

COUNCIL ON GOVERNMENTAL RELATIONS

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The Council on Governmental Relations (COGR), an association of leading research universities, affiliated academic medical centers, and independent research institutes, submitted comments on the Department of Health and Human Services (HHS) Federal Policy for the Protection of Human Subjects (Common Rule) Notice of Proposed Rulemaking (NPRM) on December 8, 2015.

Overview

COGR indicated support for the elimination of continuing review for minimal risk studies that qualify for expedited review, although without additional notification requirements; identification of the types of research that are excluded from the regulations with an indication that the list is not all-inclusive; adding a new provision that would explicitly give Common Rule departments and agencies the authority and obligation to enforce compliance directly against unaffiliated Institutional Review Boards (IRBs) that are not operated by an assured institution; the elimination of the requirement that the IRB review grant applications for congruency with IRB applications; and updating and expanding the Secretary's list of research eligible for expedited review -- COGR suggested that any research deemed to be no more than minimal risk by a reviewer be considered eligible for expedited review. COGR supported the expansion of exempt research, but suggested that if additional requirements are necessary (e.g., notice or safeguards), the activity should be added to the Secretary's list of minimal-risk research qualified for expedited review. We believe these revisions would reduce administrative work for investigators and institutions without reducing human subjects protections.

COGR opposed proposed revisions that would lead to a significant increase in burden, delay, ambiguity, and cost, and a loss of valuable research without increasing protections for human subjects. These include expanding the definition of a "human subject" to include biospecimens; the proposed requirements for consent for all biospecimens regardless of identifiability and restrictions on the use of consent waivers; mandatory use of Health Insurance Portability and Accountability Act or alternative, but yet-to-be determined, data security provisions; mandatory reliance on a single IRB for multi-site studies; and the inclusion of non-regulated, unfunded trials under the regulations for organizations which receive federal grants.

In our comment letter, COGR expressed concern that elements of the NPRM are undeveloped (e.g., the decision tool; consent template; and Secretary's safeguards) and suggested that they be removed from the proposed rule and developed independently in collaboration with the research community. COGR also expressed concern about the lack of balance among the ethical principles articulated in the Belmont Report, with an emphasis on the principle of respect for persons (autonomy), and seemingly little regard for beneficence and justice. The letter also suggests a significant imbalance with respect to the benefits and costs of proposed provisions.

Biospecimens

Regarding biospecimens, COGR indicated strong opposition to the proposal to expand the definition of "human subject" to cover research with non-identified biospecimens. We believe non-identifiable biospecimens should remain excluded from the regulations and not subject to consent. There is a very low risk of harm arising from research conducted with these specimens. COGR suggested that risk to donors is addressed by removing identifiers and through the use of institutions' security safeguards and can be further mitigated by prohibiting unauthorized re-identification and imposing sanctions.

The proposed rules are of greatest concern regarding the use of excess non-identified biospecimens collected during the course of clinical care. At the time of collection, whether and how these specimens will be used in research cannot be predicted. There is no IRB protocol with an investigator at hand to obtain consent, even broad consent, and no system in place to maintain the documentation for a time when an investigator with a protocol requires access. We believe that hospitals and clinics are unlikely to develop the costly infrastructure required to obtain and track research consent for clinical specimens and that many of these specimens will be lost. We also note that many universities will not have the resources to implement tracking systems. COGR noted that a summary of ANPRM comments presented to SACHRP by an HHS Office for Human Research Protections (OHRP) staff member, indicated that a “strong majority” opposed consent for research on non-identified biospecimens that have been collected outside of a research study (i.e., leftover tissue following surgery). COGR suggested that while the intended goal of increasing autonomy is laudable, the considerable cost and potential loss of research and capacity to benefit the public at large renders this an unrealistic approach. Regarding waiver of consent for the collection and study of existing data and biospecimens, COGR noted that per the aforementioned ANPRM summary, a “very strong majority” favored allowing waiver of consent provided they are non-identified and met existing criteria. COGR questioned why the NPRM proposes to make such waivers “rare.”

Cooperative Research

Regarding cooperative research, COGR does not support a mandate for the following reasons: there is a lack of data demonstrating that relying on a single IRB, as it is proposed in the NPRM and National Institutes of Health (NIH) draft policy, is more efficient and cost effective and that such a requirement will not diminish human subjects protections; there are significant costs and timelines associated with establishing reliance agreements between collaborating research sites and maintaining required documentation at the reviewing IRB; there are ancillary review processes (e.g., conflict of interest, biosafety and radiation safety) which must still occur at each local institution and state specific requirements that may necessitate additional local review and site-specific changes to informed consent; a single IRB is not appropriate for all studies, including those where the role and protocol differs at participating sites, studies with a small number of participating sites, and social and behavioral studies. We also noted that the HHS Secretary’s Advisory Committee for Human Research Protections (SACHRP) has suggested, in response to proposed NIH policy, that mandating single IRB review for domestic multi-site studies is not the appropriate solution to improve turn-around time for human subjects research and that it is premature at this time to mandate use. COGR suggested that OHRP address institutional liability issues through guidance and partner with agencies and the research community to assess the efficiency of existing models and evaluate new models as necessary. The letter also suggests that use of the National Cancer Institute Central IRB and similar disease focused federal IRBs funded by NIH should be given serious consideration.

Consent Forms

COGR supports the notion that consent forms first provide essential information and that any additional information be placed in the appendix, and suggested that risks of standard care be moved to the appendix. COGR suggested that evidence-based guidance on form language and the entire consent process would be more beneficial than regulating the format of consent forms. We noted that we did not see the utility of the proposed provision to publish consent forms to a public website as it creates a new administrative burden without providing any clear additional protection for research subjects or benefit to the public at large.

Extending the Common Rule to All Clinical Trials

COGR does not support expanding the Common Rule to include all clinical trials which we believe would serve only to mandate single IRB for non-federally funded trials. We don’t believe that this would improve human subject protections for these studies as all institutions subject to the Common

Rule already extend this coverage, and it would extend coverage to social and behavioral studies that are of minimal risk and would not benefit from a single IRB.