NCI Guidelines for Administrative Supplements for The Cancer Genome Atlas (TCGA) Pilot Project

Title: Administrative Supplements for TCGA: Resolving key questions of tissue purity and new technologies while accelerating the completion of the pilot project tumor types.

Announcement Number: NOT-OD-09-056 NIH Announces the Availability of Recovery Act Funds for Administrative Supplements

Release Date: May 1, 2009

Receipt Dates: June 1, 2009 and June 1, 2010

This initiative is one of several being offered by National Cancer Institute (NCI) to help fulfill the goals of the American Recovery and Reinvestment Act (ARRA) to help stimulate the economy through support of biomedical and behavioral research. Additional information the Recovery Act and related NIH opportunities is available through the Office of Extramural Research.

Program Overview:

The Cancer Genome Atlas (TCGA) Pilot Project is a three-year project designed to systematically identify genetic alterations in human cancer and also assess the feasibility of large scale, high throughput genomic characterization, and sequencing of statistically robust numbers of tumor and normal samples. TCGA Pilot Project is currently profiling three tumor types (brain, lung, and ovarian) by analyzing the expression profiles and genomic changes associated with each cancer sample. This characterization is followed by the sequencing of genes and regions that are altered in a significant number of samples in each cancer type. Characterization of pilot and other tumors would be accelerated using ARRA funds.

Application Guidelines:

Applicants are encouraged to review NIH Announcement Number NOT-09-056 for guidance on how to prepare an administrative supplement request under the Recovery Act.

Funds Available:

NCI will be committing \$3.5 million dollars in FY09 to support **one year** administrative supplements for TCGA U24 awardees under RFA-CA-07-014 (Cancer Genome Characterization Centers). For FY10, NCI will be committing \$10 million dollars to support **one year** administrative supplements for TCGA

U24 awardees under <u>RFA-CA-09-010</u> **only** (Genome Characterization Centers and Genome Data Analysis Centers).

Budget:

Total amount of award may be up to 50% of the amount of a single year of TCGA funding.

Eligibility:

- For FY09, awardees of U24 cooperative agreements under <u>RFA-CA-07-014</u>
 For FY10, awardees of U24 cooperative agreements under <u>RFA-CA-09-010</u>.
- Only the principle investigator from each U24 may apply for an administrative supplement and may apply for up to two supplements.

Purpose:

The purpose of the administrative supplements is to: accelerate a range of activities needed to finalize data analysis for glioblastoma, ovarian and lung cancers; address critical questions generated during the TCGA pilot project; and move into characterization and analysis of new tumors as they enter the pipeline. In addition to characterization, key areas of critical importance in facilitating the inclusion of more tumors in TCGA will be addressed including: determining the lowest threshold for percent tumor nuclei permitted by the various current and future genomic characterization methods and specific requirements for different tumor types; assessing the value of new technologies (next generation sequencing methods) in improving the quality and quantity of data generated by the centers; and optimizing the ability of each center and the centers overall to analyze highly complex, heterogenous tumors. Overall the goal of these supplements is to optimize the integrative data sets from the pilot program and insofar as possible undertake the characterization of new tumors.

Restrictions:

- Supplemental funds cannot be used to purchase capital equipment.
- NCI may choose not to use supplemental funds to continue to support certain genome characterization methods currently used in the pilot project. Under such a scenario, a center that applies for two supplements would not be considered for the first supplement, but would be considered for the second supplement independently of the decision to not continue to support the characterization method.
- The U24 awardee must have sufficient funds or apply for an administrative supplement for sufficient funds to accelerate completion of samples prior to

applying for an administrative supplement to address critical questions generated during the TCGA pilot project.

Application Review:

- Administrative supplement requests will not undergo peer review. They will be
 reviewed for scientific merit and meeting of the ARRA goals by a panel
 consisting of Center for Scientific and Strategic Initiatives (CSSI) program
 staff with expertise relevant to the supplement request. Requests will undergo
 initial administrative review by grants management staff from the NCI Office
 of Grants Administration (including the Grants Management Specialist
 assigned to the parent grant) to ensure administrative eligibility and that all
 required items are submitted.
- Specific review criteria will include but are not limited to the following:
 - Merit of proposed science
 - o Reasonableness of proposed costs for proposed research
 - o ARRA job creation and retention criteria:
 - Supplement will accelerate the research proposed in the parent grant
 - Supplement will enable hiring of additional staff
 - Supplement will enable increased hours of current part-time staff
 - Supplement enables recruitment for additional skills
- The funding decision will be provided within 8-10 weeks of application submission

Award Date:

Awards will be made by September 30, 2009 for FY09 and September 30, 2010 for FY10.

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