

CONCEPT CLEARANCE RECORD

FY 2016 RESEARCH INITIATIVE – NCATS

TITLE: NCATS Exploratory Clinical Trials for Small Business

INITIATIVE TYPE: Small Business Innovation Research (SBIR)/ Small Business Technology Transfer (STTR) phase 2 grants (R42, R44), direct to phase 2 and fast track only

OBJECTIVE(S): Examples of appropriate clinical studies under this Funding Opportunity Announcement (FOA) include, but are not limited to, those whose primary aim is to:

- Evaluate and optimize the dose, formulation, safety, tolerability or pharmacokinetics of an intervention or diagnostic in healthy volunteers or the target population.
- Conduct prospective clinical validation of a therapeutic intervention.
- Evaluate whether an intervention produces sufficient evidence of short-term activity (e.g., biomarker activity, dose-response trends, pharmacodynamic response) in a human proof-of-concept trial.

DESCRIPTION: The purpose of this proposed FOA is to support applications from Small Business Concerns (SBCs) for clinical trials (i.e., phase I and II clinical studies) of drugs, biologics, devices or diagnostics, as well as surgical, behavioral or rehabilitation therapies, that contribute to the justification for and provide the data required to design a future trial to confirm efficacy (i.e., a phase III clinical trial). Clinical trials that will be supported under this FOA will be listed on the NCATS website and in the SBIR/STTR Omnibus Solicitation. Applications must aim to generate data that inform a decision whether to continue further clinical development of the proposed intervention or diagnostic. Phase I clinical studies should be designed to provide important initial information regarding the intervention or diagnostic (e.g., safety, tolerability, dosing). Phase II clinical studies should yield data that allow a clear “go/no-go” decision regarding continued development.

IMPORTANCE: This FOA proposal is important, as it will address improving the quality of human subject research that is conducted by SBCs under the SBIR/STTR grant program.

HISTORY: NINDS has implemented a similar FOA for SBC, SBIR and STTR (phase II and fast track) grant applicants considering projects involving human subjects research. Other NIH Institutes and Centers are exploring the adoption of similar FOAs for SBIR and STTR grants involving human subjects research in order to ensure that clinical trials are conducted appropriately.

PROJECT/PROGRAM OFFICER (phone and e-mail address)

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