

University of Kentucky Office of Research Integrity Selected Changes at the Federal Level Impacting Human Research Protection			
Date	Title	Web link	Comments
Final Regulation/ Guidance 2012			
February-12	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
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(PET) Drugs	http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291573.pdf	Draft guidance differentiates regulatory and IND expectations between clinical use and investigational use of PET drugs.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.
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 subrecipients, 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) Federawide Assurance Process FAQs	http://answers.hhs.gov/ohrp/categories/1563	Establishes the Federawide 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
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).
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.
Draft or Pending Documents 2011			
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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.

November 10, 2011	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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm277670.htm#2	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.
September 7, 2011 (<i>comments due November 4, 2011</i>)	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.
August 24, 2011 (<i>comments due November 28, 2011</i>)	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 (<i>comments due October 26, 2011</i>)	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 (<i>comments due July 24, 2011</i>)	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 (<i>comments due by June 27, 2011</i>)	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.
April 11, 2011 (<i>comments due by July 12, 2011</i>)	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
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.
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-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			
Date	Title	Web link	Comments

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 <i>(comments due by January 11, 2011)</i>	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 <i>(comments due by December 28, 2010)</i>	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 <i>(comments due by Sept13, 2010)</i>	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.
May 21, 2010 <i>(comments due by July 20, 2010)</i>	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 (<i>comments due by May 18, 2010</i>)	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 (<i>comments due by May 20, 2010</i>)	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, <i>Continuing Review After Study Approval</i> (September 1998, Office of Health Affairs, Food and Drug Administration).
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: <ul style="list-style-type: none"> •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.
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: <ul style="list-style-type: none"> • 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, <ul style="list-style-type: none"> • 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
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.
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 8.20.001]	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. D86.0000
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/FederalFoodDrugandCosmeticsAct/FDCAAct/SignificantAmendments/totheFDCAAct/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/provost20080730.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.
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 across 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	
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/FederalFoodDrugandCosmeticActFDCAAct/SignificantAmendmentstotheFDCAAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm	Clinical Trial Databases/enhanced Post marketing Safety - Risk Evaluation & Mitigation Strategies (REMS)

Resources			
Title	Web link		
Regulations.gov	www.regulations.gov		
FDA News	http://www.fda.gov/NewsEvents/default.htm		
FDA Guidance	http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm		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		
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 Guidance - Devices	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm162707.htm		
CDER Guidance & Recent Guidance	http://www.fda.gov/cder/guidance/		
FDA Information Sheets	http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidanceInformationSheetsandNotices/ucm113709.htm		
FDA 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	http://www.hhs.gov/ohrp/newsroom/index.html		
OHRP Correspondence Website	http://www.hhs.gov/ohrp/policy/Correspondence/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		
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