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**NIH Request for 3-year Extension of Reporting Requirements Associated with Revised
FCOI Requirements**

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COGR

an organization of research universities

COUNCIL ON GOVERNMENTAL RELATIONS

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March 27, 2015

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SUBJECT: Proposed Collection; Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding Is Sought 42 CFR Part 50 Subpart F and Responsible Prospective Contractors 45 CFR Part 94 (OD)

Dear Michelle,

The Council on Governmental Relations (COGR) is an association of over 190 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions.

COGR appreciates the opportunity to comment, on behalf of its member institutions, on the request for a three-year extension of the reporting requirements set out in the revised Public Health Services regulations; *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors*. COGR and its member institutions fully support the intended goal of the policy to promote objectivity in PHS-funded research and to improve transparency. In offering our comments, we hope to reduce unnecessary burden for investigators and institutions while maintaining the intended policy objectives.

Revisions to the Public Health Services financial conflict of interest (FCOI) policy and the associated requirements have significantly increased the administrative workload and cost associated with identifying, reviewing, managing, and reporting FCOIs. By NIH's own estimation, annualized burden hours for these requirements are 676,130 at an estimated cost of \$23,236,238. A portion of this estimate is specific to burden on the part of institutions (\$15,921,238 for approximately 2,000 awardee institutions) but data from the Association of American Medical Colleges indicates that 70 institutions alone spent \$22.6 million to implement the rule. Through a recent survey and as part of a larger effort, COGR, the Association of American Universities (AAU) and the Association of Public and Land-grant Universities (APLU) sought to assess the impact of the revised reporting requirements on member institutions and to assess the cost and effectiveness of the revised rule and specific aspects of it. While a full assessment of the impact of each of the reporting requirements was not feasible, and assessing estimated burden for investigators is particularly difficult, we would like to address the following requirements:

1. 42 CFR 50.605(a)(1): Prior to the Institution's expenditure of any funds under a PHS-funded research project, the designated official(s) of an Institution shall, consistent with §50.604(f): review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest.

The notice suggests that it will take institutions 82 hours annually to perform the activities noted above (2,000 institutions x 82 = 164,000 annualized burden hours). This differs somewhat from the estimate in the final policy, which indicates 152,000 hours (38,000 disclosures x 2 hours and 950 management reports x 80 hours = 152,000 or 76 hours per institution). We asked institutions to provide an estimate of the time it took to conduct the activities as written above. The average estimated annualized burden for the 41 institutions that responded was 2,593 hours per institution. We would suggest that 82 hours per institution is a considerable underestimate of the time it takes to review disclosures and develop and implement COI management plans.

2. 50.604(e)(1) Require that each Investigator who is planning to participate in the PHS-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.

Investigators and subrecipients are required to disclose FCOIs no later than the time of application. NIH success rates for proposals are under 20% and even 10% for some institutes. This results in significant effort on the part of investigators and institutions when 80-90% of awards will go unfunded. We ask that NIH consider allowing for disclosure prior to activation of awards, reducing a lot of unnecessary work for investigators and institutions while retaining proper oversight of FCOIs.

This requirement is particularly burdensome as it relates to subrecipients, as prime institutions are forced to ascertain - prior to proposal submission - whether a potential subrecipient has or does not have its own PHS FCOI-compliant policy and if not, either obtain a proposal from an alternative subrecipient or obtain concurrence from the original subrecipient that it will use the prime grantee's FCOI policy. When the subrecipient uses the prime grantee's FCOI policy, the prime grantee must also obtain FCOI disclosures from each key personnel at the proposed subrecipient - all before a proposal is submitted. The prime grantee must then document its records with these parameters, arrange for subrecipient personnel to obtain FCOI training and ascertain whether or not it wishes to review any positive disclosures in advance of learning whether the proposal will be funded. This represents a labor-intensive process that is ultimately needed only 10-20% of the time. Further, for foreign collaborations, many of the foreign institutions do not have their own FCOI policies and adopt those of the prime, significantly increasing burden on the prime. As noted above, institutional staff are spending a substantial amount of time reviewing disclosures and developing management plans. Allowing for disclosure prior to activation of awards would significantly reduce this burden.

The final rule indicates that HHS will evaluate the effect of provisions of the regulations such as the *de minimis* and the public accessibility requirement within three years following implementation (August 2015). Evaluating regulatory changes to assess their effectiveness and economic impact is critical and we appreciate the inclusion of this provision. In advance of a review, we would like to submit the following data gathered in the aforementioned survey of COGR, AAU and APLU members. Please note that we are still awaiting results from several institutions. As additional data becomes available, COGR will continue to keep the agency informed. In response to our survey, institutions provided the following information:

In terms of cost, the 34 institutions that provided data on costs indicated that they spent \$10,555,993 on FCOI in the year subsequent to implementation of the PHS FCOI revisions with a significant range in cost (\$495-\$2,300,000) related to the size of an institutions research program. Among the 34 institutions that provided data on costs in the years prior and subsequent to the implementation of the revised policy and requirements, there was an increase of \$2,682,090 in costs. It must be noted that this is not an accurate assessment of the increase in cost as we learned from institutions that they were planning and implementing changes leading up to Final Rule implementation date. Therefore costs the

year prior to implementation were already significantly escalated at many institutions. Further, a number of institutions with sizable research programs were unable to provide data in the timeframe specified (20 institutions were unable to provide cost data).

Institutions reported a 110% increase in the number of disclosures in the year subsequent to the implementation of the revised rule/requirements. We have heard from members since the implementation of the revised rule, that while certain revisions have significantly increased the number of disclosures that investigators must make and institutions must review, they have not led to measurable COI to manage. Of the 5,784 disclosures reported for FY14 that only identify travel and outside income from non-profits (including foreign IHEs), 20 resulted in COI to manage. Of the 35 institutions that reported data, 29 found no COI to manage.

We have also heard that PHS disclosures >\$5K and <\$10K do not result in a measurable increase in COI to manage. For this requirement we found a greater number of disclosures with COI to manage, but with a relatively high degree of variability between institutions. Of the 2,929 disclosures reported from 33 institutions for FY14, 249 disclosures resulted in COI to manage, 185 of which were from 3 of the 33 institutions that reported data.

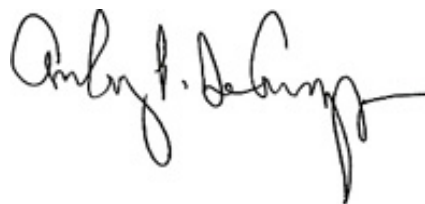
We appreciate that the 2011 revisions stem from a legislative mandate that HHS strengthen Federal and institutional oversight of financial conflicts of interest among NIH-funded investigators. At the same time, it is important to note that Congress did not identify a single investigator, or question the objectivity of their research, whose financial conflicts involved travel reimbursement or consulting fees under \$10K. Those identified fell into the category of significantly higher payments while also **failing to report under existing regulatory thresholds**. Adding unnecessary burdens through lower thresholds does not address the root cause or concern.

Although Congress was the impetus for the PHS policy revisions, members of Congress have also increasingly called for optimizing use of federal funds for research by reducing the administrative workload of investigators and the cost of research administration to institutions, most recently through appropriations language (requiring NIH to form an administrative burden working group); a Senate appointed Task Force on Higher Education Regulations; a National Academy of Sciences Committee on Federal Research Regulations and Reporting Requirements (funded with \$1 million set aside in the FY14 Omnibus); and pending legislation (H.R. 1119 – the Research and Development Efficiency Act). The revised PHS FCOI policy presents unnecessary administrative burden that could be reduced through modifications while still maintaining the enhanced Federal and institutional oversight and transparency Congress sought.

As noted earlier, we believe that the agency has underestimated annualized burden and cost. COGR is asking NIH, in its current assessment of the reporting requirements and future review of the policy revisions, to consider modifying requirements to reduce unnecessary burden and cost, including the requirement to report significant financial interests at the time of application, and eliminating policy requirements that have led to a significant increase in FCOI disclosure without contributing to a significant overall reduction in FCOI. Among them, the requirements to disclose travel expenses and outside income from non-profits and the lower reporting threshold.

Thank you again for the opportunity to comment. We appreciate your consideration of the issues highlighted in this letter.

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony DeCrappeo". The signature is fluid and cursive, with a long, sweeping tail on the final letter.

Anthony DeCrappeo