



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

Presented by

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June 22, 2007

# Background

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- ❑ NTP Program History
- ❑ Mission of NTP
- ❑ NTP studies
- ❑ NTP took steps to ensure integrity of its science and address those concerns
  - Convened a working group of the NTP Board of Scientific Counselors (BSC) to review current NTP contracts
    - ❑ Working group is a fact-finding body that gathers information, analyzes relevant issues and facts, and drafts proposed positions for final deliberations by the federally chartered advisory group

# Current COI Requirements

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Increasing potential for COI due to:

- Outsourcing

- contractors performing work previously done in-house

Limited tools available to Government to address COI

## Current COI Requirements (Cont'd)

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### Current COI Regulations Insufficient

- ❑ FAR 2.1 defines only Organizational Conflict of Interest (OCI)
  - No definition provided for personal COI
- ❑ FAR 3.1 provides policies and procedures for avoiding personal COI
  - Applicable only to government employees
  - No guidance in FAR 3.1 or elsewhere in FAR on personal COI applicable to contractors
- ❑ FAR 9.5 provides regulatory guidance on OCI
  - Leaves implementation up to each agency

# Current COI Requirements (Cont'd)

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## Additional COI Guidance

- ❑ Financial COI
  - 45 CFR 94 (Objectivity in Research)
  - Limitations of 45 CFR 94
  
- ❑ GAO Decisions



# Current COI Requirements (Cont'd)

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## Current NIH Guidance

- ❑ Solicitation Provision – “Institutional Responsibility Regarding Conflicting Interests of Investigators”
- ❑ Certification Requirement in Reqs & Certs
- ❑ Manual Chapter (MC) 6009-1

# Working Group

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- ❑ Project began April 26, 2007; report completion by July 1, 2007
- ❑ Membership
  - Chaired by Diane Frasier, Acting Director, Office of Acquisition and Logistics Management
  - Contract professionals
  - NIH intramural scientist
  - BSC representation: past and future members
- ❑ Objectives for the review of NTP contracts
  - Assess potential COI
  - Consider recommendations to reduce potential for COI to occur
  - Address how to mitigate any current or future COIs

# Methodology, Approach and Analysis

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- ❑ Includes COI terminology, information on materials provided to WG, WG tasks, guidance for evaluation of OCI, strategies for managing OCI
- ❑ Provides mechanism for WG to request further information as needed from contractors using a COI review questionnaire
- ❑ Includes a proposed COI contract clause developed by NIEHS with OGC input
  - Will be used in all current and future NTP contracts

## Methodology, Approach and Analysis (Cont'd)

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- ❑ NTP/NIEHS staff reviewed contracts classified as “research” contracts
  - To determine extent of risk for COI
  - Binning of contracts by NTP/NIEHS
    - ❑ High risk, Moderate risk or Low risk assigned to each contractor

## Methodology, Approach and Analysis (Cont'd)

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- ❑ Original NTP/NIEHS binning:
  - 4 contractors assessed as high risk for COI
  - 12 contractors assessed as moderate risk
  - 26 contractors assessed as low risk

## Methodology, Approach and Analysis (Cont'd)

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- ❑ WG members reviewed each contract and discussed COI risk based on documentation provided
- ❑ WG reviewed
  - Contract
  - SOW
  - Project Office statement of objectives
    - ❑ Summarized each contract's purpose, management oversight by government/contractor staff and output/product of contract

## Methodology, Approach and Analysis (Cont'd)

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- ❑ **WG revised initial binning as follows:**
  - 9 contracts assessed to be at high risk for COI
  - 11 contracts assessed to be moderate risk
  - 22 contracts assessed to be at low risk

## Methodology, Approach and Analysis (Cont'd)

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- ❑ WG requested additional information using COI questionnaire
  - OMB Paperwork Reduction Act limitations
  - Information requested from 9 contractors
  - Tenth contractor – information obtained under Objectivity in Research (45 CFR 94)
- ❑ WG divided into 3 teams
  - Procurement Analyst and scientific advisor on each team

# Methodology, Approach and Analysis (Cont'd)

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## □ Results of Review

- No contractor reported actual or potential COI
- 9 contractors responded to COI questionnaire:
  - Most have written COI policy
  - Those who do inform their investigators of their COI policy
  - Very few address COI on the part of subcontractors and collaborators
  - Most designate Institutional Official to solicit and review financial disclosure statements
  - Fewer require financial disclosure statement from investigators
  - Even fewer require updated financial disclosure reports
  - Very few maintain financial disclosures for 3 years
  - More than half provide guidelines for designated Institutional Official to use to determine COI
  - Very few provide for sanctions when COI identified

## Methodology, Approach and Analysis (Cont'd)

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- Most had established firewalls
- A few require employee nondisclosure agreements
- None have contract staff with financial/personal affiliations or relationships that could lead to potential COI
- None have technology interests that conflict with their contract work

## Methodology, Approach and Analysis (Cont'd)

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- Almost all claimed no impaired objectivity that could bias/impair their objectivity in contract performance
  - One exception addressed mitigation strategy
- None have unfair competitive advantage
- Only 1 is performing self-evaluation or inspection of service/product, or evaluation/inspection of another organization
  - Mitigation strategy addressed
- None are aware of any actual or potential COI/OCI in any of their contracts

## Methodology, Approach and Analysis (Cont'd)

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- ❑ Project Officers briefed WG on specific contracts and processes in place which minimize potential for COI
- ❑ WG reviewed NIH R&D solicitation provision and NIEHS contract clause
  - Also reviewed samples of COI clauses from other agencies (i.e., FDA)
  - WG recommended that improvements be made to both solicitation provision and NIEHS contract clause

# Identification of Best Practices

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- ❑ NTP Pathology Review Process
  - Regarded as “gold standard”
- ❑ NIEHS contract clause language
  - Is being inserted in current and future NTP contracts
- ❑ Solicitations address financial COI and 45 CFR 94 requirements in 2 sections
  - Section L Provision
  - Reps and Certs



## Identification of Best Practices (Cont'd)

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- ❑ NIH's proactive site visits to educational institutions that conduct R&D
- ❑ NIH/OER website postings re: Objectivity in Research and financial COI
- ❑ NIH Manual Chapter 6009-1 guidance for contracting and program staff

# Summary and Recommendations

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- ❑ WG did not find evidence of actual or apparent COI
- ❑ Broaden 45 CFR 94 to cover all types of COI - not just financial COI
- ❑ NIH should develop COI policies and refine contract language to include OCI and extend to non-R&D contracts
- ❑ NIH should rewrite solicitation instructions to require offerors to submit COI policy when proposing

## Summary and Recommendations (Cont'd)

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- ❑ Contracting & Project Officers should be reminded of responsibility to determine existence of OCI and COI
- ❑ NIH should consider OCI & COI training for contracting officers, project officers and contractors
  - How to identify COI
  - How to address COI if found
  - Remedies to apply when COI found
  - How to protect proprietary/confidential data during contract performance
  - Emphasize and clarify definitions in 45 CFR 94



## Summary and Recommendations (Cont'd)

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- ❑ Strengthen NIH Reps & Certs to require compliance
- ❑ Broaden NIH Annual Reps & Certs to include OCI and applicability to non-R&D contracts
- ❑ Add NIH COI certification language in ORCA Reps & Certs
- ❑ Post redacted sample contractor COI policies to NIH website

## Summary and Recommendations (Cont'd)

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- ❑ Request FAR Council to develop broader standard COI/OCI policies and clauses
- ❑ NIH HCA letter to contractors to reiterate/clarify OCI and COI requirements
- ❑ Noncompliant NTP/NIEHS contractors should be notified and required to update policies
- ❑ Augment NTP staff to have federal employees handle selected responsibilities currently done by contractors

# QUESTIONS?

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