

CTSI

Coordinator Connect



Fifth Annual Pitt Innovation Challenge (PInCH) Awards

The Pitt Innovation Challenge (PInCh) held its final round of competition on September 26th during an evening of posters and presentations on the topic of innovative solutions to improve human performance. PInCh asked entrants to consider projects that would benefit human functioning, and the research community responded with intriguing possibilities.

Many of the submissions for this year's awards focused on unique responses to healthcare problems. The winners are developing creative solutions in areas as diverse as cancer detection, chronic obstructive pulmonary disease, chronic tremors, and tendon damage. Several entrants proposed modifications to existing medical devices that have the potential to improve patient outcomes.

This year's challenge culminated in nine awards totaling \$475,000 and the promise of project management assistance from the Clinical and Translational Science Institute, sponsor of the award, for the winning teams.

PInCH is a yearly challenge which evolves through three rounds of competition, beginning with short video pitches. Advancing teams submit a project proposal and budget for round two; six finalists are then selected to pitch their projects in live presentations to a panel of judges in competition for a \$100,000 prize, with eight teams advancing to a poster presentation competition in pursuit of \$25,000. The next opportunity will be announced in April 2019; stay tuned to the CTSI [website](#) for updates and to see video pitches from this year's competition.

Issue 5, Fall 2018

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All of Us Research Program Funds Three New Genome Centers

The National Institutes of Health's All of Us Research Program is a groundbreaking national effort to gather data and biosamples from one million people to create an invaluable research resource to advance precision medicine—medicine that is tailored to take into account individual differences in environment, lifestyle, and genetic background. This resource will eventually be available to thousands of researchers studying a broad array of health issues. More than 60,000 participants have already completed the full protocol.

The program recently awarded \$28.6 million to create three new genome centers in order to generate genomic data from the biosamples of All of Us participants. The centers will include Baylor College of Medicine with Johns Hopkins University and the University of Texas Health Science Center at Houston, the Broad Institute with Color and the Laboratory for Molecular Medicine at Partners HealthCare, and Northwest Genomics Center at the University of Washington.

A local arm of the study, All of Us PA, is currently recruiting and will contribute to this historic effort. [Join us](#) to become one in a million.

Research Resources

The Innovation Institute

Is your group conducting research that may lead to an innovation or invention with commercial potential? The University of Pittsburgh [Innovation Institute](#), under the direction of Evan Facher, Director of the Institute and Vice Chancellor for Innovation and Entrepreneurship, encourages entrepreneurship across the university and provides support for every stage of the commercialization process. "Pitt researchers are at the frontier of discovery across a broad range of disciplines. Wherever a Pitt faculty member, postdoc, or student is in the innovation commercialization process, the Innovation Institute can assist in providing education, mentoring and funding to accelerate along the path to the market where their discoveries can have a positive impact on people's lives," Facher said.

The culture of innovation and entrepreneurship is growing at Pitt. The university has set records for startups for three years in a row, with 23 established in fiscal year 2018, a year in which Pitt innovators submitted a record 363 invention disclosures, nearly one for every day of the year. Ninety eight patents were awarded to Pitt innovators in the same time frame.

The Innovation Institute offers educational programming on topics like protecting intellectual property, licensing, and commercialization. It provides a pathway to commercialization by offering services like business planning, market research, innovation marketing, industry/investor relationship development, and financial resources for customer discovery, market research, prototype development and more.

In addition, through its [Entrepreneurs in Residence](#) program, the Innovation Institute also provides valuable mentorship for Pitt innovators, guiding them to resources on and off campus to help move their discoveries closer to commercialization. The program is available to students as well as faculty.

Upcoming offerings include a monthly two-hour [Innovation Igniter](#) workshop, which is held to help participants understand the commercialization process, licensing an innovation, and creating a startup company. From there participants can move to the [First Gear](#) program, where they more fully explore potential customers and a value proposition for their innovations, with the added benefit of \$3,000 from the NSF I-Corps program. December also brings several workshops related to the elements of starting a new business, from developing a business plan to the mechanics of the start up process.

For more information and to sign up for workshops, please visit the Innovation Institute [website](#).

Funding Opportunities

Stimulating Access to Research in Residency (StARR)

The National Institutes of Health created the StARR opportunity in order to help institutions recruit, train, and retain postdoctoral professionals who have demonstrated potential and a desire to pursue careers as clinician-investigators.

StARR awards will support resident investigators to engage in research projects with experienced investigators for a period of 1-2 years with the goal of transitioning participants to other research and career development support. More information [here](#).

Touch of Genius Prize for Innovation

The Gibney Family Foundation announced this annual opportunity for projects that demonstrate innovative ideas in the field of braille and tactile literacy. Past winners include projects to develop professional and software apps, educational software and apps, gaming software and apps, and braille or tactile-related hardware. More information [here](#).

HEALing Communities Study: Developing and Testing an Integrated Approach to Address the Opioid Crisis

The National Institute on Drug Abuse (NIDA) and the Substance Abuse Mental Health Services Administration (SAMHSA) are joining forces for this cooperative agreement funding opportunity announcement. They are seeking three research sites to test the impact of implementing a set of evidenced based interventions across healthcare, behavioral health, justice and other community settings with the goal of preventing and treating opioid misuse and Opioid Use Disorder. More information [here](#).

CTSI News

Research Professionals Series Launches

CTSI will hold periodic educational opportunities as part of a new Research Professionals Series. The first presentation in the series, Budgeting for Clinical Trials, was presented on October 22nd. Two experienced research professionals from Children's Hospital of Pittsburgh of UPMC, Elizabeth Hartigan, RN, MPH, clinical research manager, and Paul Dee MBA, research administration manager, provided an in-depth look at budgeting considerations for clinical trials.

The series is intended to extend the educational experience provided by the CTSI-sponsored Orientation to Research Fundamentals, a two day workshop conducted twice yearly which covers basic concepts required to successfully coordinate a research study with an emphasis on regulatory requirements and research resources available at the University of Pittsburgh.

One of the series' organizers, Katelyn Collinger, noted that the inspiration for the series came from the research coordinator community: "Through the Research Coordinator Advisory Board, we learned that coordinators and other research professionals continue to thirst for research knowledge on topics that are not typically covered through other educational opportunities within Pitt or UPMC or are not available to them. They expressed interest in learning more about budgeting, navigating multi-center submissions and best practices in study start up and recruitment, for example. CTSI would like to be able to fill this need for research professionals."

Collinger continued, "As a former coordinator, I know the importance of feeling connected to other coordinators, so it is our hope that this series will be an opportunity to meet and network with others in similar positions."

Both in-person attendance and webinar options will be offered for the presentations, and the webinars will be archived on the CTSI website for easy reference.



Regulatory Updates

The University of Pittsburgh Human Research Protection Office (HRPO) recently announced a change to their policy and procedures regarding the order of selection for proxy consent when a potential participant has no legal guardian or health care proxy designated. Updates were made so that policy reflects current Pennsylvania state laws regarding proxy consent; changes include a different order in which a person providing proxy consent is approached based on relationship to the participant, the addition of adult grandchild as person who may be approached to provide proxy consent, and broader language around other adults who can act in this capacity.

Current policy states, "If a potential subject has neither a guardian, nor a health care proxy designated, the investigator may obtain the informed consent of the subject's legally authorized representative. Where neither a court-appointed guardian, nor a health care proxy exists, investigators may seek informed consent from the following individuals, in the order listed below:

- Spouse, unless an action for divorce is pending, and the adult children of the principal are not the child of the spouse
- Adult child
- A parent (biological or adoptive)
- Adult brother or sister
- Adult grandchild
- An adult who has knowledge of the principal's preferences and values, including but not limited to religious and moral beliefs, to assess how the principal would make health care decisions"

HRPO advises researchers using proxy consent listing the previous order of selection to submit a modification in order to update. The change can be implemented prior to approval of the modification because it relates to state laws and not risk to participants. For more information about proxy consent, see the HRPO [website](#).

Dear CTSI

Hello Readers! This space is reserved for your questions. If you have a research question you would like to see answered in print, please send it to cliftons@pitt.edu and look for answers in our next edition. <http://www.ctsi.pitt.edu/contact.html>

Dear CTSI,

When is a study required to have a data and safety monitoring board (DSMB)?

Answer: A DSMB consists of a group of independent experts who periodically review study data to evaluate participant safety and risk, study conduct and progress, protocol adherence, and adequacy of recruitment and enrollment, among other important study related issues. While the federal regulations address use of DSMBs in studies involving emergent care in which informed consent cannot be obtained from the patient or a family member, they do not otherwise specify when a DSMB is required. Often sponsors determine the necessity of a DSMB; the National Institutes of Health requires DSMBs for phase III multi center clinical trials, and the Food and Drug Administration has also published [guidance](#) requiring DSMB oversight of studies in emergency settings.

In practice, boards are usually required or recommended for high risk phase III clinical trials, and for phase II clinical trials which are multi-center and randomized. Boards should be used for clinical trials of diseases with high mortality or morbidity, for trials involving high risks, and for large multi-center clinical trials. For studies that enroll vulnerable participants, like the decisionally impaired, the use of a DSMB can add an extra layer of participant protection.

Additional guidance for using DSMBs with investigator initiated studies can be found in this [manual](#) created by a consortium of Clinical and Translational Science Award recipients.

Upcoming Events

Introduction to the PERIS MyFunding Module

Presented by the University of Pittsburgh Office of Research/Human Resources Faculty and Staff Development Program

Wednesday November 28, 2018 9 a.m. -11 a.m. 342 Craig Hall

More information on this and other research administration trainings:

<https://www.hr.pitt.edu/current-employees/learning-development/fsdp/research-administration>

Good Research Practice

Presented by the Research Conduct and Compliance Office

Friday, November 30 2018 9 a.m.-11 a.m. RCCO Learning Resource Center Room 305 Hieber Building

More information: <http://rcco.pitt.edu/>

Qualitative Research Ethics (Responsible Conduct of Research Workshop)

Presented by the University of Pittsburgh Clinical and Translational Science Institute

Monday, December 3, 2018 12 p.m.-1 p.m. Forbes Tower Room 7039

More information: <https://ctsievents.pitt.edu/Applicants/Create?eventGuid=65cecc05-5fda-4e68-adcf-a29fbbcd7a80>

<http://www.ctsi.pitt.edu/contact.html>

Questions for us? Click the link above.

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