DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary for Health
Office of Research Integrity
1101 Wootton Parkway, Suite 750
Rockville, MD 20852

April 16, 2014

Mr. Anthony P. DeCrappeo, President
Council on Governmental Relations (COGR)
1200 New York Avenue, N.W., Suite 750
Washington, DC 20005

Re: Response to comments on "Agency Information Collection Activities; Proposed Collection; Public Comment. Document Identifier: HHS-OS-21329-60D

Dear Mr. DeCrappeo,

The purpose of this announcement was to note that the Office of Research Integrity (ORI) is modifying an existing Information Collection Request (ICR) by adding form PHS-6315. This form is to be used only for those recipients of sub-awards of Public Health Service (PHS) awards that do not otherwise have an assurance with ORI. The public comments received primarily dealt with two basic concerns: the descriptions of the burden and compliance by small institutions.

The concern that the burden statements in the table were confusing and misleading has been corrected to account for the slightly increased overall burden associated with the additional forms that are expected to result from this new requirement.

There was also apparently some confusion about whether the burden associated with this requirement was relevant to an institution's burden resulting from conducting inquiries and investigations into allegations of research misconduct. The burden related to this notice is related only to the process of filling out and electronically filing Form PHS-6315 one time, and, thereafter, PHS-6349 on an annual basis. This process is expected to take only a few minutes, and does not address the process that the entity employs to ensure that it has policies and procedures in place to qualify for the assurance being sought.

A second concern dealt with whether small entities receiving sub-awards, such as clinics and hospitals with limited research programs, would be qualified to conduct an unbiased review of allegations of research misconduct. ORI recognizes that this could be a concern but notes that there are a number of approaches that could be taken to alleviate

this concern. The issue for ORI is that, pursuant to 42 C.F.R. Section 93.300(i) all sub-awards need to be covered by an assurance. This is required of all institutions and institutional members, which include sub-awardees as defined by 42 C.F.R. Sections 93.213 and 214. However, it is also clear that the primary grant holder has a substantial interest in ensuring that the PHS funded research being carried out by its sub-awardees is performed competently and honestly, and that its sub-awardees are observant of applicable statutes and regulations. If allegations of possible research misconduct nevertheless do arise, the assurance provides ORI with jurisdiction, but the review of those allegations remains the responsibility of the assurance holder. However, how those allegations are reviewed is largely up to both the primary grantee and sub-awardee. The process following may involve a consortium, as permitted at 42 C.F.R. Section 93.306, or any degree of joint review by the primary awardee and sub-awardee, and may include experts from outside either institution.

Lastly, there was some concern about contractual language that might be used by the primary awardee to ensure that the sub-awardee obtains an assurance by filing PHS-6315. This is a matter to be resolved by the awardee.

Sincerely,

John E. Dahlberg, Ph.D.
Deputy Director
Office of Research Integrity (ORI)