

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

2015 BIENNIAL ADVISORY COUNCIL REPORT CERTIFYING COMPLIANCE WITH THE NIH POLICY ON THE INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH

January 2015

I Background

The mission of the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) is to catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.

NCATS is “disease-agnostic”. It seeks system-wide insights into what is common among diseases, and into the process of turning basic and clinical discoveries into medical interventions that improve human health. Because NCATS focuses on the translational process instead of on specific health problems, it generally supports other groups that are performing clinical studies rather than running its own clinical research. NCATS has a highly collaborative research portfolio, which makes extensive use of cooperative agreements and cofunding. The Clinical and Translational Science Awards (CTSA) program, which is the largest program within NCATS, provides resources for other NIH institutes and centers (ICs) to perform clinical research. The intramural research program has many in-kind partnerships that help advance clinical studies conducted by their collaborators. By building partnerships, NCATS enables other ICs to leverage their funding for clinical research. When other NIH ICs use NCATS resources to carry out their clinical studies, those other ICs report the patient enrollment data. So, although NCATS is deeply involved in clinical research, the collaborating ICs usually report on the participants in the research. Occasionally, NCATS awards, such as small business development awards (SBIR/STTR), may include clinical studies. This report covers years 2013 to 2014 and addresses inclusion data for an SBIR grant with a planned enrollment of 177 participants, which is directly funded by NCATS.

II Strategies for Ensuring Compliance

The NCATS program development process involves several strategies to support the inclusion of a diverse population in clinical studies and workforce development. Funding announcements contain language requiring that women and minorities be included in all clinical research studies, as appropriate for the scientific goals of the work proposed. The recent [CTSA funding announcement](#) states that the application review and award funding will include consideration of efforts to include special populations such as children, the elderly, rural populations, minorities, pregnant women, people with disabilities, and hard-to-reach populations. Applicants are encouraged to describe plans to collaborate with other centers to leverage resources for participant diversity and to set specific goals for inclusion of health disparities populations.

NCATS ensures that all science review officers, program officers and grants management officers are aware of the NIH policy on inclusion on the basis of sex/gender, race, ethnicity, and age in [clinical research](#). Internet resources are available for NCATS staff to learn about [including diverse populations in clinical research](#).

The following are some of the ways that NCATS staff is kept up-to-date in their training:

- Scientific Review Officers (SROs) keep abreast of NIH policy on inclusion by participating in training sessions offered at the NIH and also by keeping up to date with policy notices issued by NIH. SROs also ensure that peer reviewers provide the required comments on inclusion criteria and take them into account when evaluating grant applications.
- Grants management staff participates in continuous training in areas of policy, process, and leadership and are required to be certified by the NIH Grants Management Certification Review Board every three years. Staff participated in a webinar titled “Human Subject Protections: What you always wanted to know about the regulations and NIH Policy.”
- Program Officers, SROs, and grants management staff attended the Inclusion Training session on January 7, 2014. This included a discussion of recent and upcoming changes as a result of re-engineering efforts and the rollout of a new eRA module in 2014.
- NCATS staff met with the Office of Extramural Research (OER) on January 12, 2015, to receive training on the new electronic Inclusion Management System (IMS) and on efforts to re-engineer NIH inclusion reporting. The meeting also included a discussion of the requirements for this biennial report.

III Analysis and Interpretation of Data

In fiscal years 2013 and 2014, greater than 90% of the applications involving human subjects that NCATS received were found to be in compliance with inclusion policy by the integrated review groups. When an application is not in compliance with NIH inclusion guidelines, funding is barred until the problem is resolved. The single grant that had actual enrollment data in FY13 was approved by the program officer as achieving a scientifically appropriate balance for inclusion of women and minorities. There were no NCATS awards with actual enrollment data in FY14.

NCATS is not currently authorized to conduct phase III clinical trials and does not currently have any clinical trial data to report in the intramural division.