and need for IRBs/privacy boards to consider risk or GWAS datasets; provides clarification on appropriate informed consent process for individuals participating in studies for which data will be submitted to the NIH GWAS repository.

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Draft or Pending Documents 2007-2008			
Date	Title	Web link	**Comments**
September 5, 2007	SACHRP Request for Information and Comments on Research That Involves Adult Individuals With Impaired Decision-making Capacity (Extended comment period to January 14, 2008)	http://www.hhs.gov/ohrp/archive/requests/com090507.html	SACHRP Subcommittee considering committee Comments Due January 14, 2008
July 2, 2008	OHRP Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs (comments due September 29, 2008)	http://www.hhs.gov/ohrp/newsroom/rfc/com070208.html	OHRP considering comments due September 29, 2008
July 2008	Draft guidance - FAQ regarding Form FDA 1572 - impacts investigators and sponsors	http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0406-gdl.pdf	Provides practical guidance and clarification regarding completion of FDA form 1572 and investigator responsibilities.
June 5, 2008	ICH Draft Development Safety Update Report (DSUR) impacts sponsors	http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM129284.pdf	proposed common standard to harmonize annual safety reporting among ICH regions
May 10, 2007	FDA Draft Guidance for Industry: Protecting the Rights, Safety, and Welfare of Study Subjects - Supervisory Responsibilities of Investigators	http://www.fda.gov/RegulatoryInformation/Guidances/ucm127697.htm	Impacts Clinical Investigators; final published 10-29-09
April 17, 2007	FDA Draft Guidance for Clinical Investigators, Sponsors, and IRBs: Adverse Event Reporting - Improving Human Subject Protection	http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0106-gdl0001.pdf	Designed to be consistent with OHRP January 2007 Guidance
Select Final Guidance 2006-2007			
Date	Title	Web link	**Comments**
January 1, 2006	FDA Frequently Asked Questions About IRB Review of Medical Devices	http://www.fda.gov/oc/ohrt/irbs/irbreview.pdf	
January 1, 2006	FDA Significant Risk and Nonsignificant Risk Medical Device Studies	http://www.fda.gov/oc/ohrt/irbs/devrisk.pdf	

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January 1, 2006	FDA Institutional Review Board Inspections	http://www.fda.gov/oc/ohrt/irbs/reviewboard.pdf	
January 1, 2006	FDA Inspections of Clinical Investigators	http://www.fda.gov/oc/ohrt/irbs/investigator.pdf	
January 15, 2007	OHRP Guidance on Continuing Review	http://www.hhs.gov/ohrp/policy/continuingreview2010.html	Replaced with 2010 guidance
January 15, 2007	OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events	http://www.hhs.gov/ohrp/policy/advevntguid.html	
January 15, 2007	OHRP Guidance on Written Procedures	http://www.hhs.gov/ohrp/policy/irbgd107.html	Replaced with 2011 guidance
August 9, 2007	America COMPETES Act	http://www.nist.gov/admin/legislation_new/PL110-69_8907.pdf	Increase federal support for science education and research
September 27, 2007	Food & Drug Administration Amendments Act (FDAAA) impacts investigators and sponsors; requires registration of clinical trials.	http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm	Clinical Trial Databases/enhanced Post marketing Safety - Risk Evaluation & Mitigation Strategies (REMS)

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Resources			
Title	Web link		
Regulations.gov	www.regulations.gov		
FDA News	http://www.fda.gov/NewsEvents/default.htm		
FDA Guidance	http://www.fda.gov/RegulatoryInformation/Guidances/default.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery		Search, comprehensive lists, future planned guidance, and new/revised/withdrawn lists
Comprehensive list of FDA guidance	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079645.pdf		
Federal Register FDA	https://www.federalregister.gov/agencies/food-and-drug-administration		
FDA Guidance Search	http://www.fda.gov/RegulatoryInformation/Guidances/default.htm		
Newly added FDA Guidance - Drugs	http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm121568.htm		
Newly added FDA final device guidance	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm418448.htm		
FDA Guidance CROSS-CUTTING TOPICS	http://www.fda.gov/RegulatoryInformation/Guidances/ucm122044.htm		
Proposed Regulations and Draft Guidance	http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm		
CDER Guidance & Recent Guidance	https://www.fda.gov/drugs/guidances-drugs/newly-added-guidance-documents		
FDA CBER Guidances by category	https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances		

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FDA Information Sheets	http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm		
Selected FDA GCP/Clinical Trial Guidance Documents	http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm		
FDA CDRH Guidance Medical Devices	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfggp/search.cfm		
FDA GCP	http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm		
OHRP NEWS	https://www.hhs.gov/ohrp/news/index.html		
DHHS Request for Comments	https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html		
OHRP Correspondence Website	https://www.hhs.gov/ohrp/compliance-and-reporting/determination-letters/index.html		
DHHS NIH HIPAA Guidance Website	http://privacyruleandresearch.nih.gov/		
DHHS HIPAA FAQ	http://www.hhs.gov/hipaafaq/		
Office of Inspector General - what's new website	http://www.oig.hhs.gov/w-new.asp		
Federal Register	http://www.thefederalregister.com/		
Department of Defense (DoD) Issuances	http://www.dtic.mil/whs/directives/whats_new.html		
University of Kentucky October Initial Document 2008			