COGR
an organization of research universities

COUNCIL ON GOVERNMENTAL RELATIONS
1200 New York Avenue, N.W., Suite 750, Washington, D.C. 20005
(202) 289-6655/(202) 289-6698 (FAX)

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Jerry Moore
NIH Regulations Officer
Office of Management Assessment
National Institutes of Health
6011 Executive Boulevard
Suite 601, MSC 7669
Rockville MD 20852-7669

Subject: RIN 0925-AA-53, Docket No. NIH-2010-0001: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors

Dear Mr. Moore:

The Council on Governmental Relations (COGR) is an association of 183 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. The amendments proposed by the Public Health Service (PHS) to the *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought* are significant changes that will alter the relationship between a research institution and its investigators and the institution and PHS.

OBJECTIVITY

We believe that any amendments to the current regulations at 42 CFR 50, Subpart F and 45 CFR Part 94, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought should be grounded in achieving the goal of the regulations – ensuring objectivity in research. Elements that do not serve this purpose need to be weighed very carefully to make certain that the costs in terms of time, resources, and the effects on the research endeavor contribute to the benefit in terms of objectivity. We understand the increased emphasis on accountability within the Federal government and appreciate the President's goal "to promote accountability and provide information for citizens about what their Government is doing." However, in determining the best approach to accountability in research, we urge PHS to keep the principle of objectivity in mind as it considers changes to the policy.

TRANSPARENCY

Our institutions share the goal of transparency about financial conflicts but want to be sure that the methods used to achieve it provide an

objective, accurate and useful picture and do not result in misleading and damaging conclusions. The Federal government, industry and research institutions have partnered for decades to create one of the most robust and productive research endeavors in the world. It is appropriate that the existence of financial conflicts be identified, that they be managed as warranted, and, as necessary, that related information is made accessible to the public. But how this information is made available can spell the difference between effective accountability and the unnecessary harassment of researchers who have done nothing improper.

The value to the public of posting financial conflicts of interest (FCOI) in the manner proposed by PHS is debatable because the general public may not have the context to measure the relevance of the information. The damage that can result from this requirement is predictable. The danger lies in the assumption by a less-informed public that any and all FCOI is bad and will, with certainty, bias the research outcome. Because such an assumption will result in a diminution of the reputation of the investigator, we fear investigators will either limit or abandon useful translational relationships with industry. With the inclusion as reportable significant financial interest (SFI) relationships with small businesses through PHS-sponsored Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs and nonprofit organizations; the expansion of the types of remuneration to be reported; and other changes throughout the proposed rule, we are concerned that investigators, especially new investigators, will no longer be as willing to engage in the applied and development work that helps translate research to treatments and, ultimately, improvements in public health. Nor do we believe that the public posting of FCOI as described will "assist PHS in strengthening [its] oversight and ensuring proper management." PHS will have significantly more information in the reports provided by the awardees to successfully meet its oversight and management functions.

We are concerned with maintaining the privacy and confidentiality of identified financial information, a concern exacerbated for institutions, generally state-assisted, that manage FCOI as a part of their personnel systems which, given privacy issues, will be severely limited in their ability to post information as required. As PHS knows, some information often leads to requests for more information. Institutions are afraid that the time required to respond to requests for additional information under Freedom of Information (FOIA) requests and states' open records laws will detract significantly from the work of institutional systems designed to review and manage FCOI.

Reconsider the Requirement for Public Posting

We recommend that PHS eliminate the requirements proposed at §50.605 (a)(5) [and all related references] and engage in a focused consultation with the research community on how best to achieve accountability and transparency that ensures the public trust in the research enterprise. After a public consultation and consideration of comments received concerning the website from this NPRM, PHS could propose an amendment that reflects these consultations. Such a consultation must include a consideration of whether it is more appropriate for PHS, through the National Institutes of Health (NIH), to maintain a publicly accessible website or information. NIH maintains profiles of PHS/NIH supported investigators and will receive the bulk of reported FCOI. Building on this system of information, a website developed and maintained by PHS may provide greater consistency in reporting and enhanced usefulness for the public.

If PHS believes it must implement this provision for making FCOI information available via a publicly accessible web site as a part of the amendments under consideration in this NPRM, we urge PHS to delay implementation of the requirement until no earlier than October 2013. This date would coincide with the deadline faced by the Department of Health and Human Services (HHS) for meeting the provisions of the Affordable Care Act (PL 111-148) to post information concerning industry

payments to physicians and teaching hospitals. This timetable for implementation would allow for a consultation with the research community to help determine the most appropriate information, the most useful format and the most appropriate approach for implementing a publicly accessible website. Such a timetable would allow for the consideration of a reporting structure that is consistent with posted information on industry payments to physicians and teaching hospitals to avoid incompatibilities like the timing of payments or varying payment periods.

Our proposed implementation will provide time for institutions to modify and link internal electronic systems to provide for the public posting and to streamline the required annual updates to the information. It will accommodate those institutions that rely on commercial entities for electronic systems to provide for the development of a FCOI module in time for implementation of the requirement. And an extended timetable will address a major concern for the research community in implementing this provision – PHS' significant underestimation of the costs related to such a publicly accessible posting.

MEETING THE COSTS

There will be substantial costs associated with the rule as proposed. The implementation costs – modifying systems for disclosure, review and reporting, etc. – will be significant as will the on-going operational costs – reviews, monitoring of management plans, and training.

Operational Costs:

PHS' assessment of the costs of implementation and operation of the proposed rule fail to address the total burden of the policy. To identify those investigators with SFI related to research and ensure compliance, most institutions will require disclosures from all PHS-supported investigators, including negative reports. The estimate of $35 per institution for the public posting of FCOI ignores the information and business system developments and on-going operational and administrative processes that will be a part of collecting, reporting and annually updating the information. The costs of providing training, of implementing and monitoring management plans, of monitoring subrecipients, etc., increase the on-going costs of compliance. The estimates provided by PHS do not reflect these real costs.

We find it disingenuous for PHS to suggest that the costs of compliance with the amendments will be recovered through the Facilities and Administrative (F&A) costs recovered on PHS grants. While they may be allowable, PHS knows that the administrative component of the F&A has been capped at 26% since 1991 – before the original, current Objectivity in Research regulations were put in place. Institutions have been absorbing the costs of compliance with these regulations since 1995. We have been "absorbing" PHS/HHS regulatory costs across agencies and programs – including the policies and regulations covering Research Misconduct, Select Agents and Toxins, Data Sharing, Public Access, Model Organisms, Human Embryonic Stem Cells, and Genomic Inventions, to name a few – within a capped administrative cost and without fully recovering our F&A from HHS/PHS agencies – notably the career and training programs sponsored by NIH and called out as a part of the proposed amendments. If PHS believes these costs should be covered by F&A recovery, we urge PHS to ensure that full F&A is paid on any and all programs whose investigators may fall under these regulations.

Implementation Costs

In order to address some of the costs associated with the implementation of all the new requirements – education, disclosures, reporting, managing, monitoring, etc. - we ask PHS, through

NIH, to provide support in the form grants through an **Ensuring Objectivity in Research Enhancement Program** (ORE) similar to the 2002/2003 program designed to strengthen oversight of human subjects research. As with the earlier program, the ORE program would provide short-term interim support for institutional activities to address the same type of challenges of increased scrutiny and demands for oversight, enhanced protection, and increased education for those conducting research.

ORE grants could support the development of educational initiatives, the creation of tracking systems for monitoring, infrastructure and technology development, equipment to support FCOI-based activities, etc. An investment by NIH similar to the investment in human subjects' research enhancements – at least $28.5 million in the first year – will ensure its principal partners are in a position to comply with the requirement.

PHS must address in a more realistic manner the costs to the research community for implementing and operating the regulations as proposed. As with all sectors of the economy, research institutions are struggling to maintain access to higher education and research opportunities in the face of declining resources. Unlike other sectors, the research community has been confronted with an ever-increasing list of unfunded Federal regulations and policies covering a range of concerns and issues – from research involving recombinant DNA to select agents and toxins, from HIPAA privacy rules to chemical anti-terrorism standards. Without relief from additional regulations or real assistance in meeting the costs, institutions will begin to reconsider and, in some cases, decline to participate in research critical to the nation's well-being.

COMMENTS ON SPECIFIC SECTIONS OF THE PROPOSED RULE

Our comments focus on those elements of the proposed rule that will make fundamental changes to the operation of institutional efforts to identify and manage financial conflicts of interests. We have organized them in response to the proposed amendments to 42 CFR Part 50 but would urge consistent changes in Part 94 as well. This approach to organizing our comments does not imply a ranking of our concerns. We propose changes to some of the amendments because of the impact of the proposed change on a different part of the regulations.

Definitions §50.603

Institutional Responsibilities: We understand that the list included in the definition is not intended to be inclusive but is intended to identify specific responsibilities that must be considered by an investigator assessing their financial interest. However as is the case in many aspects of institutional governance, the meaning of institutional responsibilities varies by institution and by employee status. We believe it would be more appropriate for the institution's definition of responsibilities to prevail in meeting the requirements of the regulation. The definition could be modified to read:

> *Institutional responsibilities* means an investigator's professional responsibilities **as defined by the institution that may include**, but **are** not limited to, activities such …

Investigator: Because of the breadth of requirements for disclosure and management included in the proposed regulations, we are concerned that unfunded collaborators and consultants who provide informal advice and counsel to an investigator will be swept up under the policy. We suggest that collaborators and consultants be modified to include either those identified in the PHS-funded/proposed research application and/or those making a substantive contribution to the project. The definition could be modified to read:

> …including persons who are subgrantees or contractors and collaborators or consultants **identified in the grant application as senior or key personnel and making a substantive contribution to the design, conduct or reporting of the proposed research**.

Significant Financial Interest (SFI):

[50.603, SFI (1)] In order for the rule to be applied consistently across all applicant organizations and capture the individuals who should be considered in the identification of SFI, we recommend that "spouse" be changed to the more generic reference "**spouse or domestic partner, consistent with the institution's policy or general practice and/or as applicable under state law**, and dependent children" We recommend this change throughout the proposed amendments. [See also 50.603 SFI (1)(ii); 50.604 (e)(1)]

[50.603, SFI (1)] In order to focus the disclosures by investigators and assist the institution in making determinations of the relationship between the SFI and PHS supported research, we recommend the SFI "be related to the Investigator's institutional **research** responsibilities" using the examples provided in the Notice concerning responsibilities.

[50.603, SFI (1)(i), (ii)] The proposed regulatory amendments shift the parameter for an interest from remuneration anticipated in the next twelve months to remuneration received in the preceding twelve months. This could result in a situation in which an investigator discloses a SFI that no longer exists but that the institution will be forced to manage in a manner consistent with all elements of the regulations. Alternatively, an investigator may anticipate receiving more than $5,000 from an entity during the first 6 months of a project but would not, under the proposed language, be expected to disclose that future income. We recognize that the requirement effectively seeks an annual disclosure by investigators but believe that institutions should be able to establish the appropriate annual reporting period. The definition could be modified to read:

> …the **annual** value of any remuneration received from the entity and the value …

[50.603, SFI (1)(i)]: The proposed rule includes for purposes of calculating SFI, remuneration in the form of travel reimbursement. We recommend deleting travel reimbursement from the calculation of SFI. As a part of institutional and professional responsibilities, many investigators serve on advisory and peer review panels for scientific societies, journals, and non-profit research organizations. Such reasonable and customary costs related to participation in terms of travel are usually covered by the sponsoring society or organization and, in many cases, paid directly by the organization. It is unlikely such a reimbursement would constitute a FCOI but we believe that the inclusion of travel reimbursement is an unnecessary and unproductive burden and should be deleted.

[50.603, SFI (1)(iii): We recommend three changes to the description of intellectual property in the disclosure of SFI. In order to provide a consistent approach for setting a value for SFI, we propose an annual value of $5,000. Often investigators will have copyrights in publications and other materials that provide very modest royalty payments. The disclosing of these types of payments whether from royalties or copyrights will not be significant enough to warrant the level of review activity required.

We urge the exclusion of unlicensed intellectual property from the disclosure. We know that many of the university-owned patents remain unlicensed and without a license the value of an asset like a patent is impossible to determine. In a similar manner, the value of a copyright for material that is unpublished or unlicensed is indeterminate and the review of that information wastes resources without serving the public's interest. This exclusion can be added here or in §50.603 SFI (2).

Finally, we seek to clarify the relationship between intellectual property rights held by the investigator as opposed to those assigned to the institution. A related clarification concerning assigned

intellectual property could be included in §50.603 SFI (2). We recommend modifying the description of intellectual property rights in the following manner:

> **Licensed** Intellectual property rights (e.g. patents, copyrights), royalties from such rights and agreements to share in royalties related to such rights **of an annual value of more than $5,000 except for intellectual property (e.g., patents, copyrights) that are assigned to the institution employing the investigator**.

The clarification concerning assigned intellectual property in §50.603 SFI (2) could read:

> . . . the following types of financial interest: Salary, royalties, or other remuneration paid by or intangible property assigned to the Institution . . .

[50.603 SFI (2)]: The financial interests excluded from the definition of SFI *currently* includes nonprofit entities, in general, rather than proposed limitation on the exclusion to "an institution of higher education as defined at 20 USC 1001(a)." This limitation on the exclusion has a significant impact on an investigator in meeting their institutional and professional roles and responsibilities particularly when linked to the inclusion of travel reimbursements as a part of the calculation of SFI (we have recommended deleting travel reimbursement from the calculation of SFI).

The definition of an institution of higher education at 20USC1001(a) does not include many teaching hospitals and medical centers or affiliated research foundations and institutes that are separate legal entities from but closely affiliated with or controlled by institutions of higher education. In a similar manner, research institutes that function like an institution of higher education from a research perspective but do not award degrees would be swept up under the regulations as proposed. We understand that some tax exempt entities are created by and/or principally if not fully funded by for-profit entities and remuneration from those entities deserves careful review. Rather than highlighting the formal non- or for-profit status, we recommend defining the exclusion by function or role. We believe the most judicious approach is to modify the current sections and include a new definition for the purposes of this regulation. This section could be modified to read:

> Income from seminars [or service] … or an institution of higher education as defined at 20 USC 1001(a), **a medical center, foundation and/or research institute or other tax exempt entity controlled by or having the primary purpose of supporting an institution of higher education; a teaching hospital, and/or a independent nonprofit research institute with the purpose of the conduct of research governed by these regulations; and other tax exempt entities as defined for the purposes of this regulation.**

The related definition could focus on those non-profit, tax exempt entities that are included in the related exclusions and those that are not.

> *Tax-exempt, non-profit entities* means entities having as a fundamental or primary purpose supporting an institution of higher education [e.g., a research foundation]; or is controlled by an institution of higher education to support the institution and its research or educational mission [e.g., a research foundation or research laboratory]; and/or a independent nonprofit research institute with the purpose of the conduct of research governed by these regulations; or an entity, taxable or tax exempt, having a formal affiliation in support of the institution's research mission. The last category could include a formal institutional relationship with a for-profit entity to pursue a project that serves the institution's research or educational mission. If an investigator separately works for the for-profit entity as a consultant or on an advisory board, then, in some circumstances there may be a conflict. However, when the activities of the investigator are conducted within the scope of the formal agreement with the institution and the investigator is acting in his or her institutional capacity, the investigator does not have a

conflict. The agreement and related activities serve the research or educational mission. Included in this definition are organizations and entities that provide research support through competitive grant programs subject to peer review [e.g., the American Cancer Society] and/or serve as professional organizations or associations for individuals or entities engaged in research activities [e.g., the American Society for Microbiology].

Not included in this definition are tax-exempt organizations that are created by or receive principal funding from taxable entities that may have an interest in the outcome of research.

[50.603 SFI (2)] We assume and ask PHS to confirm that income received for seminars or service for a Federal, state or local government agency but passed through or paid by a private contract organization acting for the government agency, e.g., to organize a peer review panel, etc., will be excluded from disclosure as SFI.

[50.603 SFI (2)]: We recommend that mutual funds and retirement accounts be expressly exempted from the definition of SFI because investigators do not control the investment decisions made by fund managers.

Responsibilities of Institutions §50.604

Institutional Standards [50.604 (a)]. We strongly object to the assumption of institutional standards, if more stringent, as the prevailing standards governing this proposed rule. The consequence of this proposed approach will be the establishment of varying federal standards for reporting which is not, in our opinion, in the federal government interests in terms of oversight and enforcement. The alternative is the unfortunate but predictable modification by institutions of their current more stringent policies to match the proposed PHS standards so as to avoid application of the proposed amendment's requirements to situations not covered but the amendments thus taking on an increased compliance liability. Institutions should be required to adhere to the PHS standards for purposes of disclosure and review of SFI; interactions with sub-recipients; determination, management and reporting of FCOI – all operational aspects of the proposed rule.

Research institutions have divergent and sometime competing requirements if they are state-assisted institutions. States may impose different, more stringent reporting standards often as a part of their state procurement regulations. The PHS proposed approach will force these state-assisted institutions to implement a Federal requirement within the constraints imposed by state statutes that seek to address very different policy concerns.

Institutions have implemented a variety of standards for the disclosure of financial interests and relationships including, for some, the use of a $0 threshold in some or all cases. Others choose a risk-based approach to the management of FCOI. Concluding that financially driven bias introduced in clinical research has consequences beyond the integrity of the research record, some institutions apply a more stringent standard for clinical and/or drug or device driven research. These institutions use a tiered approach to disclosures and management that recognizes the risks to human subjects in clinical research as different from the risk associated with basic and social and behavioral human subjects research. How would PHS view such a tiered approach under this proposed rule?

There should be no disincentive to either broad-based or focused institutional approaches beyond the PHS requirements. With the increased management activities proposed in the rule, we anticipate that many, if not most, will modify their institutional policies for PHS-supported research to conform to the standards set by PHS. Nonetheless, these same institutions will likely choose to develop separate policies and/or standard operating procedures from the proposed PHS policy to address requirements from other Federal agencies and/or private sponsors. This result will be

detrimental to the overall purpose of the proposed rule, will increase administrative burdens without corresponding benefit and will create an unintended disincentive to establish more stringent standards.

Training [50.604(b)]: We support the training of investigators on institutional policies and the PHS regulations, as appropriate. We believe this training should occur prior to engaging in PHS-supported research. Any additional training or education should occur when additional education is warranted. This approach is the standard that NIH applies to the frequency of education in other areas, notably in human subjects protection. As NIH notes in the case of human subjects protection, "NIH policy is silent on the frequency of education. The intent of the education requirement is for investigators to keep abreast of development in human subjects protection. We believe that institutions and investigators are in the best position to determine when additional education is warranted." In the case of objectivity in research and financial conflicts of interest, institutions are in the best position to determine the frequency of education and training.

Sub-recipients [50.604 (c)]: The proposed provisions for managing the relationship between a prime PHS-funded recipient or awardee and any sub-recipients are unnecessarily cumbersome and burdensome. Moreover, the proposed provisions are unlikely to have effective results when they shift responsibility to the awardee that is less likely to have first-hands information and ability to monitor compliance. The challenges associated with holding the prime awardee responsible for the subrecipient's investigators is exacerbated when the subrecipient is a foreign entity. We are concerned that requiring foreign investigators to comply with a US law will create significant concern in the scientific community. We can reference the PHS regulations in an agreement and require a similar set of steps be followed by the subrecipient but cannot legally compel non-citizens residing in a foreign country to comply with US law. The proposed rule dictates specific elements of the agreement and moves away from the assurance process that parallels the relationship between the awardee and the PHS agency. As an alternative, we recommend the following language for 50.604(c)(1):

> When the institution participates in PHS-sponsored research with a sub-recipient, the awardee Institution will take reasonable steps to ensure that the sub-recipient is informed of its obligations to comply with all applicable financial conflicts of interest disclosure, review and reporting requirements as required/described by PHS regulations governing financial conflicts of interest. The requirement is satisfied if the contract or other agreements with the sub-recipient includes a provision setting forth these obligations. The awardee institution's agreement with the sub-recipient will establish whether the awardee institution's financial conflict of interest policy or that of the sub-recipient applies to the sub-recipient's investigators.

Determination of a Financial Conflict of Interest: [50.604 (f)]: We recognize that the institution is ultimately responsible for determining whether a financial conflict of interest related to PHS-supported research exists. We understand that PHS recommends the determination proceed in two steps: first, the determination of whether the disclosed SFI would be affected by the PHS research or is in an entity whose interests would be affected by the research and, thus, related to PHS research; and, if so, whether that SFI could directly and significantly affect the research, itself, and, thus, constitute a FCOI.

There is wide concern in the research community over how to best utilize the criteria outlined by PHS in the proposed rule and that maintaining some responsibility with the investigator – while strengthening the responsibility of the institution – is critical. We understand that PHS' assumption is that the institution will make a reasonable, as opposed to an absolute, determination in both cases. In making such an informed, reasonable decision, it is important for PHS to recognize that Institutions will make the determinations required based on the information available to it. In the first instance, this must be what the investigator discloses because he or she is the only person who can comprehensively identify all of his or her activities that involve SFI. In many cases, once all SFI activities are identified

by the investigator, the institution will consult with the investigator to determine whether the disclosed SFI has a relationship to the PHS-supported research or is in an entity that could be affected by the research.

It is critical that the institution be responsible for evaluating the relationship of the SFI to the research and the effect on the research. But it is also critical that the investigator be required to disclose all SFI activities to the institution. The institution cannot be successful without complete information from the investigator and should not bear responsibility for the investigator's failure to fully and timely disclose. We recommend that the rule make all these responsibilities clear. In a similar manner, the institution will make a reasoned decision on whether or not the SFI would directly and significantly affect the research based on the information available to it. Institutions understand their responsibility. We ask that PHS agencies understand the challenge.

Management Plan [50.604 (g)]: We recommend the deletion of the reference to a mitigation plan and will describe the rationale under the discussion of section 50.605. The end of the paragraph would read:

> …and implementation of a management plan. ~~And, if necessary, a mitigation plan pursuant to §50.605(a).~~

Management and Reporting of Financial Conflicts of Interest §50.605

Mitigation Plan [50.605 (a)(3)(ii)]: We believe the proposed creation of a mitigation plan in those cases of undisclosed SFI is entirely unnecessary and should be eliminated. The required management plan is designed to ensure that FCOI do not bias the research. The proposed mitigation plan adds nothing to that effort and sets an ambiguous, at best, expectation that a determination of bias has occurred. If research misconduct – fabrication or falsification of data – is suspected or alleged, we have separate policies to address that allegation. Even in those cases where a SFI is intentionally not disclosed, that breach of institutional policy would be addressed under professional misconduct or disciplinary rules and be dealt with at the institution. The institution could report that to PHS and the report could indicate whether a mitigation of prior published research results in warranted. We recommend that section 50.605 (a)(3)(ii) be deleted in its entirety.

Publicly Accessible Web Site [50.605 (a)5)

As noted in the earlier discussion, we recommend that PHS eliminate the requirements proposed at §50.605 (a)(5) [and all related references] and engage in a focused consultation with the research community on how best to achieve transparency that ensures the public trust in the research enterprise. After a public consultation and consideration of comments received concerning the website from this NPRM, PHS could propose an amendment that reflects these consultations.

This consultation with the research community must help determine the most appropriate information, the most useful format and the most appropriate approach for implementing a publicly accessible website. For example, we are concerned with the posting of FCOI that may be linked indirectly to the investigator, i.e., remuneration received by the investigator's spouse or partner or dependent child. The question of extending by domestic relationships the PHS policy requirement to third parties may reasonably prompt those third parties to assert their privacy rights, particularly when that third party information is potentially open to a FOIA request. If we have misread the proposed rule and PHS does not intend to post the financial interests of third parties on the publicly accessible website we are relieved. A major concern for the research community in implementing this provision is PHS's significant underestimation of the costs related to such a publicly accessible posting. We provide an extended discussion of the costs and propose solutions for meeting those costs in the earlier discussion.

50.605(a)(5)(iv): Five Year Posting: If PHS proceeds with a requirement for a publicly accessible web site, the availability of the information should conform to the **three year** federal government's record retention requirements as described in Circular A-110 Subpart C._.53./ 2CFRPart 215.53. Retention and access requirements for records, which states: "(b): Financial records, supporting documents, statistical records, and all other records pertinent to an award shall be retained for a period of three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, as authorized by the Federal awarding agency."

Reporting on FCOI to PHS [50.605 (b)]:

Eliminate reference to mitigation plan [(b)(2)]: We recommend the deletion of the reference to a mitigation plan and have described the rationale under the discussion of section 50.605(a)(3)(ii). The paragraph would end:

> …and ensure that the Institution has implemented a management plan in accordance with this subpart. ~~Where such FCOI report involves significant financial interest that was not disclosed . . . [to the end of the paragraph] or reporting of such research.~~

PHS Assessment [(b)(3)]: We urge PHS to develop guidance/training materials for the agency staff to ensure a consistent approach to the assessment of FCOI reports. We understand that the current practice is review by agency program officers, in the case of NIH, by the NIH Institute/Center (I/C) program officers. Will the process of review under the new policy change? If the I/C program officers will retain the responsibility, we worry that each program officer will develop a set of understandings and expectations for the appropriateness of a management plan that may vary significantly within an agency. Awardees need some consistency in reviews across the agency. Will PHS prepare guidelines for the agency staff consistent with the proposed rule and provide the affected communities an opportunity to comment on those guidelines?

Management Plan Elements [(b)(3) (i-vii)]

[(b)(3) (v)]: Value Ranges : We seek consistency between the value ranges used for the FCOI report to PHS and the FCOI reports posted to a publicly accessible website. A modification of the values ranges here or at 50.605(a)(5)(ii) will assist institutions in developing electronic systems that meet both requirements. We are not seeking to report detailed information above $250,000 in the public posting. Thus, the ranges here would be: less than $5,000; less than $10,000; less than $20,000; etc.

[(b)(3) (vii)(D)]: Safeguarding Objectivity: The entire purpose of the management plan is to safeguard objectivity in research. Absent a rationale for this section and/or examples of what might be included in this section (in guidance), this section is unnecessary and should be eliminated.

General Comments:

Institutional Financial Conflicts of Interest: We applaud PHS's caution in proceeding with regulations that would govern institutional financial conflicts of interest. In our opinion, any attempt to develop broad-based comprehensive regulation that would cover all the organizations that apply for and receive support from PHS would have been premature. We have worked with our member organizations to develop resources to assess and consider such institutional policies. We know from those discussions that the subject is extraordinarily more complex than it appears and requires institutionally unique responses. For PHS to have simply inserted a requirement to have and enforce an institutional conflict of interest policy within these proposed amendments without grappling with

the difference between investigator and institutional FCOI would not have been helpful in moving the discussion and efforts of the research community forward.

Implementation: PHS does not offer a proposed effective date or proposed timeline for implementation. As discussed above, if the requirement to make information available on a publicly accessible web site remains as a part of the regulations, we ask that the effective date for this requirement be no earlier than October 2013. In general, the research community needs as much time as possible to fully implement the additional requirements of the proposed rule as written. Some will need to modify internal disclosure systems to accommodate a shift from transactional disclosures to annual disclosures. To fully capture their investigators without over burdening the investigators with repetitive administrative tasks, these "transactional" institutions need at least a year to meet the annual requirement. If NIH can assist the community with Objectivity in Research Enhancement grants, we would like to be able to use the results of those grants – the materials and resources – t o assist in training, tracking, etc. We recommend that PHS stage the implementation of the amendments in such a way to ensure continuing compliance with current regulations while moving toward implementation of the new requirements.

We assume and ask PHS to confirm that the policy, when implemented, is not to be applied retroactively, particularly with regard to the inclusion of Phase 1 SBIR and STTR awards, and that it applies only to new awards, as opposed to non-competing continuations and other on-going incremental funding mechanisms. For example, with the change in threshold from $10,000 to $5,000, an investigator receiving a non-competitive continuation may hold a SFI between $5,000 and $10,000 that was not report previously. We must be able to implement the proposed rules in a reasonable manner that captures SFI as appropriate. Some institutions may elect to apply the new regulations across all awards; others may choose to narrow the applicability of certain elements to on-going activities.

Enforcement Authorities and Investigator and/or Project Transfers

In the July 21, 2010 *Federal Register* notice that extended the comment period, PHS asked for comments concerning the adequacy of its enforcement authorities and the application of the regulations in the circumstances when an investigator or PHS-funded project transfers to another institution.

We believe that the current and proposed regulations are clear concerning PHS's enforcement authorities and the range of remedies available to HHS and the PHS awarding component with regard to the grantee are sufficient. As to the need to notify another institution of a transferring investigator's FCOI, if the rule is implemented as proposed the information concerning an identified FCOI related to PHS-funded research will be posted to a publicly accessible website and should meet any need for notification. If HHS or PHS concludes that additional notification is necessary, HHS and PHS should consider placing restrictions on the investigator to conduct PHS-funded research, directly. The individual's standing with the Federal agency is the only relationship that can follow an individual to another institution.

We would not support a requirement that the designated institutional official "must consider" a FCOI determination and management plan made by another institution. Compliance with the regulations is an institutional responsibility met jointly by the institution and the investigator. Each institution will have specific policies and procedures for disclosures, determinations and management and must have the freedom to utilize whatever information it considers appropriate and germane in making its determinations.

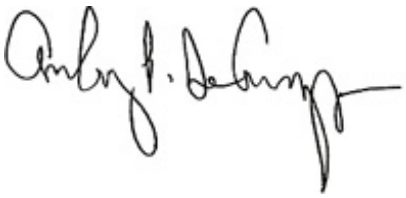
In conclusion:

We want to ensure that any amendments to the PHS *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought* requirements achieve the goal of promoting objectivity. We believe the publicly accessible web site posting of FCOI as proposed does not meet that goal and should be withdrawn at this time. We urge a consultation with the affected communities to determine the most effective approach to providing useful information to a general public on the management of financial interests as they relate to federally supported research.

We ask NIH to consider a targeted grant program to support the development of effective models for the community to use in achieving compliance. Research institutions need time to develop strategies and mechanisms to meet the compliance obligations either under the proposed grant program or independently and ask PHS to establish a timetable for the implementation of these requirements that acknowledges that complexity. We believe that the effective date for this policy should not occur before October 2013.

The research community is committed to working with PHS to ensure the objectivity of the research supported by PHS agencies.

Sincerely,



Anthony P. DeCrappeo

President