

Human Research Report

PROTECTING RESEARCHERS AND RESEARCH SUBJECTS

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Human Subject Studies Could Be “Excused” From IRB Review

In this article we expand upon a topic that we have been covering for many months; namely, the federal proposal by the Department of Health and Human Services (HHS) to create a new human subjects research category called “excused research.” As we discussed most recently in last month’s HRR, this term refers to research that would be “excused” from the usual review and approval by an IRB.

The term was introduced in the huge Advance Notice of Proposed Rulemaking (ANPRM) titled “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators” (see *FEDERAL REGISTER*, July 26, 2011). The fact that HHS is still reviewing the many comments it received four years later gives us an idea of how many changes it proposed to human subjects protection regulations.

One major response to the ANPRM was the Institute of Medicine’s (IOM’s) 136-page report titled “Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences” (January 9, 2014, emphasis added to title; at http://www.nap.edu/catalog.php?record_id=18614).

Examples of “Excused Research”

Before proceeding, note that, although the IOM report addresses nonmedical research, the ANPRM’s recommendations on “excused research” (including the aspects we present here) apply to biomedical studies as well.

The IOM report on behavioral, social, and related research remains the most extensive one available that examines human subject protections regulations and policies. We resume here where we left off last month, i.e., with the IOM report’s recommendations on types of human subjects studies that should be “excused” from IRB review. The IOM examples are based on typical such studies. We described nine of the thirteen examples previously, and conclude here with the remaining four:

“10. A study in which a sociocultural anthropologist lives for two years in an East Asian city, focusing on how ordinary rail users, transporta-

tion technicians, and transport officials talk about their experiences with high-speed rail travel.

11. A study in which a sociolinguist studying new forms of ‘reported speech’ (that is, phrases in which someone reports what someone said) observes conversational interactions between friends, with their informed consent, paying special attention to use of certain phrases.

12. A group of college students are given an anonymous survey about their mental health history and beliefs and attitudes toward school health policies.

NOTE #1: Quoted materials in this newsletter appear exactly as originally published in source documents, including any misspellings, grammatical errors, missing words, etc.

NOTE #2: Articles may be continued in subsequent issues.

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