

Inclusion of Women and Minorities in Clinical Research

2015 Biennial Advisory Council Report



National Institutes of Health
Turning Discovery Into Health



Background

NIH Revitalization Act of 1993

- Requires NIH Director to ensure women and minorities are included in clinical research
- Stipulates that each advisory council prepare a biennial report describing how the institute or center complied with the Act

Office of Research Infrastructure Programs (ORIP)

- In Fiscal Years 2013 and 2014, ORIP did not support any NIH-defined clinical trials
- ORIP projects which included human subjects were exempt from tracking, for example:
 - Science Education Partnership Award (SEPA) grants were given the exemption “Not to be Tracked”
 - Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) were given the exemption “Not Clinical Research” or Early Stage of Technology Development”

Compliance Procedures

- Initial review group: reviewers are assigned to projects to provide the gender, minority, and children inclusion codes
- Inclusion information is included in the summary statement
- ORIP program staff – applicants must respond to any concerns regarding inclusion to the satisfaction of ORIP staff and the ORIP Director prior to grant award
- ORIP staff regularly attends training activities, including updates on policies and procedures regarding human subjects

Inclusion of Women and Minorities in Clinical Research: 2015 Biennial Advisory Council Report

Discussion

Vote