COUNCIL ON GOVERNMENTAL RELATIONS
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Dr. Stuart Nightingale, M.D.
Office of the Assistant Secretary for Planning and Evaluation
Hubert H. Humphrey Bldg., Room 447D
200 Independence Ave., S.W.
Washington, D.C. 20201

Dear Dr. Nightingale:

I am writing on behalf of the Council on Governmental Relations (COGR), an organization comprising 144 of the nation's most research-intensive universities. We wish to express our appreciation for the Department's initiative in organizing and convening the August 15-16 conference on human subjects research and financial conflict of interest. The structure and the forum of the conference provided a broad perspective regarding financial conflict of interest issues and their potential impact on the objectivity of research in clinical trials. Such presentations by representatives of universities, industry groups, government, and the public are the first steps in what must be a continuing dialogue among all parties participating in the conduct of human subjects research. COGR would also like to take this opportunity to provide general comments and observations on the six questions posed for public comment upon which the conference was based.

As you are aware, the PHS regulations regarding safeguarding objectivity in research were promulgated in 1995 after a thorough study on the part of PHS including extensive public comment. It is COGR's opinion that the resulting two-phased process (the researcher's disclosure of their financial holdings which is then subjected to an institutional evaluation of the potential of these investments to distort or bias research) is a rational and prudent approach.

Concerns such as the applicability of special conditions to clinical trials vs. research and appropriate financial incentives, if any, for principal investigators (PIs) are just two of the issues with which the NIH, research institutions and the public continue to grapple. These complex concerns often are encumbered with situational variables that make management by regulation difficult. If changes are contemplated, general principles and guidelines would be more effective in preventing bias and assuring public trust in clinical research programs.

In general, two solutions have recently been offered in discussions on how best to protect human volunteers in clinical research: either eliminate all financial conflicts on the part of anyone involved in the research project; or simply disclose all financial interests to the research volunteer, because only full disclosure would inform a decision about whether or not to enter the research study.

We believe that these approaches are simplistic and neither takes the real interest of human volunteers into account. Simple elimination or prohibition of a conflicting relationship may inappropriately separate research from the university industry relationships that have served the public good through the development of modern drugs and treatments. Individual volunteers benefit as well, as the scientific basis for further clinical trials and basic research experiments is enhanced. Full disclosure, on the other hand may be too burdensome and confusing on the volunteers at an already stressful time in their life. Volunteers may be emotionally unprepared and lack time to adequately judge the significance of the disclosure. The identification and management of financial conflicts of interest must remain the responsibility of the institution, executed with special care and fully supportive of IRB operations.

Between these two approaches lie other possible options. COGR has little empirical information to assist in the design, development and evaluation of those options. Each clinical trial and its associated conflicts of interest must be evaluated contextually. Concerns valid in one case may not exist in another. We do believe that policy guidance relating to tangible financial and equity thresholds are helpful but should be evaluated periodically by both PHS and institutions.

Our membership has considered conflict management and resolution seriously for many years, and has developed institutional policies that weigh protection against acceptable risk. Several prominent speakers from institutions of higher education presented such evidence at the August conference. Their valuable experiences and insight highlighted the fact that differences between institutional structures can result in different but sound solutions. Continued meetings like the August conference will heighten awareness and motivate grantees to review and compare their current practices and policies with peer institutions.

Federal regulations for the sake of regulations are never a good solution and we would urge caution in promulgating change. Currently, universities are already obligated to perform conflict resolution and management in many areas and should continue to remain the responsible party for conflict resolution. We believe that the current NSF policy and PHS regulations are a solid basis for ongoing review, consonant with the goal of persuading other federal agencies to issue consistent rules. A simple extension of existing federal conflict of interest regulations to human subjects research irrespective of source of funding is an admirable goal but one which must be approached with caution.

Finally, COGR would like to emphasize support for your raising these issues as well as offer our full participation in future conferences and/or discussion groups. Many of the questions raised, such as relationships between entities, the optimal degree of disclosure, and the vehicles in which disclosure might best be presented – tend to have different answers depending on individual circumstances. What remains constant is the obligation of responsible parties to adhere to the ethical principles of protecting human volunteers from unnecessary risk, informing them of the risks and benefits of clinical trials, and disclosing appropriately the clinician's financial interests.

Sincerely,

Kate

Katharina Phillips