



PLEASE NOTE:

This is NOT a Traditional Pilot RFA and is significantly different than the previous funding opportunities.

Please carefully read the RFA requirements.

CTSI Clinical and Translational Science Pilot (CTSP) Program

Request for Applications for the Pilot Award to Advance [Translational Science](#)

The CTSI of Southeast Wisconsin is now accepting applications for the **2025 Pilot Award to Advance Translational Science**.[†] This CTSI award opportunity is funded by the National Institutes of Health (NIH) – National Center for Advancing Translational Sciences (NCATS) and is designed to support proposals that advance [Translational Science](#).

[†]**Awards are contingent upon funding of the CTSI parent award.**

It is the goal of the CTSI to diminish the barriers between institutions and disciplines while encouraging novel approaches to solving complex health related problems. Ultimately, we strive to improve health outcomes by creating new, bidirectional flows of information between our biomedical research enterprise and the community we serve. The Clinical and Translational Science Pilot (CTSP) Program offers this coordinated inter-institutional and interdisciplinary granting mechanism to stimulate, evaluate, and fund collaborative translational science Pilot proposals. In turn, our CTSP Program will converge scientists and the community of stakeholders around topics of mutual interest to advance translational science research.

The purpose of this award is to promote translational science and the development of innovative tools and methods to address barriers to translational and clinical research. Applications should adhere to the [principles of translational science](#), particularly generalizability, creativity, cross-disciplinary teams, and promotion of efficiency in research. As indicated by NIH-NCATS ([PAR-21-293](#)):

- **NOT ALLOWED:** Traditional research projects, i.e., projects focused on a particular scientific question for a particular target or disease.
- **ALLOWED:** [Translational Science](#) Projects which are intended to:
 - explore possible innovative new leads or new directions for established investigators;
 - stimulate investigators from other areas to lend their expertise in research in CTS; and
 - provide initial support to establish proof of concept.See examples below.
- Projects must be feasible within the proposed timeframe (12-months), have high methodological and scientific quality, and answer important scientific questions.

The duration of the award is 12-months. **Under this mechanism, up to 4 awards for meritorious translational science proposals will be selected for up to \$25,000 each.**



THE INTENT OF THIS AWARD IS TO:

- Model best practices in team science research;
- Foster interdisciplinary and inter-institutional collaborations;
- Maximize scientific interactions between junior and senior investigators;
- Support proposals that prioritize community engaged research through Diversity, Equity, Inclusion and Accessibility (DEIA)

SPECIAL EMPHASIS

Special consideration will be provided to at least one meritorious proposal focused on barriers to research on women's health.

EXAMPLES OF TRANSLATIONAL SCIENCE INCLUDE:

- Development of new research methodologies, tools, or resources that will increase the efficiency and effectiveness of research
- Development of novel technologies and/or novel approaches and applications to clinical practice and community health that will advance the effectiveness of translation
- Development of novel methods to improve the efficiency and feasibility of biostatistical and computational methodology that will advance the efficiency of clinical and translational research
- Early-stage development of new therapies or technologies with generalizable application to a translational roadblock
- Dissemination of effective tools, methods, processes, and training paradigms
- Secondary analysis of existing data
- Integrating data from clinical trials and observational studies to optimize analysis efficiency



KEY DATES

Mandatory Translational Science (TS) Information Sessions:

All interested applicants are *required* to attend the TS Information Session prior to submitting an intent to apply to ensure optimal responsiveness to the RFA.

June 11, 2024, 11:00 a.m. - 12:00 p.m.

June 25, 2024, 4:00 - 5:00 p.m.

The link to the Intent to Apply form will be made available to those who attend the mandatory information sessions.

Intent to Apply due: July 15, 2024, 5:00 p.m. CDT.

For Intent to Apply submissions that are identified by the Translational Science Pilot Review Committee as not meeting the Translational Science or other RFA requirements, the re-submission deadline is:

September 6, 2024. (New submissions are not allowed after the July 15th deadline.)

Grant Application Deadline:

For projects with any MCW investigators:

1. **An MCW eBridge funding proposal (FP) must be submitted by October 8, 2024, and**
2. **Once the FP has been institutionally approved, the completed application must be submitted via REDCap by October 15, 2024, 5:00 p.m. CDT***

For projects without an MCW investigator: the completed application must be submitted via REDCap by October 15, 2024, 5:00 p.m. CDT*

Notification of recommendation for award: by February 28, 2025

IRB/IACUC Submission deadline: March 10, 2025**

Mandatory orientation for PIs/mPIs whose project has been recommended for funding:

March – April 2025

NCATS Prior Approval submission form deadline: May 1, 2025, 5:00 p.m. CDT***

†Project start date: July 1, 2025***

Project end date: June 30, 2026****



IMPORTANT INFORMATION:

* Applications must meet the respective institution's grant/research office notification requirements. This includes eBridge (MCW research submission/management system) funding proposal deadlines. Applications that include any MCW PI/mPI/Co-investigator will be required to **submit an FP by required date noted under Key Dates** and provide the appropriate eBridge funding proposal number within the grant application. Appropriate documentation from partner institutions is also required.

**CTSI is supported by the National Institutes of Health (NIH) National Center for Advancing Translational Sciences (NCATS). As such:

- "NIH expects that all sites participating in multi-site studies, which involve non-exempt human subjects research funded by the NIH, will use a single Institutional Review Board (sIRB) to conduct the ethical review required for the protection of human subjects." ([NIH Single IRB Policy](#)) **Please reach out to your respective IRB Reliance office at the time of application if needed.** Because Pilot projects involve inter-institutional collaboration, IRB reliance might be appropriate. If it is determined that an IRB other than the MCW IRB would serve as the IRB of record, then a request would need to be entered into and processed via eBridge. There may be a fee for MCW to serve as single IRB; fees are based on type of funding, complexity of the project, and number of relying sites. Additionally, please be aware that IRB reliance is a process that can take some time as all sites must ensure that they understand the project, are willing to rely on or accept IRB oversight, ensure their local requirements have been satisfied, and agree with the terms of the reliance. Each site may have their own unique reliance documentation system. MCW IRB Reliance can be reached at MCWIRBReliance@mcw.edu.
- CTSI is required to obtain documentation based on IRB/IACUC approval for each applicable pilot project that has been recommended for funding. IRB/IACUC must be submitted no later than the date noted under Key Dates or the recommendation for funding may be withdrawn. **Verifiable proof of submission is required.** If applicable, proof of any non-human subjects designation or approved [Public Data Set](#) by the IRB must be provided.
 - NOTE: Because these awards are NIH funded, for proposals that are using an existing IRB documented FLEX/Registration project, an amendment (AME) will need to be submitted to ensure the project is moved off the FLEX/Registration pathway and granted approval under HSS regulations.

†Awards are contingent upon funding of the CTSI parent award.

*** CTSI is required to submit documentation based on IRB and/or IACUC approval for each applicable project that has been recommended for funding to NIH NCATS for prior approval. NCATS requires at least 30-days to review approval requests. To accommodate this requirement, applicants whose project has been recommended for funding are required to provide regulatory, safety, or other ancillary committee approvals and submit documentation for NCATS Prior-Approval by the date noted under Key Dates. Timeliness is important to avoid delays that could affect the project timeline. **Funding will not be released until all regulatory and NCATS prior approvals are in place.**

**** **No-cost extensions and project budget changes will not be allowed; All funds must be EXPENDED within the 12-month award period.**



DEFINITIONS

Translation is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes.

Translational research is the endeavor to traverse a particular scientific question or barrier for a particular target or disease.

Translational science is the field that generates scientific and operational innovations that overcome longstanding challenges along the translational research pipeline. These include scientific, operational, financial and administrative innovations that transform the way that research is done, making it faster, more efficient, and more impactful.

Translational Science Principles apply to research anywhere along the translational continuum and are intentionally broad:

- **Prioritize Initiatives That Address Unmet Needs**
 - Focus on pursuing scientific goals that address unmet scientific, patient or population health needs.
- **Produce Generalizable Solutions for Common and Persistent Challenges**
 - Develop innovations that address persistent challenges to advancing translational progress that are found across multiple research initiatives or projects, or span research on multiple diseases or conditions.
- **Emphasize Creativity and Innovation**
 - Leverage creativity and innovation in research design, conduct, and facilitating factors, with the goal of increasing the impact of the research.
- **Leverage Cross-Disciplinary Team Science**
 - Engage team members with expertise across disciplines, fields, and professions to produce research that advances translation along the translational research continuum.
- **Enhance the Efficiency and Speed of Translational Research**
 - Implement evidence-informed practices and scientific and operational innovations to accelerate the pace of translational research.
- **Utilize Boundary-Crossing Partnerships**
 - Leverage collaborations across agencies and sectors and engage patients and communities in research to advance translational progress.
- **Use Bold and Rigorous Research Approaches**
 - Develop ambitious research questions and address them with rigorous and robust methods toward generating reproducible findings that contribute to advancing translation.
- **Prioritize Diversity, Equity, Inclusion and Accessibility (DEIA)**
 - Leverage diversity, equity, inclusion, and accessibility to produce research outcomes that are relevant to the full diversity of the population.



Based on the CTSA External Reviewer Exchange Consortium (CEREC) and CEREC II manuscript, the below may aid in determining whether a proposal is Translational Science:

7 Translational science principles questions

Generalizable Solutions

- This project addresses a common roadblock or bottleneck in translational research
- The knowledge gained from this project will be generalizable to a variety of diseases
- This project approaches research challenges and development of solutions by seeking commonalities across research on a range of diseases and conditions.

Efficiency and Speed

- If successful, this project will improve translational research by making it more efficient or effective.
- This project will develop and implement innovations in scientific approaches, methods and/or technologies to accelerate the pace of translational research.
- This project encourages transformative ideas and risk taking toward achieving the overall goal of improving the translational process.
- If successful, this project will yield information that will accelerate translational research.

REQUIREMENTS

DATA MANAGEMENT SHARING POLICY

Applicants must agree to abide by the [NIH 2023 Data Management Sharing Policy](#) and if proposed study is a clinical trial, applicants must submit Data Management Sharing Plan.

INTER-INSTITUTIONAL REQUIREMENT

- Proposals must be inter-institutional at the time of the Intent to Apply submission; the scientific team must include investigators (PI/mPI or co-I) from at least two different CTSI partner institutions: Versiti, Children's Wisconsin, Froedtert, MCW, MSOE, MU, UWM, Milwaukee VA (Zablocki). Please note, this condition is based on the investigator's institution of **primary employment**. Volunteer appointments do not qualify.
- Community partners or investigators from other academic institutions would be welcome additions to projects as co-investigators, but alone do not meet the inter-institutional requirement.
- Faculty from the MU/MCW joint department of biomedical engineering should use their primary employment platform to determine institutional affiliation.
- Investigators that are interested in forming new collaborative relationships are encouraged to contact the CTSI Pilot Program Director, Renee McCoy, at rmccoy@mcw.edu.

CROSS DISCIPLINARY TEAM SCIENCE

These awards are intended to stimulate inter-institutional and interdisciplinary/multidisciplinary clinical and translational research among the CTSI partner institutions. In supporting such collaboration, these Pilot awards promote and support best practices in team science research. For more information on team science, see: [Collaboration and team science: From theory to practice](#); [Making virtual teams work: Ten basic principles](#); [Team science learning module from Northwestern University](#)



PRINCIPAL INVESTIGATOR & STUDY TEAM ROLES

Note that in the language of this RFA, the roles of Principal Investigator (PI) and multiple-Principal Investigator (mPI) are equivalent. For this Pilot Award to Advance Translational Science, only CTSI partner institution faculty meeting their institution's requirements to serve as PI can be listed as PI or mPI. These are distinct and have different requirements from the roles of the Co-Investigator (Co-I).

PI REQUIREMENTS

- This award allows for, but does not mandate, a multiple PI model. In cases where a project has multiple PIs, **any investigator in a PI/mPI role must be from a CTSI partner institution.**
- The PI/mPIs must have full-time or full professional effort status. Adjunct and part-time faculty are not eligible to apply as a PI. (Please work with your respective Office of Research/Sponsored Program in advance to ensure PI requirements and that all needed documentation is available before the respective deadlines. MCW faculty please see: [MCW Principal Investigator Eligibility](#).)
- A PI may submit only one application as the lead PI per funding cycle.
- The PI must have meaningful contribution to the science of the proposal (cannot be an administrative PI only).
- The role of PI must remain as originally submitted in the Intent to Apply.
- The lead PI has the responsibility for the conduct of a research project, including all technical, programmatic, financial, compliance, and administrative aspects. The PI is responsible for controlling the technical direction and academic quality of the project and will ensure that the project is carried out in compliance with the terms, conditions, and policies of the institution and sponsor, when applicable.
 - **Important:** If an **MCW investigator** is involved in the project, then that individual should be the contact investigator. This investigator's role and effort does not need be that of the lead PI. The MCW investigator will need to enter a funding proposal in MCW's eBridge system and be listed as the contact investigator.
 - An MCW contact investigator will have the additional expectation of managing the award through their department.
- The PI/mPIs must have a minimum of 1% effort and be fully vested in the project in both spirit and practice and contribute actively on the project. *Note: cost-sharing is not allowed.*
- Lead PIs are responsible for fulfilling reporting requirements as a condition of receipt and continuation of funds. Non-compliance of benchmark, final, and/or annual reporting could result in the rescission of funds by CTSI.
- PI/mPIs must be CTSI Members. To become a member, please complete the [CTSI Membership Form](#).

CO-INVESTIGATOR / OTHER PERSONNEL

- A co-investigator must have the requisite research training/credentials/expertise to make a substantive contribution to the science of the study and must have a minimum of 1% effort on the project. *Note: cost-sharing is not allowed*
- Study personnel such as research assistant, study coordinator or other staff needed for the conduct of the study may not serve as a Co-investigator



- Any change in the role of Co-investigator must be approved by the Pilot Management Oversight Committee.
- All investigators must be CTSI Members. To become a member, please complete the [CTSI Membership Form](#).

REGULATORY REQUIREMENTS

- Applicants are encouraged to contact CTSI IRB Navigator, Charlotte Klis for assistance at cklis@mcw.edu.
- Lead PIs must provide verifiable proof within the grant application that **all regulatory applications** (IRB/IACUC, etc.) are in at least pre-submission status. If applicable, proof of non-human subject research (NHSR) status must be provided.
- **Please note that all applicable projects that receive recommendation for funding must provide proof that the IRB application/amendment and/or the IACUC application have been submitted by the date indicated under Key Dates; this is a firm deadline.** This requirement is to accommodate necessary timelines for obtaining regulatory and NCATS prior approvals as well as receiving notice of award and funding.
 - ***NOTE: Because these awards are NIH funded, for proposals that are using an existing IRB documented FLEX/Registration project, an amendment (AME) will need to be submitted to ensure the project is moved off the FLEX/Registration pathway and granted approval under HSS regulations.***
- All individuals involved in the design, conduct or review of human subjects research (HSR) are required to have current CITI training. If your project involves human subjects research, all study team members must obtain [CITI training](#) or equivalent training in human research protections.
 - For research involved in clinical trials of drugs, biologics, and devices, as well as those involved in behavioral intervention and social science research studies, FDA regulated research or NIH-funded clinical trials, all study team members must also obtain training in [Good Clinical Practice \(GCP\)](#).
 - Documentation of HSR training is not required at the time of application; however, documentation will need to be provided upon notification of recommendation for funding.
- Clinical research and clinical trials that utilize any Froedtert Hospital (FH) resources – medical records (PHI), staff, facilities, equipment, invoicing/billing, etc. – must be reviewed via the Office of Clinical Research and Innovative Care Compliance (OCRICC) to ensure that FH has the staff, equipment, and other resources to successfully support the study. The Froedtert Health OCRICC Administrative Approval process has been updated to streamline processes and improve approval timelines. We highly suggest you visit the [OCRICC website](#) before beginning your project.

To help expedite OCRICC approval:

- Submit your project's OCRICC application at a minimum at the same time as your IRB submission. Note: OCRICC application requires ALL project documents such as Protocol, ICF, Operational Feasibility tool. This supports OCRICC's timely and efficient operational and financial feasibility review. **A project submitted without all required documents is placed On Hold.**
- Add "CTSI PILOT" in the title of your OCRICC application



- Notify OCRICC when you receive IRB approval
- This program has an accelerated nature and only a 12-month funding period. If your project requires working with federal agencies such as NIDA, FDA (e.g., IND, IDE applications) or pharmacological agreements (e.g., clinical trial agreements, material transfer agreements), you must contact the CTSI Pilot Program Director, Renee McCoy, at rmccoy@mcw.edu **prior to applying**.

BUDGET & FUNDING PROPOSAL REQUIREMENTS

- Projects will be funded at a level of up to \$25,000.
- Project duration will be 12-months. No-cost extensions or project re-budgets will not be allowed.
- All funds must be EXPENDED within the 12-month period. Costs directly related to the approved award must be purchased during the award period and purchased item(s) must be allocable and/or consumable during the award period. Items that are not consumed within the award period must be allocated to another funding source.
- Funding under this RFA cannot be used as “bridge funding” for lapsed grants from any extramural source and is intended to be used for new projects.
- Funds are limited to MCW and/or CTSI Partner purchasing regulations.
 - funds cannot be used to supplant funds or resources that are available from other sources.
- No “indirect costs” may be charged.
- All salary support is subject to the current NIH salary cap at time of award. Current NIH salary cap is \$221,900.
- Effort must be specified for all investigators (& personnel). **Cost-shared effort is not allowed.**
 - Institutional base salary must be listed for any individual providing effort / receiving salary support from the project.
- One budget form is required **for each partner institution** providing personnel effort on the study that is not considered consultative or fee-for-service. Consultant and/or service fees sourced from another institution or agency such as CW or Froedtert Hospital need not be paid via a subcontract. Use the appropriate budget template provided within the How to Apply section. Please work with your respective Office of Research/Sponsored Program in advance to ensure that all needed documentation is available before the respective deadlines (see Additional Requirements by Institution section).
- **Funding Proposals (FP):** FP applications for this award are required to be submitted in MCW’s eBridge system by **the date noted under Key Dates, for applications with any MCW investigators.**
 - Contact Renee McCoy at rmccoy@mcw.edu **before the FP Deadline** if guidance is needed for responding to FP questions.



2025 Pilot Award to Advance Translational Science

PROCEDURE

HOW TO APPLY

STEP 1: Attend one of the Mandatory Translational Science (TS) Information Sessions. All interested applicants are required to attend the TS Information Session prior to submitting an intent to apply to ensure optimal responsiveness to the RFA.

[REGISTER FOR THE TRANSLATIONAL SCIENCE INFORMATION SESSION](#)

STEP 2: The link to the Intent to Apply form will be emailed to those who attend the mandatory information sessions. Check your email for the communication from rmccoy@mcw.edu. (see LOI PDF for reference)

STEP 3: Submit your Intent to Apply by July 15, 2024, 5:00 p.m. CDT.

STEP 4: Once your Intent to Apply is approved, you will receive an email with the link to the full Grant Application. Check your email for the communication from rmccoy@mcw.edu. (see Grant Application PDF for reference)

STEP 5: Submit the full Grant Application by October 15, 2024, 5:00 p.m. CDT. *Proposals with any MCW investigator must submit an FP in MCW's eBridge system by October 8th and include the full grant application and materials.*

REQUIRED GRANT APPLICATION MATERIALS

- 2025 CTSI Translational Science Pilot Award Proposal Form**
(see Proposal Form for reference)
- Budget and Budget Justification Forms**, one form is required for each partner institution providing personnel effort on the project that is not considered consultative or fee-for-service.
- NIH Biosketch** in the most current NIH format is required for all PIs, Co-Investigators, and Other Significant Contributors (limit 5 pages per individual). Biographical Sketch Format Page (non-fellowship) Template can be found at <https://grants.nih.gov/grants/forms/biosketch.htm>.
- Letters of Support / Intent**
 - From Co-Investigators to PI/mPI(s)**
 - A Letter of Support is required from each co-Investigator to the PI/mPI(s) explaining her/his intention and commitment to this project.
 - Letters of Support should be addressed to *all* PI/mPIs.
 - A Letter of Support is *not required* from a mPI to the PI.
 - From Department Chair(s) to the project PI(s).**
 - To acknowledge awareness and support of the project (including cost-sharing).
 - From other institutions - Letters of Intent to establish consortium**
 - A Letter of Intent/Support to establish consortium is required from any non-MCW institution indicating a willingness to negotiate a project-specific subaward and validation that the institution is on-board with the project and is aware of the effort commitments being made.



ADDITIONAL REQUIREMENTS BY INSTITUTION

Funding Proposals submitted via eBridge are required for applications with *any* MCW investigators and are due as noted under **Key Dates (*five business days prior to the grant application submission deadline*). Please work with your respective Office of Research/Sponsored Program in advance to ensure all needed documentation is available before this deadline.**

For **Marquette University (MU)** investigators involved in a grant application, please contact the Proposal Planning and Development team in the Office of Research and Sponsored Programs (ORSP) early in the proposal development process. You can reach ORSP through your normal contacts or at orspppd@marquette.edu. Following contact with ORSP, next steps and the process for internal routing and approvals will be determined. ORSP can assist with forms, budget formulation, proofreading, securing sub-award letters of intent, etc. ORSP involvement is essential in making sure your application has received any necessary approvals prior to submission. If you are unaffiliated with MU and would like to collaborate with a Marquette investigator, please contact the Proposal Planning and Development team within ORSP at orspppd@marquette.edu or if the collaborator has been identified, they can contact ORSP.

UW-Milwaukee investigators: applications will need to be routed using the WISPER system and approved by the Office of Sponsored Programs (OSP) prior to submission. Please contact an OSP staff member (<https://uwm.edu/officeofresearch/contact/#pre-award>) early in your application preparation process to ensure accurate compliance. Email: grant-notice@uwm.edu

MSOE investigators, please contact Sheku Kamara, Dean of Applied Research (kamara@msoe.edu) and submit your proposal in [MSOE's OneAegis](#) grant portal.

Versiti investigators/collaborators: Please contact your designated point of contact early in the proposal process. These proposals will need to be processed through the Versiti Grants and Contracts office observing Versiti's standard internal deadlines.

Children's Wisconsin investigators (those who are Children's Wisconsin employees) planning to submit an application or who are involved as key personnel on an application, please contact Amber Krueger, Senior Grants Development Specialist with the Grants Development Office (AJKrueger@childrenswi.org). The Grants Development Office can assist with pre-award activities, including: biosketch review, budget set-up, securing institutional letters of intent, and requesting eRA Commons usernames. The proposals will need to be routed through Children's Wisconsin Finance for budget review and approval.



REVIEW PROCESS

Each Intent to Apply that has been received by deadline will be reviewed; for those that meet the Translational Science and eligibility criteria and are approved, the lead PI will be notified and sent the link to proceed with the full application.

Criteria that must be met for funding of any proposal include:

- the clear potential to directly translate anticipated results into improved preventative health, diagnostics, therapeutics, or health outcomes for our southeast Wisconsin community; and
- the potential for proposed studies, when completed, to generate extramural funding.

CTSI and the CTSI Pilot Management Oversight Committee (PMOC) will initially review all applications for feasibility and compliance with above requirements. CTSI PMOC is comprised of members from our partner institutions Marquette University (MU), Medical College of Wisconsin (MCW), Milwaukee School of Engineering (MSOE), University of Wisconsin-Milwaukee (UWM), and Versiti Blood Research Institute (Versiti).

All grant applications will undergo peer-review. To assist you in developing a strong proposal, specific review criteria will be available within the online application form for your reference.

CTSI participates in a national [CTSA External Reviewer Exchange Consortium \(CEREC\)](#) to improve fairness in the scientific review process and better match applicants with feedback from experts in their respective fields. Applications for this cycle may be reviewed externally through our association with CEREC and we require that you acknowledge within the online application form that your proposal may undergo external review.

Maintaining confidentiality throughout the peer review process is essential to allow for the candid exchange of scientific opinions and evaluations; and to protect trade secrets, commercial or financial information, and information that is privileged or confidential. Similar to the NIH peer review process, the CTSI is committed to protect the integrity of and to maintain confidentiality in peer review. See [NOT-OD-22-044](#).

TERMS & CONDITIONS

CTSI follows NIH National Center for Advancing Translational Sciences (NCATS) and Medical College of Wisconsin (MCW) Terms and Conditions for all CTSI Pilot Award Projects.

CHANGES TO AWARDED PROPOSALS

Changes to the project aims/scope **are not permitted**. No-cost extensions and project budget changes **will not be allowed**. Any other changes to the awarded proposal must be requested via email to the CTSI Pilot Program Director and approved by the Pilot Management Oversight Committee before changes may be implemented.

RESTRICTION OF CLINICAL ACTIVITY BEYOND THE END OF PHASE IIB

In accordance with section 479(b) of the Public Health Service Act (as amended by the Consolidated Appropriations Act, 2012, Public Law 112-74 and by the 21st Century Cures Act, 2016, Public Law 114-255), no clinical trial activity beyond phase IIB may be supported by this grant through this Pilot award.



STEM CELLS

No funds in this award may be used for any research involving human embryonic stem cells (hESCs) until the grantee has submitted to NIH information on the specific, approved hESC line(s) that will be used from the [NIH Human Embryonic Stem Cell Registry](#). While the Registry will include lines pending review; only those hESCs listed on the Registry as eligible for NIH funding may be used in this award. Information should be submitted from an Authorized Organizational Representative to the assigned Grants Management Specialist.

The grantee may use only those hESCs that appear on the [NIH Human Embryonic Stem Cell Registry](#) as eligible for NIH funding and in accord with any restrictions placed on the use of those lines. For more information, view the [NIH Guidelines on Human Stem Cell Research](#).

RESTRICTION: DATA SAFETY AND MONITORING OF CLINICAL TRIALS

In accordance with the NIH's policy on data and safety monitoring of clinical trials NIH Grants Policy Statement (Part II, Chapter 4 <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>), the grantee must submit its data and safety monitoring plan to the NCATS for review and approval.

CLINICALTRIALS.gov

If this award provides support for one or more clinical trials, by law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see <https://clinicaltrials.gov/submit-studies/prs-help/how-register-study> and http://grants.nih.gov/ClinicalTrials_fdaaa/.

HUMAN/ANIMAL SUBJECTS RESTRICTION

- It is understood that no clinical research study member will be permitted to work on any project involving live vertebrate animals or human subjects that has not been approved by the IACUC and/or IRB, as appropriate.
- No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects by any site engaged in such research for any period not covered by both an OHRP-approved Assurance and an IRB approval consistent with 45 CFR Part 46. See "Human Subjects Protections" Part II, Chapter 4 (<http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>) for specific requirements and grantee responsibilities related to the protection of human subjects.

HUMAN SUBJECTS EDUCATION CERTIFICATION REQUIREMENT

- This award reflects the NCATS' acceptance of the certification that all key personnel have completed education on the protection of human subjects, in accordance with NIH policy, "[Required Education in the Protection of Human Research Participants](#)." Any individual involved in the design and conduct of the study that is not included in the certification must satisfy this requirement prior to participating in the project. Failure to comply can result in the suspension and/or termination of this award, withholding of support of the continuation award, audit disallowances, and/or other appropriate action.



Demographic Data Collection

Per NIH requirements, recipients must submit data on participant age at enrollment in progress reports. Investigators planning to conduct research involving human subjects should design their studies in such a way that de-identified individual-level participant data on sex/gender, race, ethnicity, and age at enrollment may be provided in progress reports. Age at enrollment may be reported in units ranging from hours to years. Recipients are responsible for ensuring informed consent documents allow submission of de-identified individual-level data on participant sex/gender, race, ethnicity, and age at enrollment.

CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE (CTSI)

RESOURCES FOR APPLICANTS

CTSI provides access to numerous CTSI resources and services. These include but are not limited to the MCW Clinical Trials Office (CTO), Adult, Pediatric, Community/Mobile, and Zablocki VA/Geriatric Translational Research Units (TRU), REDCap Secure Data Collection & Storage, as well as research support services in Biomedical Informatics, and Biostatistics / Epidemiology Research Design (BERD). [Please see our website for resources available to our investigators and applicants.](#)

REPORTING

As an NIH supported program, the CTSI is required to collect benchmark, annual progress, and long-term outcomes reports of all Pilot awarded projects. Timely progress and reporting of the funded research project is a requirement of the award.

The CTSI Translational Science Pilot Awards are funded by the NIH/NCATS. All applications and awarded projects must follow respective processes including but not limited to benchmark and annual reporting requirements. Awardees may also be required to present at a CTSI Science Café or other CTSI related venue.

Failure to comply with reporting requirements may make PI ineligible for future CTSI Pilot funding.

FUNDING ACKNOWLEDGMENT

Important Reminder – Please acknowledge the National Institutes of Health (NIH) CTSA award when publishing or presenting any outcomes resulting from your study by including the [CTSI Funding Acknowledgement](#).

Questions?

Please contact Renee McCoy, CTSI Pilot Program Director, at rmccoy@mcw.edu.