CTSI Coordinator Connect

A product of the Clinical and Translational Science Institute (CTSI) at the University of Pittsburgh



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Issue 22, Summer 2025

RESEARCH RESOURCES:

Informed Consent Guidance Manual: Best Practices for Ensuring Comprehension and Obtaining Consent

This resource was created by the Recruitment Innovation Center, part of the Trial Innovation Network, to help researchers and study teams engage in a person-centered consent process to facilitate informed decision making about study participation. Research teams can use this resource to understand considerations for ensuring participant consent is informed and voluntarily given, apply strategies for supporting a person-centered consent process for empowered decision making, and identify supplemental resources for increasing comprehension during the consent process.

This helpful <u>guide</u> addresses many topics relevant to consider in order to have a truly person-centered informed consent discussion, including:

- Accessibility
- Cultural/community/religious values
- Demographics
- Educational attainment and/or learning style
- Employment status
- Experiencing homelessness
- Healthy literacy and numeracy
- Illness and/or illness severity
- Immigration status/acculturation level
- Preferred language
- Socioeconomic status

The manual also addresses enrolling pediatric populations and participants who are decisionally impaired/have a legally authorized representative, short forms for non English speaking participants, and provides links to informative articles addressing issues around the consenting process. To learn more about the manuaul and how to access it, join a virtual presentation on September 25; see the upcoming events page for registration information.





Sustainability in Healthcare Challenge

Despite its mission to improve public health, the healthcare industry generates 8.5% of greenhouse gas emissions and is the second leading contributor to landfill waste.

To that end, the Office of Sustainability in Health Sciences, Office of Multidisciplinary Innovations, and the Mascaro Center for Sustainable Innovations are proud to announce the Sustainability in Healthcare Challenge.

\$125,000 in total awards are available for funding. One project will receive \$50,000, with up to three additional projects receiving \$25,000 awards. The challenge also offers up to two \$2,500 grants to support student competitions focused on sustainability and healthcare.

Advancing the Science of Engagement in Research

The Engagement Award Program is accepting Letters of Intent (LOIs) for the Engagement Award: Convening Support funding opportunity. This opportunity supports projects that include multi-party convenings, meetings and conferences which bring together communities of patients, families, caregivers and other members of the broader healthcare community. These must align with PCORI's mission and help expand patient-centered comparative clinical effectiveness research (CER). All proposed projects must show how they will expand patient-centered CER. You may propose projects that will last up to one year and cost up to \$125,000.

Projects must focus on one of two funding tracks: Convening Around Patient-Centered CER or Convening Around Dissemination of PCORI-Funded Research Finding. Applicants will self-select the focus at the time of LOI submission.

CTSI UPDATES

Recharge Your Research

The CTSI Facilitator Team hosts a monthly series on the first Tuesday of each month from 1 to 2 p.m. titled "Recharge Your Research." Each session will begin with a 30-minute presentation and Q&A on the featured topic, followed by 30 minutes of open discussion with CTSI facilitators. This is an opportunity to connect with other research staff members and CTSI Facilitators to ask questions and to feel supported in your work. All research related faculty and staff are welcome to attend! Come for presentations and stay to discuss any research related questions after.

Next up on Recharge Your Research: join us on September 2, when our topic will be <u>Informed Consent: Because it is the Right Thing to Do</u>, <u>Not Because it is Required</u>, presented by Cynthia McCarthy, DHCE, MA, NREMT, Associate Professor, University of Pittsburgh School of Public Health. Cynthia is a Bioethicist specializing in Health Care Ethics and serves as CTSI's Research Ethics Facilitator. Her presentation will provide an overview of informed consent requirements and a reminder of its importance in protecting human subjects and maintaining trust in the research community.

Notes from the CTSI Responsible Conduct of Research Center

Do you know a new research professional looking for a program to learn about conducting research at Pitt/UPMC? The Clinical and Translational Science Institute (CTSI) is offering the Orientation to Research Fundamentals (ORF) Program, a virtual intensive workshop consisting of three half-day sessions that cover the basic concepts (and beyond) required to successfully coordinate a research study. It provides an overview of the resources and regulatory requirements for conducting clinical research at the University of Pittsburgh and UPMC. Our speakers are experts in their fields and share their wealth of knowledge and experience with attendees.

The next session of ORF will be October 7-9, 2025 held on Zoom. There is no cost and registration will open August 22 through October 6. Continuing education credits are offered. You can register for this course and other educational sessions offered by CTSI <u>here</u>.

If you have any questions about the ORF Program, please contact Teri Reiche at tmr75@pitt.edu.

REGULATORY NOTES

National Institutes of Health (NIH): Updated Public Access Policy Effective Date Moved from December 31, 2025 to July 1, 2025

The NIH Public Access Policy will now apply to papers accepted on or after July 1, 2025 (moved from the original December 31, 2025 deadline) NIH-funded researchers must now make their author accepted manuscripts freely available in PubMed Central, at the time of publication. Before submitting a manuscript, authors should review the journal's policies to ensure if/how they allow compliance with this requirement. Currently several publishers are not allowing immediate deposit unless authors pay an article processing charge (APC) to make their articles open access.

The University of Pittsburgh Health Sciences Library System (HSLS) is available for consultation regarding questions about the NIH Access policy, and has published useful <u>guidance</u> to help researchers understand the requirements and pathways for compliance. The Authors Alliance also published a helpful <u>Q&A</u> article on their website.

UPCOMING EVENTS

Thursday, August 28 | noon to 1 p.m.

Lunch and Learn: Grief and Coping

Presented by CTSI's Community PARTners Core, featured speaker Dr. Beth Hoffman

Virtual Event

Friday, August 29 | 2-3:30 p.m.

<u>Data Visualization Best Practices, Including</u> <u>Introduction to Tableau Public</u>

Sponsored by the University of Pittsburgh Library System Location: Hillman Library, Digital Scholarship Lab, G-30

Thursday, September 25 | noon to 1 p.m.

The Informed Consent Guidance Manuals:

Best Practices & Strategies for Recruiting Participants in
Research Resource Manual

Presented by the Trial Innovation Network

Virtual Event

Wednesday, October 1 | noon to 1 p.m.

Smooth Sailing with the IRB

Presented by CTSI and the Human Research Protection
Office

Virtual Event

Tuesday, October 7 - Thursday October 9 | 8:15 a.m. to 1p.m.

Orientation to Research Fundamentals

Presented by the CTSI Responsible Conduct of Research
Center

Changes to Vincent: Advice from the Human Research Protection Office

Recent enhancements to Vincent payment services will allow research participants to be compensated through either the current method of providing a physical card, or via an electronic payment option. All participants will be defaulted to the electronic option when the system is upgraded. However, there is an option to change that with appropriate justification. The Human Research Protection Office (HRPO) recently released helpful information regarding protocol submissions related to this change:

PittPRO application:

For existing studies: it is not necessary to submit a modification for this change unless your consent form specifically mentions the reloadable card as the sole payment method. If you need to modify, please follow the guidelines for new studies.

For new studies: Include a statement in the recruitment methods section, #4, that participants will be paid through the University's approved payment system. Avoid using the term "Vincent." If you are going to apply for a Man on the Street exception, that should also be stated including what you will be requesting (payment in cash, payment via gift card, etc.) For instructions on requesting this exception, see the Vincent Exceptions guidance page.

The HRPO website has a very useful step by step <u>quide</u> providing specific language to include in PIttPRO related to this change for every relevant section of the protocol. It is highly recommended that you follow this guidance when submitting or modifying your protocol.

Questions for us?

We'd love to hear from you: ctsi@pitt.edu

Pitt+Me questions: ASKPPM@pitt.edu

