BRIDGE Pilot Award 2024

1. Introduction/Overview

The Clinical and Translational Science Institute (CTSI) at the University of Pittsburgh is seeking applications for the BRIDGE Pilot Awards. The goal of this program is to stimulate projects that **use big data to develop precision interventions for individuals or communities**. These awards are designed to open up research that will bridge the gap between large population data sets (e.g. million of electronic health records or millions of consumer purchases) or other large personal data sets (e.g. genomic data or months of wearable fitness sensor data) and personalized care for the individual or the region.

Examples of projects that might fit this opportunity include:
- Using a large genomic data set to identify patients with differential response to a therapy or drug in order to guide future prescribing.
- Identify patterns of internet use that presage a particular illness or syndrome.
- Determine if consumer wearable sensor data like smart watches can predict who will develop a specific disease or who will respond to a treatment.
- Relating regional patterns of consumption or purchases to risk of developing a disease.

Projects that are not suitable are those that look at the effect of individual patient or personal condition on large data. Examples would include examining the genetics of a disease or examining the effect of having a condition on wearable data. Instead, we want to emphasize use of the large data, that might already exist or that might be acquired for other reasons in a broad population, to bring new information to benefit the individual within the population.

2. CTSI Assistance (Optional)

If you would like to request a consultation, please email CTSIPilots@pitt.edu. Make note of your intention to apply for the BRIDGE Pilot Awards in the subject line, and we are happy to provide feedback about the program or your application.

3. Key Dates

Round 1 Applications Open:	Tuesday February 12
Round 1 Letter of Intent Deadline:	Friday March 8, 11:59 p.m. EST
Notification to Advancing Teams:	Wednesday March 20
Round 2 Full Proposal Submission Date:	Monday April 15, 11:59 p.m. EDT *(by invitation)*
Notification to Awardees:	Friday May 3
Anticipated Earliest Start Date:	May 15 / June 1

Awards must start within three months of notification.

4. Funding Information

Award funding of up to **$30,000** is available to cover direct costs; no indirect support will be provided. The award period will last for 12 months, beginning when all regulatory and administrative approvals have been received. The BRIDGE Pilots do not have any mechanism for no-cost extensions; any funds that are not spent during the award period will be forfeited.

Before any funding can begin, awardees must provide documentation of all necessary regulatory approvals (IRB, IACUC, hSCRO, IBC, CORID, etc.). Once regulatory documentation is provided, awarded projects will undergo an administrative review from NCATS, which may take up to 30 days. Funding cannot begin until projects have been approved by NCATS. Because of this, all applicants are strongly encouraged to have the necessary regulatory documents ready for submission.

<u>Community Bonus Award</u> Eligibility

Applications that demonstrate a meaningful partnership or collaboration with an underrepresented community will be eligible for an **additional $5,000** of funding if awarded one of the BRIDGE $30,000 awards. A meaningful partnership or collaboration would include demonstration of a stakeholder contribution to the research project or commitment to participate in the proposed project. Examples include:

- Community stakeholder advisory group that has reviewed or participate in the development of the research proposal at the level of developing the research question to ensure that the proposed research is relevant to the community, or review of recruitment methodology to ensure lack of barriers to community participation.
- Letter of support from a community partner toward active participation in the proposal.

<u>Early Career Underrepresented Investigator Bonus Award</u> Eligibility

Applications that deliver a meaningful research experience to an early career investigator from a group underrepresented in the biomedical workforce may be eligible for an **additional $5,000** of funding. For this bonus, we will consider "underrepresented group" to includes individuals with backgrounds described in the [Notice of NIH's Interest in Diversity](). These include racial and ethnic groups that are underrepresented in biomedical research: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders; individuals with a physical or mental impairment that substantially limits one or more major life activities; and individuals from disadvantaged backgrounds. Gender is an important dimension within which there are disparities in the workforce and may be cited in combination with another dimension, but gender alone will not be a qualifying criterion for this Bonus Award.

"Early career" may include any investigator on a team who does not have a regular faculty appointment. Secondary school students, undergraduates, predoctoral students, health professional students, residents, fellows, and postdoctoral scholars are included. Persons who are University staff (e.g. research coordinators) might also be eligible if the proposal explains how the experience may lead them towards more independent or sustained research careers. Faculty members are not eligible for these bonuses, because they are already eligible to apply as the Principal Investigator. Contact CTSI staff if you are not sure about eligibility.

5. Eligibility

The Principal Investigator must be a University of Pittsburgh faculty member; postdoctoral trainees and trainees in clinical training programs are not eligible to serve as PI. Faculty members on early-career training awards or clinical research scholars (i.e. recipients of K-series or similar career development grants) are eligible. New PIs are strongly encouraged, but submissions from established investigators will be accepted if there is clear evidence that the pilot project represents a distinctly new direction from their previously funded work.

Study teams that involve cross-disciplinary collaborations are strongly encouraged. Pitt Co-Investigators (Co-Is) may be included but are not required. Co-Is may be from other universities; however, CTSI's primary mission is to promote research at the University of Pittsburgh, so applicants should justify extensive off-campus collaboration. Partnerships with non-academic community partners are also acceptable. Submissions should clearly describe the role of each investigator, with sufficient detail for reviewers to identify that all listed team members will have an active role in the research.

6. Submission and Review Information

How to Submit

All applications should be in the form of a single PDF document; please use Arial size 11 font with margins of 0.5 inches. Additional or supplemental materials cannot be accepted after the specified deadlines and will not be reviewed.

Round 1: Letter of Intent   Deadline: **Friday, March 8, 2024 (11:59 p.m.)**

Each Letter of Intent submission must include the following sections:

A. Study Title: Include the title of the proposal at the top of the page, along with the PI name and contact email.
B. Abstract and Scope of Work (500-word limit): Please provide a high-level overview of the study and the proposed work. Be sure to indicate how the study will include underrepresented populations and how the proposal represents a new direction for the PI. Additionally, if the proposed work should be considered for either Bonus Award, please be sure to describe the specifics.
C. Study Team: Please provide the names and affiliations of all members of the study team and a brief description of their roles (25-50 words per person).
D. Suggested Reviewers: To facilitate the final round of review, please suggest two to three faculty members, not from your department, who may be qualified to serve as scientific reviewers. Include email addresses for each suggested reviewer.

Round 1: Review Criteria

The review of letters of intent will be conducted by the faculty and staff of CTSI. Proposals will primarily be evaluated based on the Responsiveness to the RFA, Overall Impact to the identified populations, as well as the Overall Scientific Merit of the proposed work. The results of this evaluation will determine which investigators will be invited to submit a full proposal for the second round of BRIDGE.

Bonus Award eligibility will be assessed separately from the scientific merit of the award, and will not impact whether or not an investigator is asked to submit to the second round.

Round 2: Full Packet Submission   Deadline: **Monday, April 15, 2024 (11:59 p.m.)**

Each Full Packet should include the following sections, beginning each section on a new page:

A. Project Overview (one page): The first page should include the following:
1. <u>Scientific Abstract</u> (250-word limit): Briefly summarize the proposed work.
2. <u>Inclusion of Specific Dataset</u> (100-word limit): Indicate which dataset will be used by the proposed work, and how the proposed work represents a new direction for the investigators.

B. Research Plan (three-page limit, including tables and figures): This section should include the following NIH proposal elements to best allow reviewers to address the review criteria:
1. <u>Specific Aims</u>
2. <u>Significance</u>
3. <u>Innovation</u>
4. <u>Approach</u>

C. References (no page limit): Does not count toward the Research Plan's three-page limit.

D. Budget with Budget Justification (no page limit):
Use PHS 398 Form Page 4 and Page 5. The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested.

Grant funds may **NOT** be budgeted for:
- Salary support for the PI or faculty collaborators[*]
- Effort for post-doctoral trainees or fellows
- Routine office supplies or communication costs, including printing
- Meals or travel, including to conferences, except as required to collect data
- Professional education or training
- Computers or audiovisual equipment (exceptions require clear justification)
- Manuscript preparation and submission
- Indirect costs

<u>Community & Early Career Bonus Awards</u>: Proposals that are eligible for either/both of the $5,000 Community Bonus Award or Early Career Bonus Award will be instructed to submit a budget for $35,000. The determination of eligibility will be made during the review of the first round, and eligible teams will be informed when they are notified of their acceptance into the second round.

[*]Effort is required of the principal investigator and must be reflected on the budget page. This effort should be cost shared by the department or other entity that will support such effort. Reviewers understand that this may be a very small proportion of effort given the size of this award, but will be cautious if investigators do not appear to have sufficient time to complete a project.
Any salary support requested in the submitted budget should reflect federal fringe benefit rates. If an award is made, a budget meeting will be held between principal investigators, their respective research administrators, and financial administrators from the CTSI. If necessary, adjustments to the requested budget will be made at that meeting.

E. Proposal Timeline (up to half a page)**:**
Describe critical milestones and timeline for completion of the **one-year** project. **The CTSI Pilot program <u>does not</u> allow No-Cost Extensions.** In the event an award is made, investigators should immediately confer with CTSI staff if any delay in initiation or completion of the project is anticipated.

F. Human and/or Animal Subjects (no page limit)**:**
NIH supported pilot awards must address Protection of Human Subjects, Adequacy of Protection Against Risks, Data and Safety Monitoring Plans, Inclusion of Women and Minorities, and Inclusion of Children.

Human Research Protection Office (HRPO) approval is not required prior to submission. However, HRPO approval is required for all projects involving human subjects before NCATS will approve project funding. Likewise, the Institutional Animal Care and Use Committee (IACUC) must approve any projects involving animal subjects prior to final funding approval. Applicants must describe any human and/or animal subject issues, as well as the sources of materials that will be obtained from human subjects. If human subjects are involved, provide a description of their involvement and characteristics, specific risks to subjects who participate, and protection against those risks.

Reviewers may consider whether significant delays in approval are an anticipated barrier for project completion when selecting projects. Evidence of prior or ongoing HRPO / IACUC review is encouraged. Similarly, this section should discuss if other special regulatory approval is required prior to funding: Human Stem Cell Research Oversight (hSCRO), Institutional Biosafety Committee (IBC), Committee for Oversight of Research Involving the Dead (CORID), Radiation Safety Office (RSO), etc.

G. NIH Biosketches for the PI & key team members (no page limit). May 2021 NIH template.

Round 2: Review Criteria

Review of CTSI Pilot proposals follow the standard NIH Review Criteria, outlined below. Reviewers will score Full Packet applications on an NIH scale (1-9). Special emphasis will be given to Overall Impact.

1. <u>Overall Impact</u>: The likelihood for the project to exert a sustained, powerful influence on the research field.
2. <u>Significance</u>: Does the project address an important problem or a critical barrier to progress in the field?
3. <u>Investigators</u>: Are the PD/PIs, collaborators, and other researchers well suited, sufficient, and able to conduct the project?
4. <u>Innovation</u>: Does the project shift current research or clinical practice paradigms use novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
5. <u>Approach</u>: Are the strategies, methods, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
6. <u>Environment</u>: Are the personnel, equipment, and other physical resources available to the investigators to perform the proposed research within the time frame allotted?

Program-Specific Criteria:
7. <u>Bridges data</u>: Does the submission effectively use large data set(s) to benefit individuals?
8. <u>Path to Impact</u>: Does the submission propose a clear path to implementation or widespread use; or, if in early stages, have a plan for follow-on funding to develop idea further?