NCI Guidelines for ARRA Research and Research Infrastructure "Grand Opportunities": Coordination of Clinical/Translational Research across the NCI

Announcement Number: RFA-OD-09-004

Title: Recovery Act Limited Competition for NIH Grants: Research and Research Infrastructure "Grand Opportunities" (RC2)

The NCI is participating in the Research and Research Infrastructure "Grand Opportunities" ("GO") Program (RFA-OD-09-004; RC2 grant), which has been issued by the NIH to support research on high impact ideas that lend themselves to short-term, non-renewable funding, and may lay the foundation for new fields of investigation. Through its participation on this and other related funding initiatives, the NCI is committed to fulfilling the goals of the American Recovery and Reinvestment Act (ARRA) to help stimulate the economy through support of biomedical and behavioral research. Additional information about the Recovery Act and related NIH opportunities is available through the Office of Extramural Research.

Areas of Scientific Priority:

As part of its participation on Recovery Act Limited Competition for NIH Grants: Research and Research Infrastructure "Grand Opportunities" (RC2), the NCI is interested in furthering its high-priority goal of accelerating high impact translational research by encouraging and rewarding collaborative team science. The definition of collaboration from a report of the NCI Clinical and Translational Research Advisory Committee (CTAC) is the following:

Individuals from different institutions and across NCI/NIH Programs pool knowledge and share necessary resources to formulate and address clinical and translational research questions.

The "GO" initiative presents a unique opportunity for groups of scientists with diverse expertise, and original, creative ideas to work together on translational cancer research projects of significant scope and consequence that, nonetheless, can be completed within two years.

To qualify for this initiative, coordinating investigators must propose focused, evidence-based, hypothesis-driven correlative studies associated with either an ongoing clinical trial or a new (ready to proceed) clinical trial in multi-institutional settings, and should include, as non-coordinating, currently funded members of the team: Cancer Centers, SPOREs, P01s, R01s, Phase I U01s, Phase II N01s, Cooperative Groups including ACRIN and RTOG, CTSU, clinical consortia, or other NCI-supported translational research mechanisms.

Specifically, one or more Principal Investigators should act as the coordinator(s) of this cross-cutting "grand opportunity" and should enlist basic and clinical scientists across NCI funded mechanisms to form a team that can perform intensive, high impact, and, if possible, paradigm-shifting studies associated with clinical trials. Industrial and foundation partners may participate in the research, but will not receive government support for these studies.

Examples of the types of studies appropriate for this "GO" grants program include, but are not limited to:

1. Studies that correlate the nature, magnitude, and complex signaling pathways of an anti-tumor immunological response with outcomes in an immunotherapy clinical trial in order to discover or to dissect out the mechanism(s) of action of the therapeutic components. These studies should be based upon solid preclinical data and should seek to understand the interactions of check point inhibitors, immune cell growth and stimulatory factors, vaccine adjuvants, and/or chemokines and their roles in clinical outcomes. Assays used for these studies must be accurate and precise, and already established in the laboratory.
2. Studies that clinically validate, in a prospective clinical trial, biomarkers that are predictive for therapeutic endpoints or that lead to better patient stratification in future trials. The proposal should provide strong rational for the selection of specific markers, with emphasis on mechanistic linkage to the disease and/or therapy—either a small molecule or biological or a combination—to be evaluated, and provide data supporting appropriate assay development. Because the outcome of this study should assist in future decisions about patient treatment, assays for this trial must be performed with the highest quality control standards, preferably in CLIA-certified laboratories, in Cancer Centers or other academic medical institutions.
3. Pharmacogenomic research aimed at the identification of genomic profiles associated with increased/decreased efficacy or toxicity during various clinical interventions. Such studies might be useful in ultimately determining which patients are likely to benefit from a particular therapy. In addition, the data might lead to the determination of an agent's maximum tolerated dose in separate groups of patients. The studies may require the use of previously collected data and archived biospecimens in addition to a large prospective clinical study, in one of the cooperative groups, to validate earlier findings.
4. Studies using imaging approaches to characterize disease anatomy, physiology, and molecular biology in order to guide the administration of targeted therapies in a clinical trial. Such studies should have extensive preclinical data, and may target not only the tumor but also the tumor microenvironment or vasculature in an attempt to understand and evaluate the role of the microenvironment in tumor transformations and invasion.

Translational studies in cancers underrepresented in the NCI grant portfolio—for example, pancreatic cancer, squamous cell carcinoma of the head and neck, bladder cancer, and sarcoma—are encouraged in this initiative.

Funding Priorities:

Overall, NCI expects to make awards for a period of up to 2 years to establish 8 to 13 new translational research collaborations. NCI may devote up to $14 million (over 2 years) for successful proposals for this "GO" program: "Coordination of Clinical/Translational Research across the NCI." There is no budget cap for each proposal. However, applications must include a fully justified budget for the work proposed and may be reduced during review.

Application Guidelines:

Applications for NCI funds supporting the scientific areas listed above **MUST** follow the guidelines listed in RFA-OD-09-004.

Key Dates (RFA-OD-09-004):

Application Receipt Date: May 27, 2009
Peer Review Date: June/July 2009
Council Review Date: August 2009
Earliest Anticipated Start Date: September 30, 2009
Expiration Date: May 28, 2009

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