nobody@a1289.g.akamai.net
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Please respond to **nobody@al289.g.akamai.net**

Record Type: Record

To: John Morrall@EOP

cc:
Subject: Suggestion for Regulatory Reform

Name:
Katharina Phillips

Address:
Council on Governmental Relations COGR, 1200 New York Ave., NW Suite 320, Washington DC 20005

Telephone No.:
202-289-6655

E-mail address:
kphillips@cogr.edu

Name of Guidance:
Protection of Human Subjects

Regulating Agency:
Department of Health and Human Services

Subagency (if any):
FDA, *OHRP,* OCR

Citation (Code of Federal Regulation):
56 FR 28003 Common Rule

Authority (Statute/Regulation):
45 CFR 46 42 USC 289a, 21 CFR Parts 50 and 56, 45 CFR Parts 160 and 164

Description of Problem (Nature of Impact and on Whom):
The regulations governing the use of human participants in research have expanded rapidly over the past decade as a consequence of the growth and increasing sophistication of medical research. It is time for a thorough and thoughtful review of the regulations as a whole with the goal of ensuring that the regulations emphasize the protection of participants in the context of the type of research and level of risk for participants and that overly burdensome provisions do not inhibit critical biomedical, epidemiological and health sciences research. A strong system for protection of human research participants is a national priority. However, as Secretary Tommy Thompson has observed over regulation can

undermine the willingness of universities, health care providers and other research organizations to participate in HHS programs.

The increasingly complex regulations and guidance governing human research protections are administered principally by two HHS offices: 45 CFR 46, Protections of Human Subjects, overseen by the Office of Human Research Protections OHRP and 21 CFR Parts 50, 54 and 56, Human Subjects Protections, Informed Consent, and Institutional Review Boards IRB governing clinical investigations under the Food and Drug Administration FDA.

In addition to this broad regulatory framework established by 45 CFR 46 and 21 CFR 50, 45 and 56, policies and guidance have been issued by other HHS divisions, notably the National Institutes of Health NIH. In addition to the Data Safety Monitoring Board reviews required by NIH policy, NIHs Office of Biotechnology Activities manages the review and approval of gene therapy clinical trials by the institutional biosafety committee IBC under an entirely separate set of Guidelines for Research Involving Recombinant DNA Molecules. These often-necessary specific regulations should be reviewed to ensure consistency with the general regulatory framework.

The complexity of the human research regulatory situation is exacerbated by the introduction of mandatory privacy review of research outlined in the Health Insurance Portability and Accountability Acts Privacy Rules Standards for the Privacy of Individually Identifiable Health Information, 45 CFR Part 160-164. The research provisions of the HIPAA privacy rules require an additional layer of review a privacy review - by an IRB or by a newly created, separate Privacy Board. The criteria for the privacy review are similar to but slightly different from the criteria used by the IRB under 45 CFR 46. The recently proposed modifications of the HIPAA Privacy Rule research provisions attempt to address these differences and offer further clarifications. But the resulting confusion in review may cause health care providers to opt out of participating in research, an activity not at the core of their missions.

Recent studies and reports by the HHS Office of Inspector General, the National Bioethics Advisory Committee, and the Institute of Medicine have highlighted a system that is over-burdened and in need of reform. But the system of human research protections is built on the foundation of the regulatory framework. An essential aspect of any effort to fix or enhance the system of protections is a review of the foundation.

Proposed Solution:

The regulations governing the use of human participants in research have expanded rapidly over the past decade as a consequence of the growth and increasing sophistication of medical research. It is time for a thorough and thoughtful review of the regulations as a whole with the goal of ensuring that the regulations emphasize the protection of participants in the context of the type *of* research and level of risk for participants and that overly burdensome provisions do not inhibit critical biomedical, epidemiological and health sciences research, A strong system for protection of human research participants is a national priority.

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Estimate of Economic Impacts (Quantified Benefits and Costs if possible / Qualified description as needed):
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