

**CONCEPT CLEARANCE RECORD  
FY 2016 RESEARCH INITIATIVE – NCATS**

TITLE: Proof of Principle (POP) Awards

OBJECTIVE(S): To fund the generation of the specific piece of pre-clinical data to make a project more competitive for subsequent funding or otherwise move a project forward.

DESCRIPTION: The proposed program is aimed at pre-clinical research projects that develop, demonstrate or deploy interventions to improve human health. Often, prospective grantees have applied for NIH support but did not receive funding because they lack a specific piece of translational data. The program would fund generation of the needed data to make the project more competitive for subsequent funding or otherwise move the project forward. Key features of the program include:

- Abbreviated review to assess feasibility of the proposed experiments
- The potential of the project to have a broad and significant impact

IMPORTANCE: The program would strengthen applications for programs across NIH, and perhaps at a future stage, across the entire translational research enterprise. Applications to be considered for potential funding will be those that have a broad and significant impact, and each project will be completed in a relatively short time.

HISTORY: Experience with pre-clinical programs has revealed that there are many applications that lack a critical piece of data that would make those projects strong candidates for the program. The POP micro-award program is envisioned as a way to provide that funding using micro-awards of a maximum of \$100,000 for up to one year. As a first step, the program will focus on funding projects (mostly in the pre-clinical space) that previously did not receive NIH support due to the lack of a specific piece of translational data. The goal of the award will be to strengthen the project by enabling the researchers to obtain that data and thus make the project a stronger candidate to re-apply for NIH funding or otherwise move the project forward.

NIH has a number of such grant programs for limited amounts and short timeframes. However, most of these programs are not:

- Focused on projects that develop, demonstrate or deploy interventions to improve human health
- Aimed at projects that have already undergone the NIH review process and received feedback indicating the lack of a limited yet critical piece of data

Note that the National Institute of Neurological Disorders and Stroke (NINDS) has just launched a similar effort called [Innovation Grants to Nurture Initial Translational Efforts](#) (IGNITE). The IGNITE program is intended to advance projects to the point at which they can meet the entry criteria for translational programs such as the NINDS Cooperative Research to Enable and Advance Translational Enterprises program for biologics and biotechnology products or the Blueprint Neurotherapeutics Network for small molecules. The IGNITE program consists of four funding opportunities: two using the R01 mechanism and the other two using a two-phase R21/R33 approach. Both the budget and the timeframes of these awards are much longer than those envisioned for the POP program.

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