

CTSI Coordinator Connect

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



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RESEARCH RESOURCES | Informed Consent Toolkit

The Trial Innovation Network (TIN) is a consortium of over 60 Clinical and Translational Science Awardee sites across the country; it aims to leverage and share resources across all participating sites to promote research and improve the quality and efficiency of research processes nationwide. The TIN compiled a publicly available collection of recruitment, retention, and engagement resources, known as the TIN Toolbox. The Toolbox is available at no cost to the Pitt research community, and recently added an [Informed Consent Toolkit](#).

The Informed Consent Toolkit compiles and divides resources into five categories:

- **TIN Informed Consent Group Resources:** includes information on improving accessibility, special population considerations, and supporting consent operations. These resources have accompanying materials that are available in the appendix of the toolkit
- **Global Resources:** provides informed consent information that is not focused specifically on the United States and may be helpful for those who work with international organizations or participants
- **National Resources :** offers toolkits, guidance, and templates such as those available from the CDC and the NIH
- **Health Literacy Resources:** offers templates and tools to support the use of plain language
- **Literature Collections:** includes peer-reviewed manuscripts relevant to informed consent, divided into the following categories: improving accessibility, special population considerations, supporting consent operations, and broad or large-scale consent.

The toolkit is comprised of many useful resources, including:

- An informed consent concise summary template that will support investigators to present the key information that is most likely to assist a prospective participant in understanding the reasons why one might or might not want to participate in the research
- Guidance on developing clinical trial informational videos to be used during screening in order to educate potential participants so they can make an informed decision about consent
- Guides on health literacy and readability
- Information on enhancing recruitment of underrepresented populations

TRIAL INNOVATION NETWORK



FUNDING OPPORTUNITIES

Call for Letters of Intent-Alzheimer's Disease Research Center Developmental Projects, 2024-2025 Grant Year

One of the research missions of the Alzheimer's Disease Research Center (ADRC) at the University of Pittsburgh is to fund developmental projects to stimulate new and innovative research relevant to Alzheimer's disease. Types of research can range from basic science to clinical/psychosocial, with particular attention given to novel approaches. Proposed research may involve humans, animals or in vitro studies. The subject population, clinical, neuropathological and neuroimaging databases of the ADRC are available resources for approved proposals. Additional resources include the database from the National Alzheimer Coordinating Center (NACC). Applicants should be postdoctoral or junior faculty level investigators at the University of Pittsburgh but may be awarded to a more senior investigator whose research is primarily in areas other than Alzheimer's Disease and Alzheimer's Disease Related Dementia or who wants to work in the dementia field.

Letter of Intent: A brief description of the proposed developmental project should be e-mailed to Leslie Dunn, MPH, Center Administrator (dunnlo@upmc.edu) by end of business August 21, 2023. Please include title of the proposal, names of investigators/co-investigators, brief description of project, and a brief statement of relevance of the proposed research to the field. If using ADRC resources, discuss with appropriate ADRC core leader to determine availability of subjects, data, imaging scans or samples.

The awards will support \$75,000 in direct costs. Investigators who are invited to submit a full proposal will be notified by August 31, 2023. Applications must be received no later than September 29, 2023.

CTSI UPDATES

Dissemination and Implementation Science Pilot Award (DISPA) Opportunity

Dissemination and Implementation (D&I) science is the study of strategies to spread evidence-based interventions and increase or improve their use. CTSI'S most recent [pilot award opportunity](#) will support new or ongoing research that uses dissemination and implementation science research methods to support the adoption, implementation or maintenance of an evidence-based practice or program. Inherent in D&I research is a focus on ensuring equitable dissemination and implementation; investigators are encouraged to consider their work in the context of health equity. Examples of projects that might fit this opportunity include evaluating barriers to, and facilitators of, an evidence-based practice or program; and engaging stakeholders to collaboratively develop dissemination or implementation strategies.

Interested individuals may contact the Implementation to Maximize Population and Community Translation (IMPACT) Core if they have questions concerning project ideas. The IMPACT Core is a new core at the CTSI with unique expertise in the theories, frameworks, and methods of D&I Science. If you would like to meet with the IMPACT Core, please contact the CTSI Pilot Core at ctsipilots@pitt.edu. The application deadline is August 25.

Save the Date: Orientation to Research Fundamentals Returns in the Fall

CTSI's Orientation to Research Fundamentals (ORF) Program is an intensive and interactive 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. Topics covered include informed consent, study documentation, recruitment and retention, standard operating procedures, community engagement, working with the IRB, and more. ORF will be held October 3-5; registration will open in September 1. Please save the date and join us! Registration links will be available on our [website](#).

September Lunch and Learn:

The Community Health Series Partnership, a collaboration between CTSI, the Urban League of Greater Pittsburgh, the UPMC Center for Engagement and Inclusion, and the New Pittsburgh Courier, will explore oral health and its connections to the social determinants of health in our September presentation. [Join us](#) on Thursday, September 14 at noon as we hear from community and academic experts on this critical topic.

Please visit our [website](#) for a video library of past Lunch and Learns on a number of research and public health topics.

REGULATORY NOTES

Updates from the Office of Research Protections (ORP)

The University of Pittsburgh Office of Research Protections, in cooperation with the University's Purchasing Services Department, recently executed three University-wide Contracted Suppliers Agreements with the following Contract Research Organizations (CROs): Scope International, Pintail Solutions, LLC, and Pearl Pathways. These agreements eliminate the need for a separate contract for each project. Additionally, investigators have free access to the CRO for assistance in determining the scope of work required, including cost estimates, to ensure that required services are identified and are fiscally feasible.

CRO services include multi-center trial monitoring, project management, database development, data management, and regulatory support. CROs may be especially useful to researchers conducting multi-center trials involving investigational drugs and devices, to ensure regulatory compliance. Please see the ORP [website](#) for more information.

UPCOMING EVENTS

Tuesday, September 6 | noon to 1 p.m.

[Responsible Conduct of Research Principles and Applications](#)

Presented by the CTSI Responsible Conduct of Research Center

Virtual Event

Thursday, September 14 | 9:45 a.m. to 4:15 p.m.

[Old Trips, New Destinations: Exploring the Ethical and Practical](#)

[Considerations of Psychedelics Research](#)

Presented by the Office for Human Research Protections

Virtual Event

Monday, October 2 | noon to 1 p.m.

[A Community Engaged Approach to Recruitment and Retention](#)

[of Underrepresented Populations in Research](#)

Presented by the Trial Innovation Network

Virtual Event

Recorded Webinar

[Voices Yet to Be Heard: Including People With Disabilities in](#)

[Clinical Research](#)

Presented by The Center for Information and Study on Clinical

Research (CISCRP)

Recorded Webinar

[Working Towards a More Inclusive Environment: Transgender](#)

[and Non-Binary Participants in Clinical Research](#)

Presented by The Center for Information and Study on Clinical

Research (CISCRP)

For more upcoming events sponsored by the CTSI Responsible Conduct of Research Center, please visit our [website](#)

For more campus-wide events, check the [University of Pittsburgh Events Calendar](#)

DEAR CTSI,

Question:

Our group recently received funding for a grant that includes collaborators at a university in Egypt. It is a minimal risk study, and our partners say that locally an official ethical approval for minimal risk studies is not required. Are there additional steps we should take here to make sure we are in regulatory compliance?

Answer:

If it has been officially determined that the foreign regulations do not require ethics review of your minimal risk study, documentation that the study design and procedures do not conflict with the local cultural and social standards in the form of a Memo of Cultural Appropriateness is required for submission to the Pitt Human Research Protections Office (HPRO). The Memo of Cultural Appropriateness should contain the following elements:

- The memo must be dated
- The memo must come from someone who is independent of your research study (cannot be an investigator, mentor or research team member)
- The memo must reference the title of the research protocol
- The memo must indicate how the individual providing it has expertise in the culture and social norms of the country/region where the study will take place
- The memo must indicate the individual providing it is aware of the topic and procedures of the research study
- The memo must attest that the study and its procedures do not conflict with the local cultural and social norms of the country/region where the study will take place and must have an official signature

Please see the HPRO [website](#) for information/examples.

Questions for us?

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

Pitt+Me questions: ASKPPM@pitt.edu

Pitt CTSI

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