

OMB’s Peer Review Bulletin Establishes Uniform IQA Conflict of Interest Standards to Ensure Validity of Agency-Disseminated Third-Party-Developed HISAs Supporting Major Regulations

One objective of OMB’s IQA-implementing Peer Review Bulletin was to create uniform high-level federal agency peer review institutional conflict of interest (“COI”) standards applicable to the third party-developed highly influential scientific assessments (“HISAs”) agencies use and *disseminate* (‘outputs’) as support for major regulations, no matter whether agencies initially acquired the research and data (‘inputs’) ultimately incorporated within such HISAs by means of research & development (“R&D”) procurement contracts or extramural grant awards and cooperative agreements. To such end, the Peer Review Bulletin refers to National Academy of Sciences (“NAS”) peer reviewer COI standards which are sufficiently broad to encompass institutional as well as individual conflicts, consistent with the rigorous peer reviewer COI standards of the National Institutes of Health.^{1 2} Since NIH is the federal government’s largest provider of biomedical research grants to third parties,³ its institutional peer review COI standards effectively set an upper procedural benchmark for the review processes agencies employ to validate the quality of the science they acquire for use at the ‘input’ stage.

Under the NIH policy, a COI would be deemed to arise for a peer reviewer of research grant and R&D contracts in the following scenarios: 1) where the peer reviewer “is contributing to the scientific development or execution of any project under review [...] in a substantive, measurable way;” 2) where the peer reviewer “is a salaried, full or part-time employee of any of [...] any of the institutions submitting an application or proposal;” or 3) where the peer reviewer’s “professional associate (colleague, scientific mentor, student, collaborator, etc., within the last three years) plays a major professional role on a [g]rant application [...] or [o]n an R&D contract; and 4) the “situation that could cause a reasonable person with all the relevant facts to question the impartiality of the reviewer or that leads a reviewer to question his or her objectivity.⁴ Under any of these circumstances, the NIH COI policy prohibits the peer reviewer from “participat[ing] in the evaluation of that grant application [...] or [...] contract proposal,”⁵ unless an applicable exception applies, or an agency waiver of the COI, once identified and publicly disclosed, has been granted.⁶

The Peer Review Bulletin’s incorporation of NAS peer reviewer institutional COI standards effectively supplemented OMB’s prior efforts to create uniform COI standards for Federal agency audits of States, local governments, and non-profit organizations expending Federal awards pursuant to Circular A-133.⁷ Indeed, prior to the Peer Review Bulletin’s development, the administrative requirements, including COI standards, applicable to third party research agencies obtained through R&D grants and cooperative agreements, were distinct from those applicable to third party research agencies obtained via procurement contracts. The former arose from OMB Circular A-110 - *Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations*,⁸ while the latter were contained in the Federal Acquisition Regulation (FAR) [*Part 35—Research and Development Contracting*] and agency FAR supplements, e.g. the Defense Federal Acquisition

Regulations Supplement (DFARS))”.⁹ This distinction in treatment was based on the *Federal Grant and Cooperative Agreements Act of 1977*, in which Congress had identified the “need to distinguish Federal assistance relationships from Federal procurement relationships and [...] to standardize usage and clarify the meaning of the legal instruments which reflect such relationships.”¹⁰

¹ See Office of Management and Budget, *Final Information Quality Bulletin for Peer Review* [Hereinafter “OMB-PRB”] (Dec. 16, 2004), at Preamble, pp. 6 and accompanying notes, 19-20, available at: <http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf> (“A wide variety of authorities have argued that peer review practices at federal agencies need to be strengthened. Some arguments focus on specific types of scientific products (e.g., assessments of health, safety and environmental hazards). The Congressional/Presidential Commission on Risk Assessment and Risk Management suggests that “peer review of economic and social science information should have as high a priority as peer review of health, ecological, and engineering information.”) *Id.*, at p. 6.

² *Id.*, at p. 20 (“[W]hen an agency determines that it is necessary to use a reviewer with a real or perceived conflict of interest, the agency should consider publicly disclosing those conflicts [...] and shall inform potential reviewers of such disclosure at the time they are recruited.”) See *Id.*, at § III.3.b, pp. 39-40 (“The agency [...] shall [...] (ii) in selecting peer reviewers who are not government employees, *adopt or adapt the National Academy of Sciences’ policy* for committee selection with respect to evaluating the potential for conflicts (e.g., those arising from investments; agency, employer, and business affiliations; grants, contracts and consulting income). *For scientific assessments relevant to specific regulations, a reviewer’s financial ties to regulated entities (e.g., businesses), other stakeholders, and the agency shall be examined*”) (emphasis added).

³ See National Research Council, *The Funding of Young Investigators in the Biological and Biomedical Sciences*, (National Academies Press, Wash., D.C. ©1994), at p. 25, available at: <http://www.nap.edu/catalog/4746/the-funding-of-young-investigators-in-the-biological-and-biomedical-sciences>.

⁴ See U.S. Department of Health and Human Services, National Institutes of Health Office of Extramural Research, *Grants and Funding - Managing Conflict of Interest in NIH Peer Review of Grants and Contracts – When Does COI Arise?*, available at: http://grants.nih.gov/grants/peer/peer_coi.htm.

⁵ *Id.*

⁶ See U.S. Department of Health and Human Services, National Institutes of Health, *NIH Conflict of Interest Rules: Information for Reviewers of NIH Applications and R&D Contracts*, NIH/OER/OEP (Approved 9/20/2011 for implementation by January 25, 2012), at Sec. 5, pp. 2-3, available at: http://grants.nih.gov/grants/peer/COI_Information.pdf; U.S. Department of Health and Human Services, National Institutes of Health, *Advance Notice: Revised Policy for Managing Conflict of Interest in the Initial Peer Review of NIH Grant and Cooperative Agreement Applications*, NOT-OD-11-120 (Nov. 30, 2012), at Sec. II.B.7, available at: <http://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-13-010.html>; U.S. Department of Health and Human Services, National Institutes of Health, *NIH Policy for Managing Conflict of Interest in the Peer Review of Concepts and Proposals for Research and Development Contract Projects*, NOT-OD-13-010 (March 20, 2014), at Sections I, II.B.1-3, 6, available at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-069.html>.

⁷ See, e.g. The White House, Executive Office of the President, Office of Management and Budget, *OMB Circular A-133 - Audits of States, Local Governments, and Non-Profit Organizations*, 68 FR 38401 (June 27, 2003), at Sec. 1, available at: <http://www.gpo.gov/fdsys/pkg/FR-2003-06-27/pdf/03-16355.pdf>; <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a133/a133.pdf>; The White House, Executive Office of the President, Office of Management and Budget, *OMB Circular A-133 Compliance Supplement* (March 2006), at Part 5 – Research and Development Programs, p. 5-2-1, available at: http://georgewbush-whitehouse.archives.gov/omb/circulars/a133_compliance/06/compliance_supplement_march2006.pdf.

⁸ See White House, Executive Office of the President, Office of Management and Budget *Circular A-110 - Uniform Administrative Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations* (11/19/1993) (further amended 09/30/1999), available at: http://www.whitehouse.gov/omb/circulars_a110/, codified at 2 CFR, Part 215, at pp. 39-68, available at: <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a110/2cfr215-0.pdf>.

⁹ See The White House, Executive Office of the President, Office of Management and Budget, *OMB Circular A-133 Compliance Supplement* (March 2006), at Part 5 – Research and Development Programs, p. 5-2-1, available at: http://georgewbush-whitehouse.archives.gov/omb/circulars/a133_compliance/06/compliance_supplement_march2006.pdf.

¹⁰ See also the *Federal Grant and Cooperative Agreements Act of 1977*, P.L. 95-224, 95th Cong., 92 STAT 3 (Feb. 3, 1978), at Sec. 2, available at: <http://www.gpo.gov/fdsys/pkg/STATUTE-92/pdf/STATUTE-92-Pg3.pdf>, codified at 31 U.S.C. 6301-6308 , available at: <http://www.commerce.gov/sites/default/files/documents/2011/october/uscode-2010-title31-subtitlev-chap63.pdf>.