UCI Office of Research

HUMAN RESEARCH PROTECTIONS (HRP)

Special Edition News Brief

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2017 Updated Human Subjects Policies and Regulations

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On September 16, 2016, the **Department of Health and Human Services** (HHS) issued a new *regulation*, and the **NIH** has issued a new *policy*, regarding clinical trials. Both initiatives aim to increase the availability of clinical trials status and outcomes to the public in a timely manner. Some of the key elements are summarized

Elements	DHHS *Regulation*	NIH *Policy*
Applicability	Applicable clinical trials are: (1) clinical trials of drug and biological products that are controlled, clinical investigations, other than phase 1 investigations, of a product subject to FDA regulation; and (2) prospective clinical studies of health outcomes comparing an intervention with a device product against a control in humans (other than small feasibility studies) or any pediatric post-market surveillance studies required by FDA under the FD&C Act.	All clinical trials funded wholly or partially by NIH. Includes phase 1 clinical trials and trials that do not involve any FDA regulated product such as trials involving only behavioral interventions. Applies to NIH-funded clinical trials where applications or proposals are received by NIH on or after the policy's effective date. Applies to NIH-conducted clinical trials initiated on or after the policy's effective date.
Timeframe	**Registration: Not later than 21 days after enrollment of the first participant.** **Results: Not later than 12 months after primary completion date**	**Same**
Effective Date	**January 18, 2017.** ***Compliance date** is 90 days from the effective date [**April 18, 2017**].*	**January 18, 2017**
Resources	♦ Summary of changes from current practice ♦ Applicable Clinical Trial [Checklist] ♦ Responsible Party ♦ Timelines ♦ FAQs ♦ 2016 NEJM special report article from NIH NLM ***Potential Consequences of Noncompliance***	♦ Decision-tree for identifying an "Applicable Clinical Trial" [Flow-chart] ♦ Decision-tree for identifying the "Responsible Party" [Flow chart]] [Table of Actions] ♦ FAQs ***Potential Consequences of Noncompliance***

On January 19, 2017, the **U.S. Department of Health and Human Services (HHS)** and fifteen other Federal Departments and Agencies announced 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. The **Final Rule will be effective January 19, 2018***, with the exception of *cooperative research* (single IRB review) which will not be effective until January 20, 2020. Some key elements of the final rule are:

Elements	Summary
Biospecimens and Private Information	Does not expand the definition of "human subject" to include non-identified biospecimens; however does alter the definition which now includes identifiable biospecimens. Identifiable Biospecimens and identifiable private information are treated equally in the final rule. These definitions will be re-examined within one year of publication and every four years thereafter.
Informed Consent	Informed consent must begin with a concise and focused presentation of key information to facilitate understanding of the reasons why one might or might not want to participate in the research. Additional elements of informed consent have been added, including a requirement for language indicating that identifiers might be removed from identifiable private information or identifiable biospecimens and whether such information or biospecimens might or will not be used for future research studies. In addition, "where appropriate," information on whether biospecimens will be used for commercial profit; whether results will be disclosed to the subject; and whether the research might include whole genome sequencing. Any version of an IRB approved consent form for clinical trials conducted or supported by a Common Rule department or agency must be posted on a publicly available federal website after recruitment ends but not later than 60 days after the last study visit by any subject. The final rule allows for redaction with approval.
Exclusions and Exemptions	The definition of research has changed. It now includes, "what constitutes research," and names activities not considered research such as certain scholarly and journalistic (including oral history), public health surveillance and criminal justice and intelligence activities. The rule adds to and modifies existing exempt categories. This includes modifying previous exemptions to allow use of identifiable information with limited IRB review; inclusion of benign behavioral interventions; and storage, maintenance and secondary use of identifiable private information and identifiable biospecimens where broad consent is obtained. Secondary research using identifiable private information or identifiable biospecimens without consent qualifies as exempt if the research only involves collection and analysis of identifiable information regulated under HIPAA or non-research government information in compliance with applicable federal requirements.
Continuing Review	Continuing review is eliminated for studies that undergo expedited review and research that has progressed to the point that it involves only data analysis or accessing follow-up clinical data as part of clinical care, unless the IRB documents a rationale for conducting continuing review. The final rule does not require investigators to provide annual confirmation to the IRB that research is ongoing and that no changes have been made.
Extending Coverage	The final rule does not extend FWA coverage to non-federally funded clinical trials.
Cooperative Research (sIRB)	The final rule mandates the use of a single IRB for multisite studies. Federal departments or agencies supporting or conducting the research can determine that the use of a single IRB is not appropriate for particular types of studies.
Privacy and Security Safeguards	The final rule "does not adopt the privacy and security provisions proposed …but rather retains and acknowledges the IRB's role in ensuring that privacy safeguards are appropriate..."

2017 NEJM article - Perspective from OHRP

* *At this time, the Final Rule is on hold for 60 days pending review by the Trump Administration. The rule could move forward as is, be revised, or be rescinded.*

Scope	On September 16, 2016, the **National Institutes of Health (NIH)** issued a new ***policy*** *stating that* ***NIH-funded investigators and staff should be trained in Good Clinical Practice (GCP)****, consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2).* ***This policy became effective on January 1, 2017****.*
Applicability	**The policy applies to** all NIH-funded investigators and staff "who are involved in the conduct, oversight, or management of clinical trials."
Definition	**NIH defines a clinical trial** as 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.
GCP Courses	**Acceptable GCP courses include** the Collaborative Institutional Training Initiative (CITI) GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) course as well as the CITI GCP FDA Refresher Course. Other GCP courses from NIAID and National Drug Abuse Treatment Clinical Trials Network are also acceptable. GCP training may also be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. **GCP Training is required every three years**. The UCI Human Research Protections (HRP) office will monitor completion of the CITI GCP training courses. **For individuals who complete non-CITI GCP training, please retain and submit certification of GCP training to the HRP unit (via email at irb@research.uci.edu).**
Timeline	**Full implementation of this policy is expected by March 1, 2017**. *Noncompliance could result in delays in IRB approval.*

Scope	The **Final NIH Policy** on the **Use of a Single Institutional Review Board (sIRB) for Multi-Site Research** was published by the **NIH Office of Science Policy** in the **Federal Register** on June 21, 2016. Guidance on the *Use of Direct and Indirect Costs for Single IRB Review was also published.*
Applicability	**The policy applies to** domestic NIH-funded multi-site studies carried out at more than one site "where each site will conduct the *same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards."*
Timeline	**The policy will take effect September 25, 2017**. *Ongoing, non-competing awards will not be expected to comply until the grantee submits a competing renewal application.*
Resource	**FAQs**

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