Clinical & Translational Science Institute
of Southeast Wisconsin

CTSI Pilot Translational and Clinical Studies Program (PTCS)

Request for Applications for NIH-NCATS funded Traditional Pilot Awards

This CTSI Translational and Clinical Studies Program Traditional Pilot funding opportunity is funded by the National Institutes of Health (NIH) - National Center for Advancing Translational Sciences (NCATS).

Up to 2 NIH-NCATS Funded meritorious projects will be awarded at up to $50,000 each for the 2024 Traditional Pilot cycle, which may include at least one meritorious scoring proposal with the special emphasis of Commercialization potential.

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.[1]

[1]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

KEY DATES

Intent to Apply due: July 7, 2023, 5:00 p.m. CDT

For projects with any MCW investigators:

1. **An eBridge funding proposal (FP) must be submitted by** August 24, 2023, and
2. Once the FP has been institutionally approved, the completed application must be submitted via REDCap by September 1, 2023, 5:00 p.m. CDT*

For projects without an MCW investigator: the completed application must be submitted via REDCap by September 1, 2023, 5:00 p.m. CDT*

Notification of recommendation for award: Mid-January 2024

IRB Submission deadline: February 2, 2024**

Mandatory orientation for PIs/mPIs whose project has been recommended for funding: February 2024

NCATS Prior Approval submission form deadline: April 1, 2024, 5:00 p.m. CDT***

Project start date: June 1, 2024***

Project end date: May 31, 2025****

** 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 August 24, 2023** 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 February 2, 2024 or the recommendation for funding may be withdrawn.* **Verifiable proof of submission is required.**

*** *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 April 1, 2024. 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.***

OVERVIEW & PURPOSE

ABOUT THE CTSI PILOT TRANSLATIONAL AND CLINICAL STUDIES PROGRAM (PTCS)

This program is designed to advocate, facilitate, and foster the continuum of research from bench to bedside, and from bedside to community practice. In a sense, translational research focuses on discovery and the application of scientific findings into a real-world setting. 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.

GOALS OF THIS FUNDING OPPORTUNITY

The fundamental goal of this RFA is to stimulate clinical and translational research among the institutions that comprise the CTSI of Southeast Wisconsin through meaningful collaboration and high-quality team science. This award uses a multiple investigator model to encourage inter-institutional and interdisciplinary collaboration between clinical and basic biomedical scientists, social scientists, ethicists, engineers, biostatisticians, informatics specialists, and other members of the clinical health care delivery team with the appropriate training and expertise to make a substantive scientific contribution to the study.

FUNDS WILL BE PROVIDED TO:

- Support new and promising clinical and translational projects across all disciplines.
- Support projects across the translational continuum in Translational Research Track 1 (T1 to T2) and Translational Research Track 2 (T3 to T5)

- Generate preliminary data for projects poised to be competitive for new extramural grant submissions;
- Model best practices in team science research;
- Maximize scientific interactions between junior and senior investigators;
- Stimulate collaborative research between bench and clinical investigators from similar research areas;
- Foster interdisciplinary and inter-institutional collaborations;
- Support research in novel technologies and/or novel approaches and applications to clinical practice and community health

DEFINITIONS & REQUIREMENTS

CLINICAL & TRANSLATIONAL RESEARCH

This CTSI Pilot Translational and Clinical Studies Program (PTCS) funds clinical and translational research according to the NIH definitions described below:

CLINICAL RESEARCH

The NIH definition of clinical research[2] has three parts:

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
2. Epidemiologic and behavioral studies
3. Outcomes research and health services research

[2] Glossary of NIH Terms

TRANSLATIONAL RESEARCH

Applications will be reviewed and considered for funding based on NIH-identified translational areas. **Translation**[3] 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.

[3] NCATS Factsheet PDF

TRANSLATION-LEVELS (T-levels)

Applications must provide a T-level designation for the proposed research according to the CTSI translational continuum described below, based on NIH guidelines. Applications for this funding mechanism must be in a T1-T5[4] translational area. T0 proposals are not eligible. Preference will be given to meritorious T3-T5 proposals.

Proposals that are only T-0 research - Basic Biomedical Science or Discovery (Goal: To understand the human condition and environment as it exists) are ***not*** eligible to apply.

[4]**T-levels of Translational Research:**

- T-1 Translation to Humans – Clinical Insights
  GOAL: To identify and analyze the effects of an intervention or relationship on the human condition or environment
- T-2 Translation to Patients – Practice Implications
  GOAL: To identify and analyze the optimal effects of an intervention or relationship on the human condition or environment
- T-3 Translation to Practice
  GOAL: To incorporate into practice the optimal intervention or relationship
- T-4 Translation to Communities
  GOAL: To provide communities with the optimal intervention or relationship
- T-5 Translation to Global Communities
  GOAL: To provide global communities with the optimal intervention or relationship

DATA MANAGEMENT SHARING POLICY

Applicants must agree to abide by NIH data management sharing policy.[5]
[5]NIH 2023 Data Management Sharing Policy

SPECIAL EMPHASIS CATEGORY

Funds may be set aside for at least one meritorious scoring proposal with the special emphasis of Commercialization potential. This is the potential to file a patent, file an IND or IDE or 510(k), secure seed funding for a start-up company, initiate commercial licensing discussions, or provide preliminary data for a SBIR/STTR grant. Please visit the Accelerating Medical Product Development – using Networked Resources (or AMPDNR) website or contact Renee McCoy with questions.

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 the Traditional Pilot Awards, only CTSI partner institution faculty meeting their institution's requirements to serve as PI can be listed as PIs or mPIs. These are distinct and have different requirements from the roles of the Co-Investigator (Co-I).

A PI can be from any CTSI Partner Institution for these NIH funded Traditional Pilot Awards.

A PI can submit more than one application and a second award of a meritoriously scored proposal may be considered if the following are clearly explicated and justified:

1) the study proposed is part of the program of research of the mPI from another partner institution;

2) the PI has meaningful contribution to the science (cannot be an administrative PI only);
3) the study protocols are distinctly different; and,
4) the scientific research teams are substantially different.

For questions, please contact the CTSI Pilot Award Program Director, Renee McCoy, at rmccoy@mcw.edu.

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**.
- 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 eBridge and be listed as the contact investigator***.
- The role of PI must remain as originally submitted.
- 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.[7]
    - An MCW contact investigator will have the additional expectation of managing the award through their department.
- The lead PI must have a minimum of 5% effort and be fully vested in the project in both spirit and practice and contribute actively on the project. All other mPIs must have a minimum of 1% effort. *Note: Investigators will be required to attest to effort and cost-sharing intent on the application.*
- All PIs must have full-time or full professional effort status. Adjunct and part-time faculty are not eligible to apply as a PI.[7]
- 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.
- All PIs must be CTSI Members. To become a member, please complete the CTSI Membership Form.

[7] Principal Investigator Eligibility

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: Investigators will be required to attest to effort and cost-sharing intent.

- 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
- The role of Co-investigator must remain as originally submitted
- All investigators must be CTSI Members. To become a member, please complete the CTSI Membership Form.

INTER-INSTITUTIONAL REQUIREMENT

- Proposals must be inter-institutional: 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 Award Program Director, Renee McCoy, at rmccoy@mcw.edu.

REGULATORY REQUIREMENTS

- Applicants are encouraged to contact CTSI IRB Navigator, Charlotte Klis for assistance at cklis@mcw.edu.
- Lead PIs must provide verifiable proof that **all regulatory applications** (IRB/IACUC, etc.) are in at least pre-submission status. If applicable, proof of any exempt status must be provided.
- **Please note that all applicable projects that receive recommendation for funding must provide proof that the IRB application/amendment has been submitted by February 2, 2024; this is a firm deadline.** This requirement is to accommodate necessary timelines for receiving notice of award and funding.
- 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 subject 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, 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 up-dated to streamline processes and improve approval time lines. 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. 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 Award 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 $50,000.
- 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.
- 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 purchasing regulations.
  - funds cannot be used to supplant funds or resources that are available from other sources. However, matching funding and opportunities to leverage Traditional Pilot funds to obtain other sources of financial support are encouraged.
- 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 $212,100.
- Effort must be specified for all investigators (and personnel), even when effort is fully cost-shared by the institution/department. Indicate any cost-sharing within the budget justification under each investigator's name, under 'Sharing', and within a Letter of Support; cost-sharing commitment forms are not required at the time of application; however, these will need to be provided from MCW departments upon notification of recommendation for funding.
  - Institutional base salary must be listed for any individual providing effort and/or 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.
- **Funding Proposals (FP)**: FP applications for this award are required to be submitted in eBridge by **August 24, 2023**, **for applications with *any* MCW investigators**.
    - FP guidance: Under **Proposal Attachments**; section 1.0 "Do you have any comments for the Grants and Contracts office related to this project?" – select Yes then indicate "Per CTSI, this opportunity would be funded by UL1 TR001436-10."
    - Contact Renee McCoy at rmccoy@mcw.edu **before August 24, 2023** if additional guidance is need for responding to FP questions.

PROCEDURE

HOW TO APPLY

FIRST STEP: THE ONLINE INTENT TO APPLY FORM MUST BE COMPLETED AND SUBMITTED BY July 7, 2023, 5:00 P.M. CDT.

REQUIRED APPLICATION MATERIALS

Once the Intent to Apply Form is reviewed and approved, applicants will be sent a link to an online application form which must be submitted along with the following documents (templates are available at 2024 Traditional Pilot Awards).

1. 2024 CTSI Traditional Pilot Award Proposal Form
2. 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.
3. 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.
4. Letters of Support / Intent
    - **a. From Co-Investigators to PI/mPI(s)**
        - a.i. A Letter of Support is required from each co-Investigator to the PI/mPI(s) explaining her/his intention and commitment to this project.
        - a.ii. Letters of Support should be addressed to *all* PI/mPIs.
        - a.iii. A Letter of Support is *not required* from a mPI to the PI.
    - **b. From Department Chair(s) to the project PI(s).**
        - b.i. To acknowledge awareness and support of the project (including cost-sharing).
    - **c. From other institutions - Letters of Intent to establish consortium**
        - c.i. 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 <u>are required</u> for applications with *any* MCW investigators and are due by *August 24, 2023* *(prior to the grant application submission deadline of September 1, 2023)***.** Please work with you 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.

REVIEW PROCESS

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

To ensure that the results of scientific research will be used to directly benefit human health, proposals in all disciplines relevant to biomedical investigation will be considered for funding. 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 Award Committee (PAC) will initially review all applications for feasibility and compliance with above requirements. CTSI PAC is comprised of members from 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

Although not directly funded with National Institutes of Health (NIH) dollars, 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.

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 at http://prsinfo.clinicaltrials.gov. NIH encourages registration of all trials whether required under the law or not. For more information, see 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
  Similar to NIH requirements, recipients/offerors 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/offerors 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.

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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 Traditional Pilot Awards are funded by the Medical College of Wisconsin (MCW). All applications and awarded projects must follow respective processes including but not limited to reporting requirements.

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 Award Program Director, at rmccoy@mcw.edu.