

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

**2015 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 30, 2015 council meeting. This summary report documents ORIP's compliance with the legislative mandate.

The Office of Research Infrastructure Programs (ORIP), located within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), NIH Office of the Director, provides the research infrastructure and support for intellectual and physical infrastructure related to research programs, and coordinates NIH's science education efforts. The trans-NIH nature of ORIP, consistent with DPCPSI's mission, includes coordination of research and other activities to advance medical research in all disease areas and across the basic, translational, and clinical research continuum.

ORIP, through all of its programs, is sparking innovation and leveraging shared resources to: (1) provide access to state-of-the art technologies and instruments that enable both basic biomedical research and clinical investigations of a multitude of health issues, from cancer to infectious diseases; (2) develop and provide access to critical animal models, which offer essential clues to a broad range of human disorders such as Parkinson's disease, multiple sclerosis, and AIDS; (3) train veterinary scientists to become valuable partners in an integrated, multidisciplinary approach to biomedical/translational research; (4) provide funding to renovate existing research facilities; (5) improve the public understanding of medical research and provide adults and children with information about healthy living and science career opportunities; and (6) plan, develop, and coordinate comprehensive science education programs to strengthen and enhance efforts of the NIH to attract young people to biomedical and behavioral science careers and to improve science literacy in both adults and children.

In Fiscal Years 2013 and 2014, 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 had the exemption code of "NC" (Not Clinical Research) or "ET" (Early Stage of Technology Development).

Compliance with the inclusion regulations/policies involves: the initial scientific peer review group; delineation of the reviewers' concerns/issues in the summary statement; and approval of the applicant's response to these concerns by ORIP staff and the ORIP Director.

As part of the initial review process, the Center for Scientific Review (CSR), informs all initial scientific peer review groups of the review considerations for compliance with regulations/policies involving human subjects. This is done in writing prior to the initial scientific peer review group meeting and again verbally at the 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 it is provided at the meeting. Members of the peer review group are informed that they play an important role in ensuring the proper protection and inclusion of human subjects in research. Reviewers are assigned to each application to determine the appropriate 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. The reviewers are aware that each application that deals with human subjects research must address the required criteria regarding the use of human subjects and must include the target/planned enrollment tables.

The summary statement provided to the applicant includes the reviewers' comments/concerns about the project complying with inclusion regulations/policies. 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 prior to grant award.

In FY 2013 and 2014, ORIP staff attended training activities on new policies and updated procedures regarding human subjects research. In addition, ORIP staff members are represented at the NIH Inclusion Operating Procedures Workgroup meetings. These activities ensure that ORIP staff members are fully knowledgeable about the latest changes to inclusion regulations/policies in order to fulfill their programmatic responsibilities in this area.