Special Institutional Statement Regarding Human Subjects Research Under R25T Support

The National Cancer Institute (NCI) Cancer Education and Career Development Program (R25T) must be in compliance with all NIH/NCI policies pertaining to the use of human subjects. These policies apply to all research involving human subjects, not just clinical trials. The R25T is a training and career development grant in which candidate positions are filled at the discretion of the institution and assignment of candidate positions is generally not known at the time of application or at the time of an award. Due to this uncertainty, the word "Indefinite" should be placed in the box for IRB review date on the face page of the application and the applicant institution must provide in the submitted grant application a Special Statement on Human Subjects Research.

Rationale:

The purpose of this institutional statement is to ensure compliance with NIH policies and guidelines when submitting R25T applications.

The institutional statement should include the following:

(1) An institutional IRB has been established and operates in accordance with the requirements of the Federal Policy for the Protection of Human Subjects (45CFR46).

(2) All research involving human subjects (except for research that is exempt as defined in CFR 46.101(b)), in which any R25T appointee participates and receives partial or total salary support from the grant or in which other research costs provided by the grant become associated with the research, will be reviewed and approved by its IRB prior to the use of grant funds in the research and that the IRB will conduct continuing reviews of this research in accordance with 45CFR46.

(3) The applicant institution agrees to comply with all of NIH and NCI data safety and monitoring (DSM) requirements for cancer clinical trials; and that the applicant institution guarantees that all such trials have appropriate DSM plans or boards, as appropriate, before any candidate participates in or resources from the R25T grant are used for these clinical trials. The essential features of a DSM plan for NCI-supported clinical trials can be found at the following websites:
http://www.nci.nih.gov/clinicaltrials/conducting/dsm-guidelines/page1
http://www.nci.nih.gov/clinicaltrials/conducting/dsm-guidelines/page4
http://www.nci.nih.gov/clinicaltrials/conducting/dsm-guidelines/page4#grants

(4) The applicant institution will comply with all NIH policies regarding the inclusion of women and minorities as participants in research conducted in R25T programs. NIH policies for inclusion of women and minorities can be found at the following website:
http://grants.nih.gov/grants/funding/women_min/women_min.htm

(5) The applicant institution will comply with all NIH policies regarding the inclusion of children as participants in research involving human subjects in research conducted in the R25T programs. NIH policies for inclusion of children can be found at the following website:

http://grants2.nih.gov/grants/policy/hs/children.htm

This Special Institutional Statement should be co-signed by the Principal Investigator of the R25T grant application, an appropriate official from the applicant institution, and the Chairperson of the applicant institution's Institutional Review Board (IRB).

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