

**Office of Research Infrastructure Programs
Division of Program Coordination Planning and Strategic Initiatives**

**2013 Biennial Advisory Council Report Certifying Compliance with the NIH Policy on the
Inclusion of Women and Minorities in Clinical Research**

The NIH Revitalization Act of 1993 requires the Director of NIH to ensure that women and minorities are included as participants in clinical research. The Act also stipulates that the advisory councils of the national research institutes and centers prepare biennial reports describing how the institutes and centers complied with the congressional mandate. The Council of Councils (CoC) reviewed the Office of Research Infrastructure Programs (ORIP) aggregate tracking and inclusion report at the January 22, 2013 council meeting. This summary report documents ORIP's compliance.

In Fiscal Years 2011 and 2012 ORIP did not support any NIH-defined clinical trials. The projects which included human subjects were all exempt from tracking. For example, the Science Education Partnership Award (SEPA) program exemption code was "NT" (Not to be Tracked) while the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) programs usually had the exemption code of "NC" (Not Clinical Research) or "ET" (Early Stage of Technology Development).

Procedures used for compliance include: 1) the role of the initial review group, 2) the information included on the summary statement, and 3) the role of ORIP program staff. In compliance with the NIH Revitalization Act of 1993, applicants must respond to any concerns regarding inclusion to the satisfaction of ORIP staff and the ORIP Director.

As part of the initial review process, the Office of Review, NCATS, informs all review committees of human subjects review considerations. This is done in writing prior to the review and the policies are reviewed verbally at the review meeting, leaving sufficient time for any questions that may arise in this regard. A copy of the instructions to reviewers regarding the coding of human subjects research is included in each reviewer's packet and is provided at the review meeting. Members of the peer review panel are told that they play an important role in ensuring the proper protection and inclusion of human subjects. Reviewers are assigned to individual projects to provide the gender, minority, and children inclusion codes. For inclusion of women, minorities, and children (<21 years), data should be provided in the application as appropriate for each project and the reviewers are aware that each application that deals with human subjects research must address the required points regarding use of human subjects and must include the target/planned enrollment tables.

ORIP staff attended training activities, including updates on new policies and procedures regarding human subjects. In addition, ORIP staff is represented at the Inclusion Operating Procedures Workgroup meetings.