REPORT OF
THE BOARD OF SCIENTIFIC COUNSELORS WORKING GROUP
FOR THE REVIEW OF
THE NATIONAL TOXICOLOGY PROGRAM CONTRACTS
FOR CONFLICTS OF INTEREST

6/22/2007

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Executive Summary

The National Toxicology Program (NTP), an interagency program within the Department of Health and Human Services (HHS), was established to coordinate toxicology testing, develop and validate improved testing methods, carry out research and testing to strengthen the science base in toxicology, and to provide information about potentially hazardous substances to regulatory and research agencies, medical and scientific communities, and the public. To help accomplish its mission, NTP utilizes the services of a number of contractors.

In response to concerns about potential conflicts of interest in NTP contracts and to ensure the integrity of its science, the NTP director committed to convening a Working Group (WG) of the NTP Board of Scientific Counselors (BSC) to evaluate and assess existing NTP contracts for conflicts of interest (COI), including personal and organizational conflicts of interest (OCI).

The NTP assembled the BSC WG. Members included the Head of the Contracting Activity (HCA) as Chair, NIH procurement analysts, and scientists in relevant fields of expertise (Attachment 1). Current COI requirements were reviewed and discussed by the WG. In conducting their review, the WG analyzed each NTP contract and Statement of Work (SOW) as well as the extent of government oversight to determine the degree of risk for potential conflicts and/or impaired objectivity. Questions were sent to a cross-section of NTP contractors in an effort to assess the compliance of their COI policies with law and regulation, and to determine the existence of any COI. The WG relied on the contractor's self-certifications regarding conflicts with current clients as the HHS Office of the General Counsel (OGC) has indicated that this is normal, reasonable business practice in the absence of specific factual allegations of impropriety. To gain a better understanding of the contracts and how they operate and interrelate, the WG also held discussions with NTP project officers responsible for various contracts including the NTP contract for pathology support. Based on the data provided, the WG did not find any evidence of actual or apparent COI in any of the cross-section of contracts reviewed.

The WG identified a number of best practices and specific areas where improvements could be made by NTP/NIEHS, as well as by the entire NIH, that could result in identifying COI as early in the acquisition process as possible in order to avoid, neutralize or mitigate those COI. This report represents the consensus of the WG.

Background

The National Toxicology Program (NTP) was established in 1978 as an interagency program within the Department of Health and Human Services (HHS) to serve as a focal point for toxicology research and testing activities. The Director of the National Institute of Environmental Health Sciences (NIEHS), a part of the National Institutes of Health, also serves as director of the NTP. NTP has four main goals: (1) to coordinate toxicology testing programs within the federal government; (2) to strengthen the science base in toxicology; (3) to develop and validate improved testing methods; and (4) to provide data and information to health and regulatory agencies, medical and scientific communities, and the public. NTP maintains a number of complex, interrelated research and testing programs that provide unique and critical information needed by health, regulatory, and research agencies to evaluate potential human health effects from chemical and physical exposures. NTP invites public input and participation in many of its activities. The program receives oversight from several advisory groups including the federal NTP Executive Committee, which has members from HHS and non-HHS health research and regulatory agencies, and two federally chartered advisory groups, the NTP Board of Scientific Counselors whose members are appointed by the Secretary, HHS, and the Scientific Advisory Committee on Alternative Toxicological Methods, a congressionally mandated committee whose members are appointed by the Director, NIEHS. NTP is recognized as a leader in toxicology research and testing both nationally and internationally. To maintain its leadership role, NTP is continually evolving to remain at the cutting edge of scientific research and to develop and apply new technologies.

The NTP has evaluated more than 2,500 substances for a variety of health-related effects, among them, general toxicity, reproductive and developmental toxicity, genotoxicity, immunotoxicity, neurotoxicity, metabolism, disposition, and carcinogenicity. The NTP generally uses rodent models for research and testing and conducts short-term studies for up to thirteen weeks and long-term studies for up to two years. In addition, NTP conducts several evaluation activities through special centers and prepares the biennial Report on Carcinogens, a listing of substances known or reasonably anticipated to be cancer hazards. The findings from NTP research and testing activities are peer reviewed prior to finalization and published in NTP reports or the peer reviewed literature. Most of NTP's studies and evaluation activities are carried out via contracts that provide administrative, logistical, and/or scientific support. NTP staff serves as project officers to oversee, review, and approve activities conducted under contract. NIEHS/NTP currently has 42 contracts and 90 federal employees. Additional information about the NTP and its activities is available on the NTP website (http://ntp.niehs.nih.gov).

In response to concerns about potential COI in NTP contracts and to ensure the integrity of its science, Dr. Schwartz committed to convening a working group of an NTP federal advisory committee that would include contract professionals and scientists from within and outside NIH to evaluate existing NTP contracts and to assess each contractor's business relationships for potential conflicts and consider what recommendations are appropriate. Specifically, the WG was charged to (1) assess potential COI, (2) develop

recommendations appropriate for reducing the potential for COI to occur, and (3) address mechanisms for mitigating any current or future COI.

Current Conflict of Interest (COI) Requirements

The potential for COI, whether personal COI or OCI, is a growing concern as the federal government (hereafter referred to as the government) outsources more technical, advisory and oversight services to private companies. Work that was previously the responsibility of the government is now being performed by contractors. Additionally, contractors have also taken over the business of preparing and analyzing technical reports for many government agencies on public health policy here and abroad. Although the potential for COI is increasing exponentially, there is no uniform government-wide policy on how best to identify, evaluate, and mitigate any potential COI nor are there federal standard clauses prescribed for use in solicitations and contracts. The tools available to the government to address either type of COI are limited predominantly to Government Accountability Office (GAO) decisions and the following regulations, all of which have their own limitations:

- Federal Acquisition Regulation (FAR) subpart 2.1 defines OCI but does not provide a definition for personal COI (Attachment 2.)

- FAR subpart 3.1 prescribes policies and procedures for avoiding personal COI but is applicable only to government employees. No regulatory guidance is provided in this subpart, or anywhere else in the FAR, for identifying, evaluating, and resolving personal COI related to contractors (Attachment 3.)

- FAR subpart 9.5 sets forth the regulatory guidance governing OCIs with the focus on prescribing responsibilities, general rules, and procedures for identifying, evaluating, and resolving OCIs (Attachment 4.)

Personal COI result from personal activities or relationships that affect contract work. Personal COI occur when contractor staff, including spouses and dependent children, receive personal financial reward from an external company, agency, institution, individual, or any other entity which may bias the individual's judgment, or compromise his or her ability to carry out their contractual obligation to the contracting organization. The responsibility to notify the government of an actual or potential conflict of this type rests with the contractor and results from their review of employee financial disclosure statements.

Additional guidance used by NIH to address personal COI can be found in the Code of Federal Regulations (CFR). Title 45 of the Code at Part 94 (45 CFR 94) (Attachment 5) addresses objectivity in research for government contractors. 42 CFR Part 50 is the regulatory counterpart for grants and cooperative agreements. 45 CFR 94 contains provisions to ensure that there is no reasonable expectation that the design, conduct, or reporting of research supported by the Public Health Service (PHS) will be biased by any conflicting financial interest of an investigator. Though this regulation is helpful in managing, reducing or eliminating conflicting financial interests, it also has various limitations as follows:

- it is limited to research contracts only;
- it applies only to investigators involved in the design, conduct, or reporting of research;
- it addresses only significant financial interests of an investigator; and
- it does not require the contractor to provide a copy of their COI policy to the government.

An actual, apparent or potential OCI means that a relationship exists whereby a current or prospective contractor has present or planned interests related to the work to be performed under a government contract which: (1) may diminish its capacity to give impartial, technically sound, objective assistance and advice, or may otherwise result in a biased work product; or (2) may result in it being given an unfair competitive advantage.

The FAR and GAO decisions address three types of OCIs:

1. **Unequal Access to Information** – In this instance a firm has access to nonpublic information as part of its performance of a government contract, and that information may provide the firm a competitive advantage in a later competition for a government contract (FAR subpart 9.505-4). The concern here is limited to the risk of the firm gaining a competitive advantage; there is no issue of bias.

2. **Biased Ground Rules** – In this instance a firm, as part of its performance of a government contract, has in some sense set the ground rules for another government contract by writing the statement of work or the specifications. The primary concern is that the firm could skew the competition, whether intentionally or not, in favor of itself (FAR subparts 9.505-1 and 9.505-2). Another concern would be that the firm could have an unfair advantage in the competition for those requirements because of its knowledge of the agency's future requirements.

3. **Impaired Objectivity** – In this instance a firm's work under one government contract could result in the evaluation of its own work or a related entity's work, either through an assessment of performance under another contract or an evaluation of proposals (FAR subpart 9.505-3). The concern is that the firm's ability to render impartial advice to the government could appear to be undermined by its relationship with the entity whose work product is being evaluated.

The responsibility for determining whether or not an actual, apparent or potential OCI will arise, and to what extent an organization should be excluded from competition, rests with the contracting agency. Because conflicts may arise in factual situations not expressly described in the relevant FAR sections, the regulation advises contracting officers to examine each situation individually and to exercise "…common sense, good

judgment, and sound discretion…" in assessing whether a significant potential conflict exists and in developing an appropriate way to resolve the conflict (FAR subpart 9.505).

In addition to the existing regulations above, the NIH has developed a provision entitled "Institutional Responsibility Regarding Conflicting Interests of Investigators" (Attachment 6) for incorporation in research solicitations issued by the agency. A certification (Attachment 7) which addresses the requirement of 45 CFR 94 for offerors to have in place a written, enforced financial COI policy prior to responding to research solicitations or within 30 days of proposal submission is also required. The NIH has also written policy guidance for its contracting officers concerning their responsibilities in identifying, verifying, and preventing potential COI. NIH Manual Chapter (MC) 6009-1 (Attachment 8) requires the contracting officer and project officer to work together to investigate and determine whether a COI exists under a specific contract. The contracting officer is also responsible for the drafting and inclusion of solicitation provisions and contract clauses if an actual, apparent or potential COI exists.

As the scope and complexity of contractor activity in support of the government continues to increase, the potential for COI also rises. To meet the government's needs, contractors are turning to subcontractors, partners, associates, consultants and other parties on both a temporary and permanent basis to assist with performance under their contracts. The individuals performing the work and sometimes interacting with the public may be representatives of any of the aforementioned organizations. Yet the numerous contractors who may ultimately be performing under a contract are not required to reveal their business clients. Rather, the government must largely rely on the self-certification submitted by the contractor to determine whether or not a COI exists. This has unfortunately resulted in the government being placed in the position of responding to allegations of COI that may or may not be true.

Methodology, Approach and Analysis

In order to assess the potential for COI in the NTP contract program, the WG developed a methodology document (Attachment 9) that was reviewed, extensively discussed, and finalized by the WG. The methodology included COI terminology, information on materials to be provided to the WG, WG tasks, guidance for evaluation of OCI in contracts and strategies for managing OCI. The methodology included a provision for the WG to request additional information, as needed, from contractors through the use of a COI review questionnaire that addressed COI policies and whether or not contractors were aware of any actual or apparent COI. This questionnaire was also reviewed, discussed and finalized by the WG. A copy of the methodology is included as Attachment 1 to this report and includes two attachments; (1) a COI contract clause developed by NIEHS in concert with the Office of the General Counsel (OGC) and Division of Acquisition Policy and Evaluation in the NIH Office of the Director that is being added to all current and future NTP contracts, and (2) the COI review questionnaire.

NTP program staff and NIEHS acquisition staff reviewed all active contracts supporting the NTP program to determine the potential risk for COI in each. Contracts were triaged into "bins" categorized as low, moderate, or high risk based on the NTP program staff and NIEHS acquisition staffs' perception of the risk that COI could influence the results of the contract effort. Definitions used by NTP and NIEHS staff in triaging the contracts into bins are described in Section 3.0 of the attached methodology. Of the 42 NTP contracts, four (4) were "binned" as high risk for potential COI, 12 were considered to be moderate risk and 26 were low risk.

Subsequent to the initial binning of the contracts by NTP and NIEHS staff, the WG was provided access to copies of each contract, including the Statement of Work. In addition, each contract's Project Officer prepared a statement of objectives that summarized the contract's purpose, management oversight by government staff, and output or product of the contract. The WG reviewed the documentation provided for every contract to determine whether the initial COI risk level determinations were appropriate. Based on analysis of the documentation provided and extensive discussions among the WG, revisions were made to the initial risk assessments developed by the NTP and NIEHS. As a result of the WG's analysis nine (9) contracts were "binned" as high risk for potential COI, 11 were "binned" as moderate risk and 22 were put in the low risk "bin" for potential COI.

The WG concluded that additional information was needed from contractors determined to be at either high or moderate risk for COI. This information was to be obtained through the COI review questionnaire developed by the WG. However, the WG was limited by the requirements of the Paperwork Reduction Act of 1980 in terms of the number of contractors who could be requested to respond to the COI questionnaire. The Paperwork Reduction Act of 1980 provides that a federal agency shall not collect or sponsor a collection of information on identical items from 10 or more public respondents without obtaining survey approval from the Office of Management and

Budget (OMB). Obtaining this approval typically requires 12 to 18 months. Due to the time constraints placed upon the WG for completion of its report for presentation to the NTP Board of Scientific Counselors (BSC), requesting OMB approval for administration of a questionnaire to all contractors was not possible. The WG selected nine (9) contractors whose contracts represented a cross-section of high and moderate risk of COI potential to complete the COI review questionnaire. Some of the nine contractors also had contracts identified by the WG as low risk. These nine NTP contractors received letters requesting completion of the COI review questionnaire. A tenth contractor with a high volume of NTP contract activity was requested to respond to a different set of COI compliance questions under the authority of 45 CFR Part 94 which requires the contractor to make information regarding conflicting financial interests available to HHS, upon request.

The WG was divided into three teams with each team consisting of a scientist and a procurement analyst. The ten contractors covering 29 contracts were divided among the teams. None of the contractors reported an actual or potential COI. Each contractor's COI policy was evaluated to determine the policy's compliance with the requirements of 45 CFR Part 94. The first requirement is that each contractor must maintain a written enforced COI policy. Most of the contractors responding to the questionnaire have written policies that were submitted to the WG for review. Those contractors who have a policy informed their investigators about it. The policies are supposed to address COI on the part of subcontractors and collaborators, but very few do so. The regulation requires that contractors designate an institutional official to solicit and review financial disclosure statements from each investigator and most contractors have done that. Fewer contractors meet the requirement to collect from each investigator, upon funding of the contract, a disclosure statement listing significant financial interests (including those of spouses and dependent children) and even fewer contractors update these financial disclosure reports during the period of the award. Very few contractors state they maintain the financial disclosures for three years after final payment. More than half of the contractors provide guidelines for their organization's designated COI official to use in identifying COI. Very few contractors provide for sanctions to be applied if instances of COI are identified. The responses of the tenth contractor (with the high volume of NTP contract activity) indicate that they have a written enforced policy for COI, that they have financial disclosure requirements for investigators and other key personnel, and that they have firewalls to separate employees working on NTP matters from those working on other clients' matters.

Analysis of additional questions that were included in the questionnaire resulted in the following information. Contractors were asked what types of firewalls they had established that separate personnel involved in an NTP contract from those in the organization working on other contracts. Most had established a firewall whereby employees working on an NTP contract could not work on other contracts and many contractors required physical separation of the two groups. A few require employees to sign a nondisclosure agreement guaranteeing they will keep information confidential.

A series of questions addressed bias and objectivity. All contractors responding to the questionnaire indicate that no staff involved in performance of their contracts have financial or personal relationships or affiliations that could influence their work product or ability to render objective advice. None of the contractors indicate any involvement with or interest in technologies and/or substances which may be subjects of the contract(s) or which can be substituted for such technologies or substances. Most do not do business with organizations that might appear to be in conflict with the mission of the NIEHS or have a relationship (financial, organizational, contractual, or otherwise) with such organizations or firms that could impair their objectivity or independence in performance of the contract: the one exception addressed its mitigation strategy. None of the contractors indicate that any unfair competitive advantage would accrue to them in either their private or government business pursuits resulting from access to data generated under the contract, information concerning NTP's plans and programs, or confidential and proprietary data. Only one indicates that it is performing self-evaluation or inspection of a service or product, or evaluation or inspection of another organization with whom a relationship exists that could impair objectivity: that contractor addresses its mitigation strategy. Finally, they all indicate that they are not aware of any information relating to the contracts that they hold that could reasonably be construed as creating an actual or potential COI, including either an OCI or personal COI. The WG relied on the contractor's self-certifications regarding conflicts with current clients. HHS OGC indicated that this is normal, reasonable business practice in the absence of specific factual allegations of impropriety.

As a result of the WG's discussions, questions arose regarding specific contractors' responses to the COI questionnaire in relation to their contract requirements. NTP's project officers for those specific contracts briefed the WG regarding the contract requirements and answered questions posed by the WG. The WG learned that the contracts have largely been established in such a way that no one contractor carries out more than a single task/set of tasks. For example, one set of contractors carries out animal toxicology studies and prepares tissues for analysis. This provides the basic study data that include such things as clinical observations, clinical pathology measures, necropsy records, preparation and histologic evaluation of tissue sections, and summary tables of relevant findings. A second set of contractors carries out the pathology quality assessment of the tissues/sections. This involves an audit of the pathology specimens, and includes a review of: slides, blocks and wet tissues; the physical quality of the materials; specimen identification; the quality of the documentation; and the degree of adherence to the NTP specifications. A pathology data review, carried out by a mix of NTP staff and contractor staff, determines the organs to be reviewed for all lesions and for specific lesions, the specific lesions to be reviewed, all neoplasms, and determines whether additional special studies are needed to refine or confirm a diagnosis. A Pathology Working Group (PWG), consisting of NTP pathologists, the study pathologist, Quality Assurance (QA) pathologist, and outside experts identified by NTP, reviews all pathology analyses and findings as a group, using a set of standardized criteria to determine lesion diagnoses. The PWG's role is to resolve discrepancies and confirm treatment effects. This presentation made clear that the contracts and processes in place were carefully constructed to minimize as much as possible any risk that one contractor

might be able to unduly influence the findings. In fact, the NTP study data are considered to be the gold standard by regulatory agencies in the U.S., Europe and Japan.

The WG also heard about contracts involved with assisting in document preparation, with clarification that NTP provides content and interpretation, identifies references and interprets literature, and writes the results and conclusion sections. Contractors provide editing and document preparation support only.

The WG reviewed both the solicitation provision incorporated in R&D Requests for Proposals (RFPs) in Section L entitled "Institutional Responsibility Regarding Conflicting Interests of Investigators" as well as the COI clause entitled "Conflict of Interest" which was developed by NTP staff in concert with OGC and the Division of Acquisition Policy and Evaluation in the NIH Office of the Director which is being incorporated in current and future NTP contracts. The WG concluded that, while adequate for current purposes, improvements could be made to both the solicitation language and the current contract clause to refine, strengthen and extend the coverage for both R&D and non-R&D requirements. Several samples of current COI clauses from other agencies such as the FDA were reviewed and discussed.

Identification of Best Practices

Based on the review detailed above and discussions within the WG as well as with NTP program staff, a number of best practices that encourage objectivity and minimize the risk for COI were either in place or have been developed. These best practices are as follows:

- The NTP has an established pathology review process designed specifically to promote objectivity in research. In fact, NTP study data has been cited as "…the gold standard by regulatory agencies in the U.S., Europe and Japan." The pathology review process has three layers of review (study lab pathology, pathology QA, and the PWG). The NTP project officer, in conjunction with NTP pathologists, directs all levels of pathology review at contract laboratories, thus ensuring objectivity in the analysis of specimens. Other activities such as chemical synthesis, procurement, purity determinations, dosing formulations, and animal exposure/treatment, necropsy, and specimen preparation and data summarization and review are protected by virtual firewalls through the utilization of different contractors. Standardized criteria are used to determine lesion diagnoses. The PWG chair has a defined role and does not vote; he/she resolves differences of opinion regarding study data.

- NIEHS has developed clause language in concert with OGC and the Division of Acquisition Policy and Evaluation in the NIH Office of the Director that is being inserted into current and future NTP contracts. This clause calls for immediate notification to the NIEHS of any actual or apparent COI that may arise during the performance of the contract.

- NIEHS/NTP currently addresses financial COI and objectivity in research in its solicitations in two locations: Section L of each research solicitation contains the provision entitled "Institutional Responsibility Regarding Conflicting Interests of Investigators." This provision provides offerors with a description of the requirements of 45 CFR 94 and requires offerors to provide a certification at the time of proposal submission. Solicitations also contain a section entitled "Representations and Certifications," including a provision that requires offerors who are proposing on R&D contract projects to certify that they have in place a written and enforced administrative process to identify and manage, reduce or eliminate conflicting financial interests. If the offeror certifies that it does not have such a process in place, the certification requires prospective contractors to have one in place within 30 days after submission of the offer or prior to award, whichever is earlier.

- For several years, the NIH has conducted proactive site visits with educational institutions that conduct research and development projects under grants, cooperative agreements and contracts using NIH funding. COI are discussed with faculty and investigators during these educational sessions.

- The NIH, through the Office of Extramural Research, has posted several educational fact sheets regarding objectivity in research and financial COI on websites such as: http://grants.nih.gov/grants/policy/coi/index.htm.

- In its efforts to educate both contracting and program staffs, NIH has developed and posted its policies on identifying and managing OCI at its Manual Chapter 6009-1, "Contracting Officer's Responsibility in Verification of Conflict of Interest in Advisory and Assistance Services and Other Contracts." (Attachment 8)

Summary and Recommendations

The NIH was tasked with conducting a review of the NIEHS' National Toxicology Program (NTP) contracts to: (1) assess potential COI, (2) develop recommendations appropriate for reducing the potential for COI to occur, and (3) address mechanisms for mitigating any current or future COI.

The NTP convened the BSC WG that reviewed the NTP contracts with respect to the COI issues outlined above. The WG reviewed each NTP contract and determined the degree of risk for potential conflicts and/or impaired objectivity. Questions were sent to a cross-section of NTP contractors in an effort to further understand their policies and their efforts to avoid or mitigate COI. The WG also held discussions with NTP project officers responsible for various contracts including the NTP project officers responsible for the pathology support contracts. Based on the available data reviewed, the WG determined no actual or apparent COI exists in any of the cross-section of contracts reviewed. A number of best practices and areas where improvements could be made by NIH/NIEHS/NTP were identified, These areas of improvement could result in identifying COI as early in the acquisition process as possible in order to avoid, neutralize or mitigate those COI. This report and the recommendations below represent the consensus of the WG for the cross-section of NTP contracts reviewed.

The WG identified several areas that could be improved and strengthened with respect to eliminating or reducing the risk of a COI. The following recommendations are made for the NTP, and merit consideration by the NIH or the government as a whole:

- Currently, 45 CFR 94 addresses only R&D contracts and only those COI that are financial conflicts. The WG recognizes the need to ensure that COI regulations and policies include OCI and suggests that the regulations be broadened to include a requirement for contractors to have written, enforced policies that cover all types of COI.

- In addition, the WG recommends that the NIH consider formulating a policy and contract language that includes OCI and extends to non-R&D contracts. If such language is developed, the NIH should look to other agencies for examples of OCI language that can be adapted for any unique NIH circumstances. For example, HUD has developed a clause regarding OCI that provides for certification regarding the contractor's organizational, financial, contractual or other interests and stipulates sanctions for noncompliance (HUD Clause 2452.209-72). In addition, the FDA and Department of the Navy are other examples of agencies that have developed COI and/or OCI contract language that should be reviewed. Finally, the CFR and FAR should be revised to give examples of the types of sanctions that might be applied for noncompliance.

- The NIH should consider rewriting its solicitation instructions to include a requirement, where appropriate, that offerors provide a copy of their written, enforced COI policy when they submit their proposals. The policy should address

how the offeror proposes to provide firewalls as necessary to prevent COI and should also present a COI mitigation plan that will be evaluated for its adequacy. The NIH can then evaluate the policy to determine if it is in compliance with 45 CFR 94 and FAR 9.5 and require the policy to be rewritten if it is not in compliance.

- Contracting Officers and Project Officers should work together to determine the existence of OCI and COI, both prior to issuing a solicitation and while reviewing proposals. One of the ways this can be accomplished is to carefully review the corporate experience section of the offeror's proposal to detect potential conflicts.

- The WG recommends that NIH consider training in addition to the proactive site visits it already performs. The entire NIH contracting and program community could benefit from OCI and COI training, as would contractors themselves. NIH should consider providing guidance to staff on how to handle COIs and OCIs. Training should include: (1) how to identify actual, apparent and potential COI; (2) how to address COI when found (e.g., guidance on reporting requirements for COIs and OCIs, steps involved in handling a disclosure of COI/OCI, etc.); (3) remedies to apply when conflicts occur; and (4) how to ensure the protection of confidential and/or proprietary data during contract performance. It is also apparent that certain terms, such as "significant financial interest" and "investigator" are not well understood. Such definitions should be emphasized and fully explained in any training session and/or guidance developed. The terms should also be clearly defined in any clauses or certifications developed. Examples of effective firewalls to avoid or reduce COIs and OCIs should also be provided for guidance. Other educational efforts could include postings to an easily located NIH website, fact sheets, forums, presentations at professional forums, etc.

- The certification contained in the Representations and Certifications should be strengthened and include a reference to 45 CFR 94 for financial COI. It should also be clarified that this certification must be completed if the contract is identified as R&D.

- The WG recommends that NIH consider broadening the Representations and Certifications to cover OCI and to extend to non-R&D contracts. This may need to be accomplished with two separate Representations and Certifications.

- The WG noted that the Annual Representations and Certifications used by offerors which is posted via the Online Representations and Certifications Application (ORCA), a part of the Business Partner Network (BPN) and prescribed by FAR Part 4, does not include the NIH COI certification and recommends that NIH follow up with the FAR Council to pursue inclusion of such language in ORCA.

- During the course of its review of contractor responses to specific questions, the WG noted that several COI policies it reviewed were exceptional in their detailed and clear explanations and disclosure forms. The WG recommends that these contractors be asked if a redacted form of their policies could be posted to a training website as an example for other contractors to follow when formulating their policies.

- It may be useful to require all R&D contractors and non-R&D service contractors to take a course similar to the government's ethics training, which includes relevant COI and OCI information.

- NIH should consider a request to the FAR Council to develop standard policies and clauses regarding COI and OCI that are broader in scope than those currently in place. The policies should also address ensuring protections when one contractor is privy to another's confidential and proprietary information in the performance of its contract.

- The WG also recommends that the NIH Head of the Contracting Activity develop a letter to be sent to all NIH R&D contractors reiterating and clarifying the requirements of 45 CFR 94, as well as OCIs as set forth in FAR 9.5, and reminding these contractors of their responsibilities.

- Where the WG determined that contractor COI written policies as reviewed were not adequate or in full compliance with 45 CFR 94, NIEHS/NTP contracting staff should so inform these contractors and require updated policies which are compliant.

- While the methods currently employed by the NTP to ensure objectivity in research and reduce the risk of COI are commendable, the system could be further strengthened if the PWG Chair was an NTP employee (rather than a contractor), and if more functions could be assigned to NTP staff, rather than contractor staff. This may be difficult to accomplish within the constraints of the current budget and given the small circle of expertise available for this work.

In conclusion, the WG found no actual or apparent COIs in its examination of the data presented to it by NIEHS and the contracts and contractors it reviewed. The WG recognizes the efforts of the NIEHS and NTP to avoid or reduce incidences of COI and makes the above recommendations for improvement in the hopes that further education and guidance to both the contractor community and the government contracting/program staff will have the effect of ensuring the integrity of the acquisition system.

ATTACHMENTS:

Attachment 1 – Working Group Roster
Attachment 2 – FAR subpart 2.1
Attachment 3 – FAR subpart 3.1
Attachment 4 – FAR subpart 9.5
Attachment 5 – 45 CFR Part 94
Attachment 6 – Solicitation Provision: "Institutional Responsibility Regarding Conflicting Interests of Investigators"
Attachment 7 – Representations and Certifications language
Attachment 8 – NIH Manual Chapter 6009-1
Attachment 9 – Methodology with attachments

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Attachment 1

(ii) $25,000 in the case of any contract to be awarded and performed, or purchase to be made, outside the United States.

"Minority Institution" means an institution of higher education meeting the requirements of Section 1046(3) of the Higher Education Act of 1965 (20 U.S.C. 1067k), including a Hispanic-serving institution of higher education, as defined in Section 316(b)(1) of the Act (20 U.S.C. 1101a).

"Multi-agency contract (MAC)" means a task-order or delivery-order contract established by one agency for use by Government agencies to obtain supplies and services, consistent with the Economy Act (see 17.500(b)). Multi-agency contracts include contracts for information technology established pursuant to 40 U.S.C. 11314(a)(2).

"Must" (see "shall").

"National defense" means any activity related to programs for military or atomic energy production or construction, military assistance to any foreign nation, stockpiling, or space.

"Neutral person" means an impartial third party, who serves as a mediator, fact finder, or arbitrator, or otherwise functions to assist the parties to resolve the issues in controversy. A neutral person may be a permanent or temporary officer or employee of the Federal Government or any other individual who is acceptable to the parties. A neutral person must have no official, financial, or personal conflict of interest with respect to the issues in controversy, unless the interest is fully disclosed in writing to all parties and all parties agree that the neutral person may serve (5 U.S.C. 583).

"Nondevelopmental item" means—

(1) Any previously developed item of supply used exclusively for governmental purposes by a Federal agency, a State or local government, or a foreign government with which the United States has a mutual defense cooperation agreement;

(2) Any item described in paragraph (1) of this definition that requires only minor modification or modifications of a type customarily available in the commercial marketplace in order to meet the requirements of the procuring department or agency; or

(3) Any item of supply being produced that does not meet the requirements of paragraphs (1) or (2) solely because the item is not yet in use.

"Novation agreement" means a legal instrument—

(1) Executed by the—

(i) Contractor (transferor);

(ii) Successor in interest (transferee); and

(iii) Government; and

(2) By which, among other things, the transferor guarantees performance of the contract, the transferee assumes all obligations under the contract, and the Government recognizes the transfer of the contract and related assets.

"Offer" means a response to a solicitation that, if accepted, would bind the offeror to perform the resultant contract. Responses to invitations for bids (sealed bidding) are offers called "bids" or "sealed bids"; responses to requests for proposals (negotiation) are offers called "proposals"; however, responses to requests for quotations (simplified acquisition) are "quotations," not offers. For unsolicited proposals, see Subpart 15.6.

"Online Representations and Certifications Application (ORCA)" means the primary Government repository for contractor submitted representations and certifications required for the conduct of business with the Government. ORCA is part of the Business Partner Network (BPN). ORCA is located at *http://orca.bpn.gov*.

"Offeror" means offeror or bidder.

"Option" means a unilateral right in a contract by which, for a specified time, the Government may elect to purchase additional supplies or services called for by the contract, or may elect to extend the term of the contract.

"Organizational conflict of interest" means that because of other activities or relationships with other persons, a person is unable or potentially unable to render impartial assistance or advice to the Government, or the person's objectivity in performing the contract work is or might be otherwise impaired, or a person has an unfair competitive advantage.

"Outlying areas" means—

(1) *Commonwealths.* (i) Puerto Rico.

(ii) The Northern Mariana Islands;

(2) *Territories.* (i) American Samoa.

(ii) Guam.

(iii) U.S. Virgin Islands; and

(3) *Minor outlying islands.* (i) Baker Island.

(ii) Howland Island.

(iii) Jarvis Island.

(iv) Johnston Atoll.

(v) Kingman Reef.

(vi) Midway Islands.

(vii) Navassa Island.

(viii) Palmyra Atoll.

(ix) Wake Atoll.

"Overtime" means time worked by a contractor's employee in excess of the employee's normal workweek.

"Overtime premium" means the difference between the contractor's regular rate of pay to an employee for the shift involved and the higher rate paid for overtime. It does not include shift premium, *i.e.*, the difference between the contractor's regular rate of pay to an employee and the higher rate paid for extra-pay-shift work.

3.000 Scope of part.

This part prescribes policies and procedures for avoiding improper business practices and personal conflicts of interest and for dealing with their apparent or actual occurrence.

Subpart 3.1—Safeguards

3.101 Standards of conduct.

3.101-1 General.

Government business shall be conducted in a manner above reproach and, except as authorized by statute or regulation, with complete impartiality and with preferential treatment for none. Transactions relating to the expenditure of public funds require the highest degree of public trust and an impeccable standard of conduct. The general rule is to avoid strictly any conflict of interest or even the appearance of a conflict of interest in Government-contractor relationships. While many Federal laws and regulations place restrictions on the actions of Government personnel, their official conduct must, in addition, be such that they would have no reluctance to make a full public disclosure of their actions.

3.101-2 Solicitation and acceptance of gratuities by Government personnel.

As a rule, no Government employee may solicit or accept, directly or indirectly, any gratuity, gift, favor, entertainment, loan, or anything of monetary value from anyone who (a) has or is seeking to obtain Government business with the employee's agency, (b) conducts activities that are regulated by the employee's agency, or (c) has interests that may be substantially affected by the performance or nonperformance of the employee's official duties. Certain limited exceptions are authorized in agency regulations.

3.101-3 Agency regulations.

(a) Agencies are required by Executive Order 11222 of May 8, 1965, and 5 CFR 735 to prescribe "Standards of Conduct." These agency standards contain—

(1) Agency-authorized exceptions to 3.101-2; and

(2) Disciplinary measures for persons violating the standards of conduct.

(b) Requirements for employee financial disclosure and restrictions on private employment for former Government employees are in Office of Personnel Management and agency regulations implementing Public Law 95-521, which amended 18 U.S.C. 207.

3.102 [Reserved]

3.103 Independent pricing.

3.103-1 Solicitation provision.

The contracting officer shall insert the provision at 52.203-2, Certificate of Independent Price Determination, in solicitations when a firm-fixed-price contract or fixed-price contract with economic price adjustment is contemplated, unless—

(a) The acquisition is to be made under the simplified acquisition procedures in Part 13;

(b) [Reserved]

(c) The solicitation is a request for technical proposals under two-step sealed bidding procedures; or

(d) The solicitation is for utility services for which rates are set by law or regulation.

3.103-2 Evaluating the certification.

(a) Evaluation guidelines.

(1) None of the following, in and of itself, constitutes "disclosure" as it is used in paragraph (a)(2) of the Certificate of Independent Price Determination (hereafter, the certificate):

(i) The fact that a firm has published price lists, rates, or tariffs covering items being acquired by the Government.

(ii) The fact that a firm has informed prospective customers of proposed or pending publication of new or revised price lists for items being acquired by the Government.

(iii) The fact that a firm has sold the same items to commercial customers at the same prices being offered to the Government.

(2) For the purpose of paragraph (b)(2) of the certificate, an individual may use a blanket authorization to act as an agent for the person(s) responsible for determining the offered prices if—

(i) The proposed contract to which the certificate applies is clearly within the scope of the authorization; and

(ii) The person giving the authorization is the person within the offeror's organization who is responsible for determining the prices being offered at the time the certification is made in the particular offer.

(3) If an offer is submitted jointly by two or more concerns, the certification provided by the representative of each concern applies only to the activities of that concern.

(b) Rejection of offers suspected of being collusive.

(1) If the offeror deleted or modified paragraph (a)(1) or (a)(3) or paragraph (b) of the certificate, the contracting officer shall reject the offeror's bid or proposal.

(2) If the offeror deleted or modified paragraph (a)(2) of the certificate, the offeror must have furnished with its offer a signed statement of the circumstances of the disclosure of prices contained in the bid or proposal. The chief of the contracting office shall review the altered certificate and the statement and shall determine, in writing, whether the disclosure was made for the purpose or had the effect of restricting competition. If the determination is positive, the bid or proposal shall be rejected; if it is negative, the bid or proposal shall be considered for award.

(3) Whenever an offer is rejected under paragraph (b)(1) or (b)(2) of this section, or the certificate is suspected of being false, the contracting officer shall report the situation to the Attorney General in accordance with 3.303.

(4) The determination made under paragraph (b)(2) of this section shall not prevent or inhibit the prosecution of any criminal or civil actions involving the occurrences or transactions to which the certificate relates.

3.103-3 The need for further certifications.

A contractor that properly executed the certificate before award does not have to submit a separate certificate with each proposal to perform a work order or similar ordering instrument issued pursuant to the terms of the contract, where the Government's requirements cannot be met from another source.

3.104 Procurement integrity.

3.104-1 Definitions.

As used in this section—

"Agency ethics official" means the designated agency ethics official described in 5 CFR 2638.201 or other designated person, including—

(1) Deputy ethics officials described in 5 CFR 2638.204, to whom authority under 3.104-6 has been delegated by the designated agency ethics official; and

(2) Alternate designated agency ethics officials described in 5 CFR 2638.202(b).

"Compensation" means wages, salaries, honoraria, commissions, professional fees, and any other form of compensation, provided directly or indirectly for services rendered. Compensation is indirectly provided if it is paid to an entity other than the individual, specifically in exchange for services provided by the individual.

"Contractor bid or proposal information" means any of the following information submitted to a Federal agency as part of or in connection with a bid or proposal to enter into a Federal agency procurement contract, if that information has not been previously made available to the public or disclosed publicly:

(1) Cost or pricing data (as defined by 10 U.S.C. 2306a(h)) with respect to procurements subject to that section, and section 304A(h) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254b(h)), with respect to procurements subject to that section.

(2) Indirect costs and direct labor rates.

(3) Proprietary information about manufacturing processes, operations, or techniques marked by the contractor in accordance with applicable law or regulation.

(4) Information marked by the contractor as "contractor bid or proposal information" in accordance with applicable law or regulation.

(5) Information marked in accordance with 52.215-1(e).

"Decision to award a subcontract or modification of subcontract" means a decision to designate award to a particular source.

"Federal agency procurement" means the acquisition (by using competitive procedures and awarding a contract) of goods or services (including construction) from non-Federal sources by a Federal agency using appropriated funds. For broad agency announcements and small business innovative research programs, each proposal received by an agency constitutes a separate procurement for purposes of the Act.

"In excess of $10,000,000" means—

(1) The value, or estimated value, at the time of award, of the contract, including all options;

(2) The total estimated value at the time of award of all orders under an indefinite-delivery, indefinite-quantity, or requirements contract;

(3) Any multiple award schedule contract, unless the contracting officer documents a lower estimate;

(4) The value of a delivery order, task order, or an order under a Basic Ordering Agreement;

(5) The amount paid or to be paid in settlement of a claim; or

(6) The estimated monetary value of negotiated overhead or other rates when applied to the Government portion of the applicable allocation base.

"Official" means—

(1) An officer, as defined in 5 U.S.C. 2104;

(2) An employee, as defined in 5 U.S.C. 2105;

(3) A member of the uniformed services, as defined in 5 U.S.C. 2101(3); or

(4) A special Government employee, as defined in 18 U.S.C. 202.

"Participating personally and substantially in a Federal agency procurement" means—

(1) Active and significant involvement of an official in any of the following activities directly related to that procurement:

(i) Drafting, reviewing, or approving the specification or statement of work for the procurement.

(ii) Preparing or developing the solicitation.

(iii) Evaluating bids or proposals, or selecting a source.

(iv) Negotiating price or terms and conditions of the contract.

(v) Reviewing and approving the award of the contract.

(2) "Participating personally" means participating directly, and includes the direct and active supervision of a subordinate's participation in the matter.

(3) "Participating substantially" means that the official's involvement is of significance to the matter. Substantial participation requires more than official responsibility, knowledge, perfunctory involvement, or involvement on an administrative or peripheral issue. Participation may be substantial even though it is not determinative of the outcome of a particular matter. A finding of substantiality should be based not only on the effort devoted to a matter, but on the importance of the effort. While a series of peripheral involvements may be insubstantial, the single act of approving or participating in a critical step may be substantial. However, the review of procurement documents solely to determine compliance with regulatory, administrative, or budgetary procedures, does not constitute substantial participation in a procurement.

(4) Generally, an official will not be considered to have participated personally and substantially in a procurement solely by participating in the following activities:

(i) Agency-level boards, panels, or other advisory committees that review program milestones or evaluate and make recommendations regarding alternative technologies or approaches for satisfying broad agency-level missions or objectives.

(ii) The performance of general, technical, engineering, or scientific effort having broad application not directly associated with a particular procurement, notwithstanding that such general, technical, engineering, or scientific effort subsequently may be incorporated into a particular procurement.

(iii) Clerical functions supporting the conduct of a particular procurement.

(iv) For procurements to be conducted under the procedures of OMB Circular A-76, participation in management studies, preparation of in-house cost estimates, preparation of "most efficient organization" analyses, and furnishing of data or technical support to be used by others in the development of performance standards, statements of work, or specifications.

"Source selection evaluation board" means any board, team, council, or other group that evaluates bids or proposals.

3.104-2 General.

(a) This section implements section 27 of the Office of Federal Procurement Policy Act (the Procurement Integrity Act) (41 U.S.C. 423) referred to as "the Act"). Agency supplementation of 3.104, including specific definitions to identify individuals who occupy positions specified in 3.104-3(d)(1)(ii), and any clauses required by 3.104 must be approved by the senior procurement executive of the agency, unless a law establishes a higher level of approval for that agency.

(b) Agency officials are reminded that there are other statutes and regulations that deal with the same or related prohibited conduct, for example—

(1) The offer or acceptance of a bribe or gratuity is prohibited by 18 U.S.C. 201 and 10 U.S.C. 2207. The acceptance of a gift, under certain circumstances, is prohibited by 5 U.S.C. 7353 and 5 CFR Part 2635;

(2) Contacts with an offeror during the conduct of an acquisition may constitute "seeking employment," (see Subpart F of 5 CFR Part 2636 and 3.104-3(c)(2)). Government officers and employees (employees) are prohibited by 18 U.S.C. 208 and 5 CFR Part 2635 from participating personally and substantially in any particular matter that would affect the financial interests of any person with whom the employee is seeking employment. An employee who engages in negotiations or is otherwise seeking employment with an offeror or who has an arrangement concerning future employment with an offeror must comply with the applicable disqualification requirements of 5 CFR 2635.604 and 2635.606. The statutory prohibition in 18 U.S.C. 208 also may require an employee's disqualification from participation in the acquisition even if the employee's duties may not be considered "participating personally and substantially," as this term is defined in 3.104-1;

(3) Post-employment restrictions are covered by 18 U.S.C. 207 and 5 CFR parts 2637 and 2641, that prohibit certain activities by former Government employees, including representation of a contractor before the Government in relation to any contract or other particular matter involving specific parties on which the former employee participated personally and substantially while employed by the Government. Additional restrictions apply to certain senior Government employees and for particular matters under an employee's official responsibility;

(4) Parts 14 and 15 place restrictions on the release of information related to procurements and other contractor information that must be protected under 18 U.S.C. 1905;

(5) Release of information both before and after award (see 3.104-4) may be prohibited by the Privacy Act (5 U.S.C. 552a), the Trade Secrets Act (18 U.S.C. 1905), and other laws; and

(6) Using nonpublic information to further an employee's private interest or that of another and engaging in a financial transaction using nonpublic information are prohibited by 5 CFR 2635.703.

3.104-3 Statutory and related prohibitions, restrictions, and requirements.

(a) Prohibition on disclosing procurement information (subsection 27(a) of the Act).

(1) A person described in paragraph (a)(2) of this subsection must not, other than as provided by law, knowingly disclose contractor bid or proposal information or source selection information before the award of a Federal agency procurement contract to which the information relates. (See 3.104-4(a).)

(2) Paragraph (a)(1) of this subsection applies to any person who—

(i) Is a present or former official of the United States, or a person who is acting or has acted for or on behalf of, or who is advising or has advised the United States with respect to, a Federal agency procurement; and

(ii) By virtue of that office, employment, or relationship, has or had access to contractor bid or proposal information or source selection information.

(b) *Prohibition on obtaining procurement information (subsection 27(b) of the Act).* A person must not, other than as provided by law, knowingly obtain contractor bid or proposal information or source selection information before the award of a Federal agency procurement contract to which the information relates.

(c) Actions required when an agency official contacts or is contacted by an offeror regarding non-Federal employment (subsection 27(c) of the Act).

(1) If an agency official, participating personally and substantially in a Federal agency procurement for a contract in excess of the simplified acquisition threshold, contacts or is contacted by a person who is an offeror in that Federal agency procurement regarding possible non-Federal employment for that official, the official must—

(i) Promptly report the contact in writing to the official's supervisor and to the agency ethics official; and

(ii) Either reject the possibility of non-Federal employment or disqualify himself or herself from further personal and substantial participation in that Federal agency procurement (see 3.104-5) until such time as the agency authorizes the official to resume participation in that procurement, in accordance with the requirements of 18 U.S.C. 208 and applicable agency regulations, because—

(A) The person is no longer an offeror in that Federal agency procurement; or

(B) All discussions with the offeror regarding possible non-Federal employment have terminated without an agreement or arrangement for employment.

(2) A contact is any of the actions included as "seeking employment" in 5 CFR 2635.603(b). In addition, unsolicited communications from offerors regarding possible employment are considered contacts.

(3) Agencies must retain reports of employment contacts for 2 years from the date the report was submitted.

(4) Conduct that complies with subsection 27(c) of the Act may be prohibited by other criminal statutes and the Standards of Ethical Conduct for Employees of the Executive Branch. See 3.104-2(b)(2).

(d) Prohibition on former official's acceptance of compensation from a contractor (subsection 27(d) of the Act).

(1) A former official of a Federal agency may not accept compensation from a contractor that has been awarded a competitive or sole source contract, as an employee, officer, director, or consultant of the contractor within a period of 1 year after such former official—

(i) Served, at the time of selection of the contractor or the award of a contract to that contractor, as the procuring contracting officer, the source selection authority, a member of a source selection evaluation board, or the chief of a financial or technical evaluation team in a procurement in which that contractor was selected for award of a contract in excess of $10,000,000;

(ii) Served as the program manager, deputy program manager, or administrative contracting officer for a contract in excess of $10,000,000 awarded to that contractor; or

(iii) Personally made for the Federal agency a decision to—

(A) Award a contract, subcontract, modification of a contract or subcontract, or a task order or delivery order in excess of $10,000,000 to that contractor;

(B) Establish overhead or other rates applicable to a contract or contracts for that contractor that are valued in excess of $10,000,000;

(C) Approve issuance of a contract payment or payments in excess of $10,000,000 to that contractor; or

(D) Pay or settle a claim in excess of $10,000,000 with that contractor.

(2) The 1-year prohibition begins on the date—

(i) Of contract award for positions described in paragraph (d)(1)(i) of this subsection, or the date of contractor selection if the official was not serving in the position on the date of award;

(ii) The official last served in one of the positions described in paragraph (d)(1)(ii) of this subsection; or

(iii) The official made one of the decisions described in paragraph (d)(1)(iii) of this subsection.

(3) Nothing in paragraph (d)(1) of this subsection may be construed to prohibit a former official of a Federal agency from accepting compensation from any division or affiliate of a contractor that does not produce the same or similar products or services as the entity of the contractor that is responsible for the contract referred to in paragraph (d)(1) of this subsection.

3.104-4 Disclosure, protection, and marking of contractor bid or proposal information and source selection information.

(a) Except as specifically provided for in this subsection, no person or other entity may disclose contractor bid or proposal information or source selection information to any person other than a person authorized, in accordance with applicable agency regulations or procedures, by the agency head or the contracting officer to receive such information.

(b) Contractor bid or proposal information and source selection information must be protected from unauthorized disclosure in accordance with 14.401, 15.207, applicable law, and agency regulations.

(c) Individuals unsure if particular information is source selection information, as defined in 2.101, should consult with agency officials as necessary. Individuals responsible for preparing material that may be source selection information as described at paragraph (10) of the "source selection information" definition in 2.101 must mark the cover page and each page that the individual believes contains source selection information with the legend *"Source Selection Information—See FAR 2.101 and 3.104."* Although the information in paragraphs (1) through (9) of the definition in 2.101 is considered to be source selection information whether or not marked, all reasonable efforts must be made to mark such material with the same legend.

(d) Except as provided in paragraph (d)(3) of this subsection, the contracting officer must notify the contractor in writing if the contracting officer believes that proprietary information, contractor bid or proposal information, or information marked in accordance with 52.215-1(e) has been inappropriately marked. The contractor that has affixed the marking must be given an opportunity to justify the marking.

(1) If the contractor agrees that the marking is not justified, or does not respond within the time specified in the notice, the contracting officer may remove the marking and release the information.

(2) If, after reviewing the contractor's justification, the contracting officer determines that the marking is not justified, the contracting officer must notify the contractor in writing before releasing the information.

(3) For technical data marked as proprietary by a contractor, the contracting officer must follow the procedures in 27.404(h).

(e) This section does not restrict or prohibit—

(1) A contractor from disclosing its own bid or proposal information or the recipient from receiving that information;

(2) The disclosure or receipt of information, not otherwise protected, relating to a Federal agency procurement after it has been canceled by the Federal agency, before contract award, unless the Federal agency plans to resume the procurement;

(3) Individual meetings between a Federal agency official and an offeror or potential offeror for, or a recipient of, a contract or subcontract under a Federal agency procurement, provided that unauthorized disclosure or receipt of contractor bid or proposal information or source selection information does not occur; or

(4) The Government's use of technical data in a manner consistent with the Government's rights in the data.

(f) This section does not authorize—

(1) The withholding of any information pursuant to a proper request from the Congress, any committee or subcommittee thereof, a Federal agency, the Comptroller General, or an Inspector General of a Federal agency, except as otherwise authorized by law or regulation. Any release containing contractor bid or proposal information or source selection information must clearly identify the information as contractor bid or proposal information or source selection information related to the conduct of a Federal agency procurement and notify the recipient that the disclosure of the information is restricted by section 27 of the Act;

(2) The withholding of information from, or restricting its receipt by, the Comptroller General in the course of a protest against the award or proposed award of a Federal agency procurement contract;

(3) The release of information after award of a contract or cancellation of a procurement if such information is contractor bid or proposal information or source selection information that pertains to another procurement; or

(4) The disclosure, solicitation, or receipt of bid or proposal information or source selection information after award if disclosure, solicitation, or receipt is prohibited by law. (See 3.104-2(b)(5) and Subpart 24.2.)

3.104-5 Disqualification.

(a) *Contacts through agents or other intermediaries.* Employment contacts between the employee and the offeror, that are conducted through agents, or other intermediaries, may require disqualification under 3.104-3(c)(1). These contacts may also require disqualification under other statutes and regulations. (See 3.104-2(b)(2).)

(b) *Disqualification notice.* In addition to submitting the contact report required by 3.104-3(c)(1), an agency official who must disqualify himself or herself pursuant to 3.104-3(c)(1)(ii) must promptly submit written notice of disqualification from further participation in the procurement to the contracting officer, the source selection authority if other than the contracting officer, and the agency official's immediate supervisor. As a minimum, the notice must—

(1) Identify the procurement;

(2) Describe the nature of the agency official's participation in the procurement and specify the approximate dates or time period of participation; and

(3) Identify the offeror and describe its interest in the procurement.

(c) Resumption of participation in a procurement.

(1) The official must remain disqualified until such time as the agency, at its sole and exclusive discretion, authorizes the official to resume participation in the procurement in accordance with 3.104-3(c)(1)(ii).

(2) After the conditions of 3.104-3(c)(1)(ii)(A) or (B) have been met, the head of the contracting activity (HCA), after consultation with the agency ethics official, may authorize the disqualified official to resume participation in the procurement, or may determine that an additional disqualification period is necessary to protect the integrity of the procurement process. In determining the disqualification period, the HCA must consider any factors that create an appearance that the disqualified official acted without complete impartiality in the procurement. The HCA's reinstatement decision should be in writing.

(3) Government officer or employee must also comply with the provisions of 18 U.S.C. 208 and 5 CFR Part 2635 regarding any resumed participation in a procurement matter. Government officer or employee may not be reinstated to participate in a procurement matter affecting the financial interest of someone with whom the individual is seeking employment, unless the individual receives—

(i) A waiver pursuant to 18 U.S.C. 208(b)(1) or (b)(3); or

(ii) An authorization in accordance with the requirements of Subpart F of 5 CFR Part 2635.

3.104-6 Ethics advisory opinions regarding prohibitions on a former official's acceptance of compensation from a contractor.

(a) An official or former official of a Federal agency who does not know whether he or she is or would be precluded by subsection 27(d) of the Act (see 3.104-3(d)) from accepting compensation from a particular contractor may request advice from the appropriate agency ethics official before accepting such compensation.

(b) The request for an advisory opinion must be in writing, include all relevant information reasonably available to the official or former official, and be dated and signed. The request must include information about the—

(1) Procurement(s), or decision(s) on matters under 3.104-3(d)(1)(iii), involving the particular contractor, in which the individual was or is involved, including contract or solicitation numbers, dates of solicitation or award, a description of the supplies or services procured or to be procured, and contract amount;

(2) Individual's participation in the procurement or decision, including the dates or time periods of that participation, and the nature of the individual's duties, responsibilities, or actions; and

(3) Contractor, including a description of the products or services produced by the division or affiliate of the contractor from whom the individual proposes to accept compensation.

(c) Within 30 days after receipt of a request containing complete information, or as soon thereafter as practicable, the agency ethics official should issue an opinion on whether the proposed conduct would violate subsection 27(d) of the Act.

(d)(1) If complete information is not included in the request, the agency ethics official may ask the requester to provide more information or request information from other persons, including the source selection authority, the contracting officer, or the requester's immediate supervisor.

(2) In issuing an opinion, the agency ethics official may rely upon the accuracy of information furnished by the requester or other agency sources, unless he or she has reason to believe that the information is fraudulent, misleading, or otherwise incorrect.

(3) If the requester is advised in a written opinion by the agency ethics official that the requester may accept compensation from a particular contractor, and accepts such compensation in good faith reliance on that advisory opinion, then neither the requester nor the contractor will be found to have knowingly violated subsection 27(d) of the Act. If the requester or the contractor has actual knowledge or reason to believe that the opinion is based upon fraudulent, misleading, or otherwise incorrect information, their reliance upon the opinion will not be deemed to be in good faith.

3.104-7 Violations or possible violations.

(a) A contracting officer who receives or obtains information of a violation or possible violation of subsection 27(a), (b), (c), or (d) of the Act (see 3.104-3) must determine if the reported violation or possible violation has any impact on the pending award or selection of the contractor.

(1) If the contracting officer concludes that there is no impact on the procurement, the contracting officer must forward the information concerning the violation or possible violation and documentation supporting a determination that there is no impact on the procurement to an individual

designated in accordance with agency procedures.

(i) If that individual concurs, the contracting officer may proceed with the procurement.

(ii) If that individual does not concur, the individual must promptly forward the information and documentation to the HCA and advise the contracting officer to withhold award.

(2) If the contracting officer concludes that the violation or possible violation impacts the procurement, the contracting officer must promptly forward the information to the HCA.

(b) The HCA must review all information available and, in accordance with agency procedures, take appropriate action, such as—

(1) Advise the contracting officer to continue with the procurement;

(2) Begin an investigation;

(3) Refer the information disclosed to appropriate criminal investigative agencies;

(4) Conclude that a violation occurred; or

(5) Recommend that the agency head determine that the contractor, or someone acting for the contractor, has engaged in conduct constituting an offense punishable under subsection 27(e) of the Act, for the purpose of voiding or rescinding the contract.

(c) Before concluding that an offeror, contractor, or person has violated the Act, the HCA may consider that the interests of the Government are best served by requesting information from appropriate parties regarding the violation or possible violation.

(d) If the HCA concludes that section 27 of the Act has been violated, the HCA may direct the contracting officer to—

(1) If a contract has not been awarded—

(i) Cancel the procurement;

(ii) Disqualify an offeror; or

(iii) Take any other appropriate actions in the interests of the Government.

(2) If a contract has been awarded—

(i) Effect appropriate contractual remedies, including profit recapture under the clause at 52.203-10, Price or Fee Adjustment for Illegal or Improper Activity, or, if the contract has been rescinded under paragraph (d)(2)(ii) of this subsection, recovery of the amount expended under the contract;

(ii) Void or rescind the contract with respect to which—

(A) The contractor or someone acting for the contractor has been convicted for an offense where the conduct constitutes a violation of subsections 27(a) or (b) of the Act for the purpose of either—

(1) Exchanging the information covered by the subsections for anything of value; or

(2) Obtaining or giving anyone a competitive advantage in the award of a Federal agency procurement contract; or

(B) The agency head has determined, based upon a preponderance of the evidence, that the contractor or someone acting for the contractor has engaged in conduct constituting an offense punishable under subsection 27(e)(1) of the Act; or

(iii) Take any other appropriate actions in the best interests of the Government.

(3) Refer the matter to the agency suspending or debarring official.

(e) The HCA should recommend or direct an administrative or contractual remedy commensurate with the severity and effect of the violation.

(f) If the HCA determines that urgent and compelling circumstances justify an award, or award is otherwise in the interests of the Government, the HCA, in accordance with agency procedures, may authorize the contracting officer to award the contract or execute the contract modification after notifying the agency head.

(g) The HCA may delegate his or her authority under this subsection to an individual at least one organizational level above the contracting officer and of General Officer, Flag, Senior Executive Service, or equivalent rank.

3.104-8 Criminal and civil penalties, and further administrative remedies.

Criminal and civil penalties, and administrative remedies, may apply to conduct that violates the Act (see 3.104-3). See 33.102(f) for special rules regarding bid protests. See 3.104-7 for administrative remedies relating to contracts.

(a) An official who knowingly fails to comply with the requirements of 3.104-3 is subject to the penalties and administrative action set forth in subsection 27(e) of the Act.

(b) An offeror who engages in employment discussion with an official subject to the restrictions of 3.104-3, knowing that the official has not complied with 3.104-3(c)(1), is subject to the criminal, civil, or administrative penalties set forth in subsection 27(e) of the Act.

(c) An official who refuses to terminate employment discussions (see 3.104-5) may be subject to agency administrative actions under 5 CFR 2635.604(d) if the official's disqualification from participation in a particular procurement interferes substantially with the individual's ability to perform assigned duties.

3.104-9 Contract clauses.

In solicitations and contracts for other than commercial items that exceed the simplified acquisition threshold, insert the clauses at—

(a) 52.203-8, Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity; and

(b) 52.203-10, Price or Fee Adjustment for Illegal or Improper Activity.

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Subpart 9.5—Organizational and Consultant Conflicts of Interest

9.500 Scope of subpart.

This subpart—

(a) Prescribes responsibilities, general rules, and procedures for identifying, evaluating, and resolving organizational conflicts of interest;

(b) Provides examples to assist contracting officers in applying these rules and procedures to individual contracting situations; and

(c) Implements section 8141 of the 1989 Department of Defense Appropriation Act, Pub. L. 100-463, 102 Stat. 2270-47 (1988).

9.501 Definition.

"Marketing consultant," as used in this subpart, means any independent contractor who furnishes advice, information, direction, or assistance to an offeror or any other contractor in support of the preparation or submission of an offer for a Government contract by that offeror. An independent contractor is not a marketing consultant when rendering—

(1) Services excluded in Subpart 37.2;

(2) Routine engineering and technical services (such as installation, operation, or maintenance of systems, equipment, software, components, or facilities);

(3) Routine legal, actuarial, auditing, and accounting services; and

(4) Training services.

9.502 Applicability.

(a) This subpart applies to contracts with either profit or nonprofit organizations, including nonprofit organizations created largely or wholly with Government funds.

(b) The applicability of this subpart is not limited to any particular kind of acquisition. However, organizational conflicts of interest are more likely to occur in contracts involving—

(1) Management support services;

(2) Consultant or other professional services;

(3) Contractor performance of or assistance in technical evaluations; or

(4) Systems engineering and technical direction work performed by a contractor that does not have overall contractual responsibility for development or production.

(c) An organizational conflict of interest may result when factors create an actual or potential conflict of interest on an instant contract, or when the nature of the work to be performed on the instant contract creates an actual or potential conflict of interest on a future acquisition. In the latter case, some restrictions on future activities of the contractor may be required.

(d) Acquisitions subject to unique agency organizational conflict of interest statutes are excluded from the requirements of this subpart.

9.503 Waiver.

The agency head or a designee may waive any general rule or procedure of this subpart by determining that its application in a particular situation would not be in the Government's interest. Any request for waiver must be in writing, shall set forth the extent of the conflict, and requires approval by the agency head or a designee. Agency heads shall not delegate waiver authority below the level of head of a contracting activity.

9.504 Contracting officer responsibilities.

(a) Using the general rules, procedures, and examples in this subpart, contracting officers shall analyze planned acquisitions in order to—

(1) Identify and evaluate potential organizational conflicts of interest as early in the acquisition process as possible; and

(2) Avoid, neutralize, or mitigate significant potential conflicts before contract award.

(b) Contracting officers should obtain the advice of counsel and the assistance of appropriate technical specialists in evaluating potential conflicts and in developing any necessary solicitation provisions and contract clauses (see 9.506).

(c) Before issuing a solicitation for a contract that may involve a significant potential conflict, the contracting officer shall recommend to the head of the contracting activity a course of action for resolving the conflict (see 9.506).

(d) In fulfilling their responsibilities for identifying and resolving potential conflicts, contracting officers should avoid creating unnecessary delays, burdensome information requirements, and excessive documentation. The contracting officer's judgment need be formally documented only when a substantive issue concerning potential organizational conflict of interest exists.

(e) The contracting officer shall award the contract to the apparent successful offeror unless a conflict of interest is determined to exist that cannot be avoided or mitigated. Before determining to withhold award based on conflict of interest considerations, the contracting officer shall notify the contractor, provide the reasons therefor, and allow the contractor a reasonable opportunity to respond. If the contracting officer finds that it is in the best interest of the United States to award the contract notwithstanding a conflict of interest, a request for waiver shall be submitted in accordance with 9.503. The waiver request and decision shall be included in the contract file.

9.505 General rules.

The general rules in 9.505-1 through 9.505-4 prescribe limitations on contracting as the means of avoiding, neutralizing, or mitigating organizational conflicts of interest that might otherwise exist in the stated situations. Some illustrative examples are provided in 9.508. Conflicts may arise in situations not expressly covered in this section 9.505 or in the examples in 9.508. Each individual contracting situation should be examined on the basis of its particular facts and the nature of the proposed contract. The exercise of common sense, good judgment, and sound discretion is required in both the decision on whether a significant potential conflict exists and, if it does, the development of an appropriate means for resolving it. The two underlying principles are—

(a) Preventing the existence of conflicting roles that might bias a contractor's judgment; and

(b) Preventing unfair competitive advantage. In addition to the other situations described in this subpart, an unfair competitive advantage exists where a contractor competing for award of any Federal contract possesses—

(1) Proprietary information that was obtained from a Government official without proper authorization; or

(2) Source selection information (as defined in 2.101) that is relevant to the contract but is not available to all competitors, and such information would assist that contractor in obtaining the contract.

9.505-1 Providing systems engineering and technical direction.

(a) A contractor that provides systems engineering and technical direction for a system but does not have overall contractual responsibility for its development, its integration, assembly, and checkout, or its production shall not—

(1) Be awarded a contract to supply the system or any of its major components; or

(2) Be a subcontractor or consultant to a supplier of the system or any of its major components.

(b) Systems engineering includes a combination of substantially all of the following activities: determining specifications, identifying and resolving

interface problems, developing test requirements, evaluating test data, and supervising design. Technical direction includes a combination of substantially all of the following activities: developing work statements, determining parameters, directing other contractors' operations, and resolving technical controversies. In performing these activities, a contractor occupies a highly influential and responsible position in determining a system's basic concepts and supervising their execution by other contractors. Therefore this contractor should not be in a position to make decisions favoring its own products or capabilities.

9.505-2 Preparing specifications or work statements.

(a)(1) If a contractor prepares and furnishes complete specifications covering nondevelopmental items, to be used in a competitive acquisition, that contractor shall not be allowed to furnish these items, either as a prime contractor or as a subcontractor, for a reasonable period of time including, at least, the duration of the initial production contract. This rule shall not apply to—

(i) Contractors that furnish at Government request specifications or data regarding a product they provide, even though the specifications or data may have been paid for separately or in the price of the product; or

(ii) Situations in which contractors, acting as industry representatives, help Government agencies prepare, refine, or coordinate specifications, regardless of source, provided this assistance is supervised and controlled by Government representatives.

(2) If a single contractor drafts complete specifications for nondevelopmental equipment, it should be eliminated for a reasonable time from competition for production based on the specifications. This should be done in order to avoid a situation in which the contractor could draft specifications favoring its own products or capabilities. In this way the Government can be assured of getting unbiased advice as to the content of the specifications and can avoid allegations of favoritism in the award of production contracts.

(3) In development work, it is normal to select firms that have done the most advanced work in the field. These firms can be expected to design and develop around their own prior knowledge. Development contractors can frequently start production earlier and more knowledgeably than firms that did not participate in the development, and this can affect the time and quality of production, both of which are important to the Government. In many instances the Government may have financed the development. Thus, while the development contractor has a competitive advantage, it is an unavoidable one that is not considered unfair; hence no prohibition should be imposed.

(b)(1) If a contractor prepares, or assists in preparing, a work statement to be used in competitively acquiring a system or services—or provides material leading directly, predictably, and without delay to such a work statement—that contractor may not supply the system, major components of the system, or the services unless—

(i) It is the sole source;

(ii) It has participated in the development and design work; or

(iii) More than one contractor has been involved in preparing the work statement.

(2) Agencies should normally prepare their own work statements. When contractor assistance is necessary, the contractor might often be in a position to favor its own products or capabilities. To overcome the possibility of bias, contractors are prohibited from supplying a system or services acquired on the basis of work statements growing out of their services, unless excepted in paragraph (b)(1) of this section.

(3) For the reasons given in 9.505-2(a)(3), no prohibitions are imposed on development and design contractors.

9.505-3 Providing evaluation services.

Contracts for the evaluation of offers for products or services shall not be awarded to a contractor that will evaluate its own offers for products or services, or those of a competitor, without proper safeguards to ensure objectivity to protect the Government's interests.

9.505-4 Obtaining access to proprietary information.

(a) When a contractor requires proprietary information from others to perform a Government contract and can use the leverage of the contract to obtain it, the contractor may gain an unfair competitive advantage unless restrictions are imposed. These restrictions protect the information and encourage companies to provide it when necessary for contract performance. They are not intended to protect information—

(1) Furnished voluntarily without limitations on its use; or

(2) Available to the Government or contractor from other sources without restriction.

(b) A contractor that gains access to proprietary information of other companies in performing advisory and assistance services for the Government must agree with the other companies to protect their information from unauthorized use or disclosure for as long as it remains proprietary and refrain from using the information for any purpose other than that for which it was furnished. The contracting officer shall obtain copies of these agreements and ensure that they are properly executed.

(c) Contractors also obtain proprietary and source selection information by acquiring the services of marketing consultants which, if used in connection with an acquisition, may give the contractor an unfair competitive advantage. Contractors should make inquiries of marketing consultants to ensure that the marketing consultant has provided no unfair competitive advantage.

9.506 Procedures.

(a) If information concerning prospective contractors is necessary to identify and evaluate potential organizational conflicts of interest or to develop recommended actions, contracting officers first should seek the information from within the Government or from other readily available sources. Government sources include the files and the knowledge of personnel within the contracting office, other contracting offices, the cognizant contract administration and audit activities and offices concerned with contract financing. Non-Government sources include publications and commercial services, such as credit rating services, trade and financial journals, and business directories and registers.

(b) If the contracting officer decides that a particular acquisition involves a significant potential organizational conflict of interest, the contracting officer shall, before issuing the solicitation, submit for approval to the chief of the contracting office (unless a higher level official is designated by the agency)—

(1) A written analysis, including a recommended course of action for avoiding, neutralizing, or mitigating the conflict, based on the general rules in 9.505 or on another basis not expressly stated in that section;

(2) A draft solicitation provision (see 9.507-1); and

(3) If appropriate, a proposed contract clause (see 9.507-2).

(c) The approving official shall—

(1) Review the contracting officer's analysis and recommended course of action, including the draft provision and any proposed clause;

(2) Consider the benefits and detriments to the Government and prospective contractors; and

(3) Approve, modify, or reject the recommendations in writing.

(d) The contracting officer shall—

(1) Include the approved provision(s) and any approved clause(s) in the solicitation or the contract, or both;

(2) Consider additional information provided by prospective contractors in response to the solicitation or during negotiations; and

(3) Before awarding the contract, resolve the conflict or the potential conflict in a manner consistent with the approval or other direction by the head of the contracting activity.

(e) If, during the effective period of any restriction (see 9.507), a contracting office transfers acquisition responsibility for the item or system involved, it shall notify the successor contracting office of the restriction, and send a copy of the contract under which the restriction was imposed.

9.507 Solicitation provisions and contract clause.

9.507-1 Solicitation provisions.

As indicated in the general rules in 9.505, significant potential organizational conflicts of interest are normally resolved by imposing some restraint, appropriate to the nature of the conflict, upon the contractor's eligibility for future contracts or subcontracts. Therefore, affected solicitations shall contain a provision that—

(a) Invites offerors' attention to this subpart;

(b) States the nature of the potential conflict as seen by the contracting officer;

(c) States the nature of the proposed restraint upon future contractor activities; and

(d) Depending on the nature of the acquisition, states whether or not the terms of any proposed clause and the application of this subpart to the contract are subject to negotiation.

9.507-2 Contract clause.

(a) If, as a condition of award, the contractor's eligibility for future prime contract or subcontract awards will be restricted or the contractor must agree to some other restraint, the solicitation shall contain a proposed clause that specifies both the nature and duration of the proposed restraint. The contracting officer shall include the clause in the contract, first negotiating the clause's final terms with the successful offeror, if it is appropriate to do so (see 9.506(d) of this subsection).

(b) The restraint imposed by a clause shall be limited to a fixed term of reasonable duration, sufficient to avoid the circumstance of unfair competitive advantage or potential bias. This period varies. It might end, for example, when the first production contract using the contractor's specifications or work statement is awarded, or it might extend through the entire life of a system for which the contractor has performed systems engineering and technical direction. In every case, the restriction shall specify termination by a specific date or upon the occurrence of an identifiable event.

9.508 Examples.

The examples in paragraphs (a) through (i) following illustrate situations in which questions concerning organizational conflicts of interest may arise. They are not all inclusive, but are intended to help the contracting officer apply the general rules in 9.505 to individual contract situations.

(a) Company A agrees to provide systems engineering and technical direction for the Navy on the powerplant for a group of submarines (*i.e.*, turbines, drive shafts, propellers, etc.). Company A should not be allowed to supply any powerplant components. Company A can, however, supply components of the submarine unrelated to the powerplant (*e.g.*, fire control, navigation, etc.). In this example, the system is the powerplant, not the submarine, and the ban on supplying components is limited to those for the system only.

(b) Company A is the systems engineering and technical direction contractor for system X. After some progress, but before completion, the system is canceled. Later, system Y is developed to achieve the same purposes as system X, but in a fundamentally different fashion. Company B is the systems engineering and technical direction contractor for system Y. Company A may supply system Y or its components.

(c) Company A develops new electronic equipment and, as a result of this development, prepares specifications. Company A may supply the equipment.

(d) XYZ Tool Company and PQR Machinery Company, representing the American Tool Institute, work under Government supervision and control to refine specifications or to clarify the requirements of a specific acquisition. These companies may supply the item.

(e) Before an acquisition for information technology is conducted, Company A is awarded a contract to prepare data system specifications and equipment performance criteria to be used as the basis for the equipment competition. Since the specifications are the basis for selection of commercial hardware, a potential conflict of interest exists. Company A should be excluded from the initial follow-on information technology hardware acquisition.

(f) Company A receives a contract to define the detailed performance characteristics an agency will require for purchasing rocket fuels. Company A has not developed the particular fuels. When the definition contract is awarded, it is clear to both parties that the agency will use the performance characteristics arrived at to choose competitively a contractor to develop or produce the fuels. Company A may not be awarded this follow-on contract.

(g) Company A receives a contract to prepare a detailed plan for scientific and technical training of an agency's personnel. It suggests a curriculum that the agency endorses and incorporates in its request for proposals to institutions to establish and conduct the training. Company A may not be awarded a contract to conduct the training.

(h) Company A is selected to study the use of lasers in communications. The agency intends to ask that firms doing research in the field make proprietary information available to Company A. The contract must require Company A to—

(1) Enter into agreements with these firms to protect any proprietary information they provide; and

(2) Refrain from using the information in supplying lasers to the Government or for any purpose other than that for which it was intended.

(i) An agency that regulates an industry wishes to develop a system for evaluating and processing license applications. Contractor X helps develop the system and process the applications. Contractor X should be prohibited from acting as a consultant to any of the applicants during its period of performance and for a reasonable period thereafter.

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AUTHORITY: 42 U.S.C. 216, 289b–1, 289c–3.

SOURCE: 60 FR 35817, July 11, 1995, unless otherwise noted.

§ 94.1 Purpose.

This part promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under PHS contracts will be biased by any conflicting financial interest of an Investigator.

§ 94.2 Applicability.

This part is applicable to each Institution that seeks PHS funding for research and, through the implementation of this part, to each Investigator who participates in such research (see §94.4(a)); provided that this part does not apply to SBIR Program Phase I applications.

§ 94.3 Definitions.

As used in this part:

Contractor means an entity that provides property or services for the direct benefit or use of the Federal Government.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any public or private entity or organization (excluding a Federal agency)

(1) That submits a proposal for a research contract whether in response to a solicitation from the PHS or otherwise, or

(2) That assumes the legal obligation to carry out the research required under the contract.

Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of a research project funded by PHS, or proposed for such funding. For purposes of the requirements of this part relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children.

PHS means the Public Health Service, an operating division of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

PHS Awarding Component means an organizational unit of the PHS that funds research that is subject to this part.

Public Health Service Act or *PHS Act* mean the statute codified at 42 U.S.C. 201 *et seq.*

Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this part, the term includes any such activity for which funding is available from a PHS Awarding Component, whether authorized under the PHS Act or other statutory authority.

Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents copyrights and royalties from such rights). The term does not include:

(1) Salary, royalties, or other remuneration from the applicant institution;

(2) Any ownership interests in the institution, if the institution is an applicant under the SBIR program;

(3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

(4) Income from service on advisory committees or review panels for public or nonprofit entities;

(5) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or

(6) Salary, royalties or other payments that when aggregated for the investigator and the investigator's spouse and dependent children over the

next twelve months, are not reasonably expected to exceed $10,000.

Small Business Innovation Research (SBIR) Program means the extramural research program for small business that is established by the awarding components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this part, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

§94.4 Institutional responsibility regarding conflicting interests of investigators.

Each Institution must:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with this part and inform each Investigator of that policy, the Investigator's reporting responsibilities, and of these regulations. If the Institution carries out the PHS-funded research through subcontractors, or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with this part, either by requiring those Investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with this part.

(b) Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in PHS-funded research.

(c)(1) Require that by the time an application is submitted to PHS, each Investigator who is planning to participate in the PHS-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):

(i) that would reasonably appear to be affected by the research for which PHS funding is sought; and

(ii) in entities whose financial interests would reasonably appear to be affected by the research.

(2) All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with this part for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for three years after final payment or, where applicable, for the other time periods specified in 48 CFR part 4, subpart 4.7.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each contract proposal, that:

(1) there is in effect at that Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the PHS;

(2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the PHS Awarding Component the existence of any conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accordance with this part; and, for any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification.

(3) the Institution agrees to make information available, upon request, to the HHS regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias; and

(4) the Institution will otherwise comply with this part.

[60 FR 35817, July 11, 1995; 60 FR 39676, July 31, 1995]

§94.5 Management of conflicting interests.

(a) The designated official(s) must: Review all financial disclosures; and determine whether a conflict of interest exists, and if so, what actions should be taken by the institution to manage, reduce, or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

(1) Public disclosure of significant financial interests;

(2) Monitoring of the research by independent reviewers;

(3) Modification of the research plan;

(4) Disqualification from participation in all or a portion of the research funded by the PHS;

(5) Divestiture of significant financial interests, or;

(6) Severance of relationships that create actual or potential conflicts.

(b) In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, an Institution may require the management of other conflicting financial interests, as the Institution deems appropriate.

[60 FR 35817, July 11, 1995; 60 FR 39077, July 31, 1995]

§94.6 Remedies.

(a) If the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action or refer the matter to the institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

(b) The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a review of all records pertinent to compliance with this part. HHS may require submission of the records or review them on site. To the extent permitted by law HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Awarding Component may decide that a particular conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed, reduced, or eliminated the conflict of interest in accordance with this part. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

(c) In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this part, the Institution must require disclosure of the conflicting interest in each public presentation of the results of the research.

[60 FR 35817, July 11, 1995; 60 FR 39077, July 31, 1995]

PART 95—GENERAL ADMINISTRATION—GRANT PROGRAMS (PUBLIC ASSISTANCE, MEDICAL ASSISTANCE AND STATE CHILDREN'S HEALTH INSURANCE PROGRAMS)

Subpart A—Time Limits for States To File Claims

Sec.

The following language is inserted in all research and development solicitations:

Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the

regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.**

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

By submission of its signed offer, the offeror/contractor (for acquisitions) or applicant/grantee (for grants) certifies that the submitting organization will comply with the requirements of the Act and will not allow smoking within any portion of any indoor facility used for the provision of services for children as defined by the Act.

The submitting organization agrees that it will require that the language of this certification be included in any subawards which contain provisions for children's services and that all subrecipients shall certify accordingly.

4. CERTIFICATION OF INSTITUTIONAL POLICY ON CONFLICT OF FINANCIAL INTEREST (OCT 1995)

Note: This certification is applicable to Research and Development (R&D) Contracts. However, this certification does not apply to SBIR-Phase I contractors.

By submission of its signed offer, the offeror certifies that:

(1) A written and enforced administrative process to identify and manage, reduce or eliminate conflicting financial interest with respect to all research projects for which funding is sought from the NIH **[ ]**is , **[ ]** is not currently in effect.

(2) Should a process not be in effect at the time of the submission of its offer, the offeror certifies that it will, no later than 30 days subsequent to submission of its offer or prior to award, whichever is earlier, notify the Contracting Officer of the establishment of a written and enforced financial conflict of interest policy.

5. DISASTER OR EMERGENCY AREA REPRESENTATION, [FAR 52.226-3 (AUGUST 2006)**]**

[Note: This provision is applicable for acquisitions that are set-aside for a Disaster or Emergency Area under FAR Subpart 26.2. See Section L.1. of the Solicitation, paragraph entitled "Notice of Disaster or Emergency Area Set-Aside."]

(a) *Set-aside area.* The area covered in this contract is: _____
[*Contracting Officer to fill in with definite geographic boundaries.*]

(b) *Representations.* The offeror represents as part of its offer that it [ ] is, [ ] is not a firm residing or primarily doing business in the designated area.

(c) Factors to be considered in determining whether a firm resides or primarily does business in the designated area include—

(1) Location(s) of the firm's permanent office(s) and date any office in the designated area(s) was established;
(2) Existing state licenses;
(3) Record of past work in the designated area(s) (*e.g.*, how much and for how long);
(4) Contractual history the firm has had with subcontractors and/or suppliers in the designated area;
(5) Percentage of the firm's gross revenues attributable to work performed in the designated area;
(6) Number of permanent employees the firm employs in the designated area;
(7) Membership in local and state organizations in the designated area; and
(8) Other evidence that establishes the firm resides or primarily does business in the designated area.

(d) If the offeror represents it is a firm residing or primarily doing business in the designated area, the offeror shall furnish documentation to support its representation if requested by the Contracting Officer. The solicitation may require the offeror to submit with its offer documentation to support the representation.

(End of provision)

NIH POLICY MANUAL

6009-1 - CONTRACTING OFFICER'S RESPONSIBILITY IN VERIFICATION OF CONFLICTS OF INTEREST IN ADVISORY AND ASSISTANCE SERVICE (A&AS) AND OTHER CONTRACTS

Issuing Office: OA/OCGM 496-6014
Release Date: 02/05/95

1.E **xplanation of Material Transmitted:** The purpose of this chapter is to provide guidance to NIH contracting staff concerning their responsibility to identify, verify, and prevent potential conflicts of interest on the part of consultants under A&AS contracts, independent contractors, known as marketing consultants, furnishing advice to an offeror or any other contractor in support of preparation or submission of an offer to the NIH, and staff proposed by an offeror in response to a solicitation issued by the NIH.

2.F **iling Instructions:**

Remove: I&I Memorandum DCG 91-5, Contracting Officer's Responsibility in Verification of Conflicts of Interest in Advisory and Assistance (A&AS) and Other Contracts, dated 11/25/91
Insert: NIH Manual 6009-1, Contracting Officer's Responsibility in Verification of Conflicts of Interest in Advisory and Assistance (A&AS) and Other Contracts, dated 02/05/95

3.**Dis tribution:** NIH Manual Mailing Keys F-401 and F-407

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- On-line information, enter this URL: http://www1.od.nih.gov/oma/manualchapters/
- To sign up for e-mail notification of future changes, please go to the NIH Manual Chapters LISTSERV Web page.

A. Purpose:

The purpose of this Manual Chapter is to provide guidance to NIH contracting officers concerning their responsibility in identifying, verifying, and preventing potential conflicts of interest on the part of:

1. Persons who provide consulting services under A&AS contracts.

2. Independent contractors, known as marketing consultants, furnishing advice to an offeror or any other contractor in support of the preparation or submission of an offer to the NIH.

3. Staff proposed by an offeror in response to a solicitation issued by the NIH.

B. Background:

Attachment 8

Responsibility for identifying and preventing potential conflicts of interest in Government contracts is shared among the contracting officer, the program staff initiating the request, review staff, and other Government officials with involvement in activities directly related to the procurement.

The references in paragraph D. below, include policies and procedures that the NIH staff must follow in implementing conflict of interest, confidentiality, and integrity rules affecting evaluators of scientific, or technical merit evaluations on NIH contract and subcontract proposals, or active projects under NIH awards. Recent Inspector General concerns regarding possibilities of conflicts of interest among persons who provide consulting services to the NIH under A&AS contracts or who are employees of a contractor performing on NIH contracts has resulted in the need for promoting awareness among affected NIH staff of the existing conflict of interest requirements.

C. Policy:

FAR 9.507 requires the contracting officer to take certain actions with regard to advisory and assistance solicitations and contracts in excess of $25,000. It also requires the contracting officer to determine if there are any organizational conflicts of interests in solcitations, other than sealed bids, where the contract amount is expected to exceed $200,000.

D. References:

1. FAR 9.5, Organizational and Consultant Conflicts of Interest.

2. FAR 37.2, Advisory and Assistance Services.

3. OFPP Policy Letter 89-1, Conflict of Interest Policies Applicable to Consultants, issued 12/8/89.

4. HHSAR 315.406-5(b)(2)(iv), Technical Proposal Instructions.

5. I&I Memorandum OER 91-1 and DCG 91-2, Procurement Integrity Act, Conflict of Interest, and Confidentiality Certification Implications for Individuals Evaluating the Scientific and Technical Merit of NIH Contract Proposals.

6. I&I Memorandum OD 90-1, Conflict of Interest and Confidentiality Certifications for Evaluations of Grant and Cooperative Agreement Applications, Contract and Subcontract Proposals, and Active Projects.

E. Definitions:

1.C onflict of Interest - that condition or circumstance wherein a person is unable or is potentially unable to render impartial assistance or advice to the Government because of other activities or relationships with other persons, or wherein a person has an unfair competitive advantage. (OMB Policy Letter 89-1 definition.)

2.Advis ory and Assistance Services (A&AS) (also known as consultant services) - those services acquired from non-Government sources by contract or by personnel appointment to support or improve agency policy development, decision-making, management, and administration, or to support or improve the operation of management systems. Such services may take the form of information, advice, opinions, alternatives, conclusions, recommendations, training, and direct assistance.

A&AS includes consultant services provided by individuals, as defined in the Code of Federal Regulations, Chapter 304.

3.C onsultants - persons possessing special, current knowledge or skill, which may be combined with extensive operational experience. This enables them to provide information, opinions, advice, or recommendations to enhance understanding of complex issues or to improve the quality and timeliness of policy development or decision-making.

4.M arketing Consultant - any independent contractor who furnishes advice, information, direction, or assistance to any other contractor in support of the preparation or submission of an offer for a Government contract by that offeror. (FAR 9.501 definition.)

F. Procedures:

1. Advisory and Assistance Service Contracts:

a. FAR 9.507-1 requires the contracting officer to insert the provision at FAR 52.209-8, Organizational Conflicts of Interest Certificate - Advisory and Assistance Services in solicitations for A&AS if the contract is expected to exceed $25,000.

b. All A&AS contracts that exceed $25,000, require that the apparent successful offeror provide certified information describing the nature and extent of any conflicts of interest that may exist with respect to the proposed award.

Appendix 1 provides the certification required by FAR 52.209-8, which must be completed by the apparent successful offeror and returned to the contracting officer prior to award.

c. The contracting officer, along with cognizant program and review staff, and if necessary other appropriate NIH officials, must determine whether a conflict of interest exists with regard to the proposed A&AS contract staff before an award of the contract is made, based on information provided by the apparent successful offeror in its certificate. The contract file must be documented to reflect the contracting officer's determination. (NOTE: It is recommended that this documentation be placed in the Summary of Negotiations.)

Should questions arise concerning the contents of the certification, the contracting officer shall notify the offeror proposing the A&AS and provide the offeror a reasonable opportunity to respond. Any findings shall be documented and become part of the contract file. The certificate required under FAR 52.209-8, shall be maintained in the contract file.

2. Marketing Consultants Employed by Contractors

a. OFPP Policy Letter 89-1 as implemented by FAR 9.5, requires that marketing consultants certify that they have provided no information to the contractor employing them that would give the contractor an unfair competitive advantage.

b. FAR 9.507-1 requires that the contracting officer insert the provision at FAR 52.209-7, Organizational Conflict of Interest Certificate - Marketing Consultants, in solicitations, other than sealed bids, if the contract amount is expected to exceed

$200,000.

c. The individual or firm that employs, retains, or has a contractual arrangement with one or more marketing consultant in connection with a contract and which is the apparent successful offeror, must submit to the contracting officer the certificate identified at FAR 52.209-7 for each of its marketing consultants.

Appendix 2 (see paper copy) provides the certification required by FAR 52.209-7, which must be completed by the apparent successful offeror prior to award.

In addition, the apparent successful offeror must forward to the contracting officer a certificate signed by the marketing consultant that the marketing consultant is aware of FAR 9.5 and OFPP Policy Letter 89-1, and that the marketing consultant has provided no unfair competitive advantage to the prime contractor with respect to services rendered, or to be rendered in connection with the solicitation, or that any unfair competitive advantage that does exist has been disclosed to the offeror.

d. In the same manner as in F.1.c. above, based on the information provided by the apparent successful offeror in the certificate(s) it submits, the contracting officer must determine whether an unfair competitive advantage exists with respect to services provided by a marketing consultant in connection with a particular contract action, documenting the contract file accordingly.

e. All marketing consultant certificates and any associated documentation shall become part of the contract file.

3. Exclusions

Certain types of acquisitions are excluded from the requirements of FAR 9.5. These include:

a. Routine engineering and technical services (such as installation, operation, or maintenance of systems, equipment, software, components or facilities).

b. Routine legal, actuarial, auditing and accounting services.

c. Training services.

d. Services rendered in connection with intelligence activities as defined in Section 3.4 (e) of Executive Order 12333 or a comparable definitional section in any successor order, or in connection with special access programs.

e. Acquisitions subject to unique agency organizational conflict of interest statutes.

In addition to these exclusions, please refer to the exclusions cited in FAR Subpart 37.2.

4. Waivers

A waiver to the Organizational and Consultant Conflict of Interest general rules or procedures may be granted by the agency head or a designee (not below the level of head of a contracting activity). The requirements for the request for waiver are addressed in FAR 9.503.

5. All Other Contracts:

a. The technical proposal instructions must be developed to suit the needs of an individual acquisition, permitting proposal evaluators to determine a proposal's acceptability. For purposes of evaluating the qualifications, experience and resources of proposed personnel, the technical instructions may include the following statement:

"In accordance with HHSAR 315.406-5(b)(2)(iv), the technical proposal must include a list of names and proposed duties of the professional personnel, consultants, and key subcontractor employees assigned to the project. Their resumes should be included and should contain information on education, background, recent experience and specific scientific or technical accomplishments."

b. Should any evidence of existing or potential conflicts of interest be manifested as a result of a review of the documents submitted in response to the technical proposal instructions, or to the information submitted under 5.c. below, the contracting officer, in concert with program and other appropriate NIH, and peer review officials in the case of biomedical and behavioral R&D and R&D support requirements, (where appropriate), shall investigate, arriving at a determination concerning the existence of conflicts of interest.

c. Based on the type of requirement being solicited, the contracting officer shall assure that the resultant RFP contain a Summary of Related Activities (See NCI and APDS RFP preparation workforms, Section J., List of Attachments). This summary requires offerors to submit specific information pertaining to the Project Director, Principal Investigator and other proposed key professional individuals designated for performance under any resulting contract. For each aforementioned individual, an identification must be made of all active federal contracts/cooperative agreements/grants and commercial agreements plus outstanding proposals submitted by their organizations. The primary purpose of this information is to enable the contracting officer, program staff, and peer review group members (if applicable) to assess and evaluate the committed levels of effort for the offeror's proposed staff.

d. The contracting officer is alerted to the requirements in FAR 9.507-1 and 9.507-2 for the drafting and inclusion of solicitation provisions and contract clauses that would impose appropriate restraints upon the contractor's eligibility for future contracts or subcontracts in cases where questions concerning organizational conflicts of interest may arise or must be resolved as a condition of award.

Appendix 1:

ORGANIZATIONAL CONFLICTS OF INTEREST CERTIFICATE -
ADVISORY AND ASSISTANCE SERVICES

In accordance with the requirements of FAR 52.209-8, Organizations Conflicts of Interest Certificate - Advisory and Assistance Services (November 1991), and the Office of Federal Procurement Policy Letter 89-1, Conflict of Interest Policies Applicable to Consultants, as a condition of award of a contract, the apparent successful offeror submits to the contracting officer the certificate below:

Solicitation No.*(Insert RFP No.)*, with *(Insert ICD)*
for *(Provide a brief description of services to be provided)*

1. Apparent Successful Offeror Name:
   Address:

Telephone No. including area code:
Federal Taxpayer Identification No.:

2. Please list below (or use additional paper if necessary), the name, address, telephone number of the client(s), a description of the services rendered to the previous client(s), and the name of a responsible officer/employee of the offeror who is knowledgeable about the services rendered to each client, if, in the 12[1] months preceding the date of the certification, services were rendered to the Government or any other client, (including any foreign government or person) respecting the same subject matter of the instant solicitation, or directly relating to such subject matter: [Please list the agency and contract number, if applicable.]

3. The individual signing this certificate below certifies that to the best of his/her knowledge and belief, no actual or potential conflict of interest or unfair competitive advantage exists with respect to the advisory and assistance services to be provided in connection with the instant contract, or that any actual or potential conflict of interest or unfair competitive advantage that does exist with respect to the contract in question has been communicated in writing to the contracting officer or his or her representative.

Name:
Title:
Signature:
Employer's Name:
Employer's Address:
Telephone Number:

In accordance with the requirements of FAR 52.209-7, Organizational Conflicts of Interest - Marketing Consultants (November 1991), and the Office of Federal Procurement Policy (OFPP) Letter 89-1, Conflict of Interest Policies Applicable to Consultants, as a condition of award of a contract. An individual or firm that employs, retains, or engages contractually, one or more marketing consultants in connection with respect to each marketing consultant, the certificate below:

On Solicitation Number *(Insert RFP No.)*, with the *(Insert ICD)*, NIH

1. The following services have been rendered by, or are to be the following marketing consultant:

a. Name of Marketing Consultant:
b. Address:
c. Telephone No., Including Area Code:
d. Federal Taxpayer Identification No.:
e. Name, Address and Telephone No. of Officer/Employee of Marketing Consultant who has Personal Knowledge of the Marketing Consultant's Involvement in the Contract:
f. Description of Nature of Services:

2. Name, address and telephone of the client(s), name of responsible officer/employee of the marketing consultant who is knowledgeable about the services provided to such client(s), if, based on information provided to the contractor by the marketing consultant, any marketing consultant is rendering or, in the 12[1] months preceding the date of the certificate, has rendered services respecting the same subject matter of the instant solicitation, or directly relating to such subject matter, to the Government or any other client (including any foreign

Government or person). (IF NONE, PLEASE INSERT "N/A")

3. The individual signing this certificate below for the prime contractor certifies that he/she has informed the marketing consultant of the existence of Subpart 9.5 of the FAR and of the OFPP Policy Letter 89-1.

Name:
Title:
Signature:
Employer's Name:
Employer's Address:
Telephone No., Including Area Code:

In addition to this certification, the apparent successful offeror shall forward to the contracting officer a certificate signed by the marketing consultant that the marketing consultant has been informed of the existence of FAR Subpart 9.5 and of OFPP Policy Letter 89-1, and that to the best of the marketing consultant's knowledge and belief, he/she has provided no unfair competitive advantage to the prime contractor with respect to services rendered to be rendered in connection with this solicitation, or that any unfair competitive advantage that does or may exist has been disclosed to the offeror. THIS CERTIFICATE SHOULD ACCOMPANY THE ABOVE CERTIFICATE EXECUTED BY THE APPARENT SUCCESSFUL OFFEROR AND BE SENT TO THE CONTRACTING OFFICER PRIOR TO AWARD.

Footnotes:

[1] for Appendix 1, # 2 - If approved by the head of the contracting activity, this period may be increased up to 36 months.

[2] for Appendix 2, # 2 - If approved by the head of the contracting activity, this period may be increased up to 36 months.

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Methodology for Review of National Toxicology Program Research and Development Contracts

1.0 *Background*

The National Toxicology Program (NTP), an interagency program within the Department of Health and Human Services, coordinates toxicology testing within the federal government, develops and validates improved testing methods, carries out research and testing activities to strengthen the science base in toxicology, and provides information about potentially hazardous substances to regulatory and research agencies, medical and scientific communities, and the public.

The objectives for this review of NTP contracts are to:

- assess potential conflict of interest (COI).
- consider what recommendations are appropriate to reduce the potential for COI to occur.
- address how to mitigate any current or future COIs.

The NTP Board of Scientific Counselors Working Group (WG) will conduct the review for presentation to the NTP Board of Scientific Counselors (BSC) at its June 22 meeting.

2.0 *Conflict of Interest (COI) Terminology*

For the purpose of this review, the COI terminology is consistent with the standard COI clause being developed (Attachment 1) and is as follows:

(a) The Contractor warrants that to the best of its knowledge and belief except as otherwise disclosed, no actual or apparent organizational or employee conflict of interest exists as defined below:

(i) a situation in which the nature of work under a Government contract and a Contractor's organization and any of its affiliate organizations or their successors in interest (hereinafter collectively referred to as the "Contractor"), financial, contractual or other interests are such that the appearance of the Contractor's objectivity in performing the contract work may be impaired, may otherwise result in a biased work product, or may result in the contractor being given an unfair competitive advantage; or

(ii) a financial interest or relationship, professional or otherwise, of an employee, subcontractor employee, or consultant (hereinafter referred to as "employee") with an entity that may actually impair or have the appearance of impairing the objectivity of the employee in performing the contract work; or

(iii) an employee has had, currently has, or is reasonably expected to have, official responsibilities with an outside organization, or some other financial

interest or business affiliation, such that a reasonable person with knowledge of the relevant facts might question the employee's objectivity/impartiality in performing the contract.

(iv) For purposes of paragraphs a(i) - (a)(iii), the financial interests and business affiliations of the employee's spouse, minor children, and business partners are imputed to the employee.

3.0 *Materials for the WG*

3.1 NTP and NIEHS reviewed research contracts awarded for the NTP and considered various types of situations where an organizational COI might occur including having unequal access to information, an unfair competitive advantage for a future NTP procurement because of "biased ground rules," or impaired objectivity. It was concluded that risk for NTP contracts was low for potential conflicts related to having unequal access to information or unfair competitive advantage. However, there was concern about the potential for impaired objectivity, so NTP and NIEHS staff reviewed the NTP contracts and triaged them into high, medium and low risk groups. NTP contracts were tentatively assigned to these categories according to NTP's perception of the risk that COI could conceivably influence the products of the contract effort. Assignment to a category was based on the type of contract activity or product delivered to the government, in relation to the degree of direct government oversight exercised over the contract.

Low Risk- the contracts in this category provide general support services to assist NTP in its routine daily activities. These activities could be related to information cataloging and retrieval, web design, or other program-wide activities. Also in this category are contracts that test chemicals under code where their identity is not known to the contractor, as well as those that cover the bulk of the chemical testing activities where the contractor is given a detailed statement of work and the results are subjected to multiple layers of review and analysis often involving other independent contractors.

Moderate Risk- the contracts in this category are ones where the contractor has at least a limited role in developing the scope of research that would be carried out following review and approval for performance by government staff.

High Risk- the contracts in this category are generally ones that support NTP evaluation activities, such as contracts that compile background literature and information for use by government staff in reaching decisions concerning hazards or risks to human health.

3.2 NTP Project Officers will prepare information about how their contracts are managed and what products the contract produces.

3.3 NTP and NIEHS will formally request additional information from contractors based on the WG's recommendation that the WG can use in evaluating potential organizational or employee COI. General as well as specific questions will be sent to contractors for their response (see Attachment 2).

3.4 The NTP will provide the COI document that will be incorporated into current and future contracts (Attachment 1).

3.5 Through a web-based, password protected site, NTP will provide the WG access to documents for each contract including the contract document, relevant modifications to the contract, and statement of work (SOW); information prepared by the Project Officers; answers to questions provided in Attachment 2; other information as deemed necessary; and points of contact for each contract. The WG may have access to other materials as needed.

3.6 NTP staff and NIEHS acquisitions staff will be available as resources to the WG.

4.0 ***WG Tasks***

4.1 WG members will review and sign a conflict of interest pre-certification document prior to initiation of their evaluation and again following completion of this effort.

4.2 The review teams will review the contract materials and determine whether they agree with assignment of the contract to the high, medium, or low risk category. The review teams will consider the guidance provided in Section 5 in their review.

4.3 Members of the WG will be divided into review teams consisting of a scientific advisor and a procurement analyst. Each team will be assigned contracts to review.

4.4 The WG will address organizational and employee COI for the contracts in this evaluation (see COI terminology in Section 2 and guidance in Section 5). The WG will review and evaluate the contractor's responses to the questions in Attachment 2.

The WG will identify any actual/apparent/potential COI in the SOW, contract, and/or other contract-related documents based on the following:

4.4.1 roles and responsibilities of the individual contractor including nature of services provided.

4.4.2 roles and responsibilities of the Government including technical monitoring of the contract
--at the review level during contract performance.
--in oversight of contract performance.

4.4.3 access to proprietary information as deemed necessary.
4.4.4 industry ties [for duration of contract]
4.4.5 any bias based on former ties [for duration of contract].

4.5 The WG will be asked to offer their opinion whether the guidance in the COI document to be added to contracts (Attachment 1) would help prevent the likelihood for actual/apparent/potential COI in future contracts.

4.6 The WG will review and consider the contractors' responses to the questions (see Attachment 2) in their evaluation of the contracts for actual/apparent/potential COI.

4.7 The WG will work using the web-based information provided by NTP.

4.8 WG will meet at NIEHS on May 31 - June 1 to discuss the results of its review and evaluation and draft a report of its findings, conclusions and recommendations. Following the meeting, the draft report will be circulated to the WG for final approval; the deadline for completion is June 8.

4.9 The final WG report will be presented to the NTP BSC meeting at NIEHS on June 22.

5.0 *Organizational Conflicts of Interest (OCI)*

5.1 WG Questions To Evaluate Whether Actual or Potential Organizational Conflicts Of Interest (OCI) Exists in a Contract:

5.1.1 Does the contractor have access to nonpublic information as part of its performance of a government contract which may provide the firm an unfair competitive advantage in a later competition for a government contract? In these "unequal access to information" cases, the concern is limited to the risk of the firm gaining an unfair competitive advantage; there is no issue of possible bias.

5.1.2. Has the contractor, as part of its performance of a government contract, in some sense set the ground rules for the competition for another government contract by, for example, writing the statement of work or the specifications? In these "biased ground rules" cases, the primary concern is that the firm could skew the competition, whether intentionally or not, in favor of itself. These situations may also involve a concern that the contractor, by virtue of its special knowledge of the agency's future requirements, would have an unfair advantage in the competition for those requirements.

5.1.3. Is the contractor responsible for reviewing or evaluating its own work product resulting from a prior contract it had with the government in the

same subject matter? In these "impaired objectivity" cases, the concern is that the firm's ability to render impartial advice to the government could appear to be undermined by the relationship with the entity whose work product is being evaluated.

5.1.4. Are there conflicting roles that might bias a contractor's judgment in relation to its tasks or projects for the NTP? This type of situation arises if the disclosure of financial, contractual, organizational, or other interests that relate to the subject of the contract reveals information that raises concerns about bias or lack of objectivity on the part of the contractor.

5.2 Important Factors to Consider in an Evaluation of Actual or Potential OCI

5.2.1 Evaluation of other companies' contract proposals or products with a potential of a contract resulting from the recommendation.

5.2.2 Evaluation services or activities where any work or effort involves the independent study of technology, process, product, or policy.

5.2.3 Technical support services where such services typically include assistance in the preparation of preliminary designs, specifications, or SOWs, and may involve the contractors being given access to data confidential to NTP or proprietary to others including access to information from its competitors.

5.2.4 Evaluation of a contractor's products or services or the products or the services of another party.

5.2.5 Preparation and furnishing of a detailed plan for specific approaches or methodologies for incorporation into a future competitive acquisition.

5.2.6 Preparation and furnishing of advice to NTP in a technical area where the contractor is also providing consulting assistance in the same area to any other organization.

5.2.7 Access to proprietary information that cannot lawfully be used for purposes other than those authorized by the owners.

5.2.8 Revisions when the SOW is modified to add new work or the parties to the contract are changed.

5.2.9 Contractual requirements that call for rendering of advice, consultation or evaluation services, or similar activities that directly lay the groundwork for the NTP's decisions on activities, future procurements, and research programs.

5.2.10 The contract places the contractor in a conflicting role in which its judgment may be biased in relation to its work for the NTP, or would result in an unfair competitive advantage for the contractor.

5.2.11 Access to information not available to the public concerning NTP plans, policies, or programs that could form the basis for a later procurement plan.

6.0 *Strategies for Consideration to Manage an Actual or Potential OCI*

6.1 Prior to Contract Award

6.1.1 Disqualify the offeror from award.
6.1.2 Avoid or eliminate such conflicts by appropriate measures including the inclusion of appropriate Terms and Conditions suggested by Legal Counsel in the resulting contract.
6.1.3 Make suggested changes to the SOW.
6.1.4 Continue performance under the contract under the waiver provision of FAR 9.503 if unable to mitigate, or avoid the apparent conflict of interest if in the best interest of the government and there is public exigency or work cannot otherwise be obtained.

6.2 After Contract Award

6.2.1 Notify the Contracting Officer and program officials as soon as possible.
6.2.1 Require the contractor to complete a disclosure statement.
6.2.3 Avoid or mitigate the effects of the conflict of interest. (Include any appropriate clauses in the contract; require the contractor to stipulate how they intend to mitigate any potential conflict of interest, etc.).
6.2.4 Exclude the contractor from subsequent NIH contracts for work of a similar nature for a specific period of time.

6.3 Strategies to Manage an Actual or Potential Personal COI

6.3.1 Publicly disclose the financial interest.
6.3.2 Monitor the research by independent reviewers.
6.3.3 Modify the research plan; disqualify an investigator or investigators from participating in all or a portion of the research funded by the federal agency; with respect to peer reviews, the reviewer must either recuse himself/herself from review of the proposal at issue or be removed from the panel.
6.3.4 Divest the financial interest; sever relationships that create actual or potential conflicts.
6.3.4 Decline the award.

Attachment 1

The following language will be added to current and future contracts.

Conflict of Interest

(a) The Contractor warrants that to the best of its knowledge and belief except as otherwise disclosed, no actual or apparent organizational or employee conflict of interest exists as defined below:

(i) a situation in which the nature of work under a Government contract and a Contractor's organization and any of its affiliate organizations or their successors in interest (hereinafter collectively referred to as the "Contractor"), financial, contractual or other interests are such that the appearance of the Contractor's objectivity in performing the contract work may be impaired, may otherwise result in a biased work product, or may result in the contractor being given an unfair competitive advantage; or

(ii) a financial interest or relationship, professional or otherwise, of an employee, subcontractor employee, or consultant (hereinafter referred to as "employee") with an entity that may actually impair or have the appearance of impairing the objectivity of the employee in performing the contract work, or

(iii) an employee has had, currently has, or is reasonably expected to have, official responsibilities with an outside organization, or some other financial interest or business affiliation, such that a reasonable person with knowledge of the relevant facts might question the employee's objectivity/impartiality in performing the contract.

(iv) For purposes of paragraphs a(i) - (a)(iii), the financial interests and business affiliations of the employee's spouse, minor children, and business partners are imputed to the employee.

(b) The Contractor agrees that if changes in their organization or employees have occurred that give rise to the appearance of a conflict of interest since submission of their final proposal revision (FPR) and contract award or occur during the performance of this contract, it shall make an immediate and full disclosure to the Contracting Officer and Project Officer in writing. Such disclosure should include a description of the circumstances, and a description of any action which the contractor has taken or proposes to take to avoid, neutralize, or mitigate any actual or apparent conflict of interest.

(c) The Contractor has an ongoing responsibility to notify the Government Contracting Officer and Project Officer in writing if any actual or apparent conflict of interest arises during the period of performance of the contract. The

written notification must provide details of the conflict of interest and any planned mitigation.

(d) The Contractor agrees to immediately notify the Contracting Officer and the Project Officer of (1) any actual or apparent personal conflict of interest with regard to any of its employees working on, having published, or having access to information regarding this contract, or (2) any such information regarding this contract, when such conflicts have been reported to the Contractor.

(e) The Contractor agrees to notify the Contracting Officer and Project Officer prior to incurring costs for that employee's work when an employee may have a conflict of interest. In the event that the conflict of interest does not become known until after performance on the contract begins, the Contractor shall immediately notify the Contracting Officer and Project Officer of the conflict of interest. The employee shall recuse himself/herself from work on this contract when an actual or apparent conflict has been identified until such time as it is determined that the conflict does not exist or it is resolved. The Contractor shall continue performance of this contract until notified by the Contracting Officer of the appropriate action to be taken.

(f) The provisions of this clause shall be included in all subcontracts and consulting agreements to avoid, neutralize, or mitigate actual or apparent conflicts of interest.

Attachment 2

Questions for Contractors' Response

Is your company affiliated with any other company in terms of ownership, wholly owned subsidiaries, etc?

____ Yes ____ No

If yes, please describe each affiliation as it relates to this contract.

The questions below pertain to evaluating employee conflicts of interest.

1. Please describe or provide a copy of your company's conflict of interest policy.

2. Please discuss financial disclosure requirements you have for principal investigators and other key personnel.

3. What types of "firewalls" do you have that separate those personnel involved in this government contract from those in the organization that might work for other organizations?

4. Do your employees provide annual or biennial certifications regarding COI and/or their awareness of those policies?

   ____ Yes ____ No

5. Do any contractor staffs have financial, personal relationships or affiliations that could influence (or bias) their work product or ability to render objective advice?

   ____ Yes ____ No

   If yes, please elaborate.

The questions below pertain to possible Organizational Conflicts of Interests (bias or unfair competitive advantage). If the answer is no, please explain why the potential for conflict is unlikely. If the answer is yes, please explain why there exists a possible conflict.

1. Does the contractor have any involvement with or interests in technologies and/or substances which may be subjects of the contract or which are substitutable for such technologies/substances?

The involvement or interest could take any form, including interest in relevant proprietary toxicological methods or in patents as well as interests in the manufacturers of the substances.

____ Yes ____ No

2. Does the contractor do business with organizations that might appear to be in conflict with the mission of the NIH/NIEHS or have a relationship (financial, organizational, contractual or otherwise) with such organizations or firms that could impair its objectivity or independence?

____ Yes ____ No

3. Would any unfair competitive advantage accrue to the contractor in either its private or government business pursuits resulting from access to:

   (a) data generated under the contract?
   (b) information concerning NTPS plans and programs?
   (c) confidential and proprietary data of others?

____ Yes ____ No

4. Is the contractor performing any self-evaluation or inspection of a service or product, or evaluation or inspection of another with whom a relationship exists which could impair objectivity, including evaluation or inspection of goods or services which compete commercially with the contractor's goods or services?

____ Yes ____ No

5. Are any of the contractor's chief executives, directors, entities that they own or represent, and/or affiliates involved in performance of the contract?

____ Yes ____ No

If yes, have they signed disclosure or representation statements? (Please provide copies if available.)

6. Are you aware of any other information relating to this contract that could reasonably be construed as creating an OCI?

____ Yes ____ No