



CTSI Pilot Translational & Clinical Studies Program

DEFINITIONS: CLINICAL & TRANSLATIONAL RESEARCH; T-LEVELS

The CTSI Pilot Translation and Clinical Studies Program offers funding opportunities for clinical and translational research according to the NIH definitions described below:

CLINICAL RESEARCH

The NIH definition of clinical research has three parts:

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
2. Epidemiologic and behavioral studies
3. Outcomes research and health services research ¹

TRANSLATIONAL RESEARCH

Applications will be reviewed and considered for funding based on NIH-identified translational areas:

Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science. ²

¹ [Glossary of Terms for Human Subjects Protection and Inclusion Issues](#), based on the 1997 Report of the NIH Director's Panel on Clinical Research.

² [National Institutes of Health. RFA-RM-07-007: Institutional Clinical and Translational Science Award \(U54\) Mar2007.](#)

The CTSI translational continuum is described below with an outline of T-Level definitions and is based on NIH guidelines.



T-LEVELS

PLEASE NOTE: It is important to propose a project which is feasible within the given timeframe and budget of the pilot award. Pilot studies are by definition smaller in nature than those involving Phase II, III, and IV Clinical Trials, and would only provide preliminary evidence for these larger studies. In these cases, and especially for T-3 and T-4 studies, when determining the T-Level of your pilot project, use the descriptions below as a reference for the type of larger study your pilot project would directly support.

- **T-0 proposals that are only T-0 are *not* eligible to apply.** T-0 research can be described as:
 - Pre-clinical approaches designed to inform an investigator about a pathway, pathophysiology, or treatment approach. Examples include:
 - animal models of human disease, human blood or cell lines
 - development of questionnaires, computational models, and human physiological studies
 - “Bench” research which may or may not require approvals from human or animal use committees.
- **T-1 Translation to Humans**
 - Studies with human participants that yield knowledge about human behavior, physiology, pathophysiology and the potential for intervention (i.e. diagnoses, therapies, etc.)
 - findings from basic research are tested for clinical effect and/or applicability.³
- **T-2 Translation to Patients**
 - test new interventions under controlled environments to form the basis for clinical application and evidence-based guidelines.³
 - yield knowledge about the efficacy of the interventions in optimal settings.³
- **T-3 Translation to Practice**
 - study health services and community-based participatory research (dissemination, communication, implementation)
 - Cost-effectiveness/comparative effectiveness studies
 - explore ways of applying recommendations or guidelines in general practice.³
 - yield knowledge about how interventions work in real-world settings.³
- **T-4 Translation to Communities/Population Health**
 - study factors and interventions that influence the health of populations.³
 - obtain results to benefit society & improve global health in areas such as improving disease prevention and reducing medical costs.
- **T-5 Policy-level Research**
 - Proposals that incorporate T5 in addition to one of T1 through T4 are eligible to apply.

Questions? Contact CTSI Pilot Award Program Manager Christine Zeller at 414-955-2524 or czeller@mcw.edu

³ Source: [Harvard Catalyst](#)