

Clinical and Translational Science Institute (CTSI) Request for Applications for Clinical/Population Health Pilot Awards

Purpose

The purpose of this RFA is to support high impact pilot projects that help catalyze translation of discoveries to treatments or the delivery of care. The ultimate aim of this program is to make research investments that maximize healthcare value and improve population health. The immediate aim is to allow investigators to develop, test, or disseminate novel approaches to a translational research question and obtain preliminary data in support of larger follow-up investigations. Examples of pilot studies include feasibility studies, secondary analysis of existing data, development of new research methodology and/or new tools, dissemination of effective tools, methods, processes, or early development of new therapy/technology and can include investigation of patient or health care provider behaviors. Consistent with NCATS mission, projects should help catalyze translation of discoveries to treatments or the delivery of care.

Successful proposals will clearly state:

- How the proposed project advances research in a particular field to address health care needs within the population
- A rationale and potential for generalizability (if applicable)
- How the proposed project is translational (e.g., identify translational roadblocks that the proposed project will address and the anticipated benefits of overcoming them)
- A feasible project plan for the one-year award period
- Address next steps for this project: Will it lead to larger, subsequent grant applications (be specific: indicate RFA you will submit to and when)? Can it be applied to improve health or how we deliver care? How will results be disseminated? Is the project scalable? Consider the full range of possibilities for how the Medical Center and/or our community will benefit.

No pilot data is necessary to apply for this RFA, however supporting data from the recent literature is appropriate if available.

Clinical/Population Pilot Award Categories

In line with the definition of NCATS Translational Science Spectrum, a project proposal for the Clinical/Population Pilot Award **must** fall into one of the below categories.⁴

- **Clinical Research:**
Clinical research includes studies to better understand a disease in humans and relate this knowledge to findings in cell or animal models; testing and refinement of new technologies in people; testing of interventions for safety and effectiveness in those with or without disease; behavioral and observational studies; and outcomes and health services research. The goal of many clinical trials is to obtain data to support regulatory approval for an intervention.
- **Clinical Implementation:**
The clinical implementation stage of translation involves the adoption of interventions that have been demonstrated to be useful in a research environment into routine clinical care for the general population. This stage also includes implementation research to evaluate the results of clinical trials and to identify new clinical questions and gaps in care.
- **Public Health:**
In this stage of translation, researchers study health outcomes at the population level to determine the effects of diseases and efforts to prevent, diagnose and treat them. Findings help guide scientists working to assess the effects of current interventions and to develop new ones.

Projects that focus on the Academic Learning Health System ([Appendix I](#)) and meet some or all of the below CTSI priorities are strongly encouraged.

- Project addresses a “real” problem facing the Wake Forest organization.
- The project involves the development of practices, treatments, tools or approaches that will improve care.
- If the project involves an intervention, the intervention is informed by published research (i.e., based on pre-existing evidence).

- Inclusion of both a skilled researcher and clinician with expertise relevant to the project contributes to designing and implementing the approach used for learning and for testing the intervention.
- The research methods used by the project balance rigor with practicality.
- Results from the research are delivered in a timely/expedited fashion.
- The analysis of clinical data is a central aspect of the project.
- Results from the learning process are disseminated throughout the organization in a manner that leads to better patient care and improved organizational practices and policies.
- Interventions found to be effective through the project are implemented in line with the principles and practices of Implementation Science.

Projects that focus on Health Disparities ([Appendix II](#)) and meet some or all of the below criteria are strongly encouraged.

- Project must focus on racial/ethnic minority populations, socioeconomically disadvantaged populations, and/or rural populations.
- Project must go beyond describing existing health inequities to addressing health inequities.
- To be considered community-oriented research the project must include the perspectives of stakeholders outside the research team.
- Community-engaged research and CBPR is encouraged.
- Project should include how the proposed work directly focuses on improving health disparities.

Additionally, Clinical/Population projects are not limited to, but can focus in the following areas:

- Biomedical Informatics ([Appendix III](#))
- Implementation Science ([Appendix IV](#))

Funding

Successful pilots will receive up to **\$40,000** in direct costs. All projects must meet the above specifications outlined under “Purpose.” Project final budgets will be based on a complete review of the budget and budget justification. See “Budget Guidelines” below for more details. All funds are to be spent within a one-year project period; due to the restrictions on CTSA funding, no-cost extensions cannot be approved.

Between the Basic/Translational RFA and the Clinical/Population Pilot RFA, up to ten projects will be funded. Of those, up to two projects from the Charlotte or Macon region and up to eight projects from the Winston-Salem region will be funded.

Please note that the Center for Biomedical Informatics (WFBMI) is offering a \$10,000 bonus for one of the pilot awards if the proposed project involves informatics researchers, techniques, and methods. This bonus will be awarded to one pilot proposal evaluated as meritorious by CTSI Administrators and the IRSC. After an additional review by the Wake Forest Center for Biomedical Informatics leadership, the resulting pilot award will be in the amount of up to \$50,000. Please indicate in your application if you want to be considered for this bonus award.

Eligibility

These awards are open to all faculty with a rank of instructor or higher across the Atrium Health Enterprise including Atrium Health, Atrium Health Navicent, and Wake Forest Baptist Health, including Wake Forest University School of Medicine. Wake Forest University faculty and all CTSI affiliated institutions with a Wake Forest co-investigator are also invited to apply.

Clinician scientists, interdisciplinary teams that represent a combination of clinicians and basic scientists, adult and pediatric researchers and/or junior and senior investigators are all strongly encouraged to apply. Project teams comprised of researchers from multiple Regions and Markets (e.g. one investigator from Charlotte and one from Winston-Salem) are also strongly encouraged to apply.

The CTSI will allow a Co-PI structure if the PIs include both a skilled researcher and clinician with expertise relevant to the project that contributes to designing and implementing the approach used for learning and for testing the intervention.

Additional Information:

- Projects already submitted as CTSI or other intramural Pilot Proposals are eligible, but must incorporate reviewer feedback.
- Only one proposal may be submitted per faculty member serving as PI or co-PI.
- CTSI KL2 scholars whose KL2 funding is active during the pilot project period are not eligible to apply.
- Projects that have been previously funded (or projects with very similar ideas) will not be considered.
- Investigators are limited to two funded CTSI pilots unless special permission is granted in advance of the Letter of Intent submission deadline. Please email Brittney Patterson at britjack@wakehealth.edu to request permission.
- Investigators with active Ignition Funds remain eligible.

Key Dates

Date	Detail
10/14/22, 11:59 pm	Letter of Intent (LOI) Deadline
11/15/22	Investigators Invited for Full Application
12/14/22, 11:59 pm	Full Application Deadline
03/08/23	Selection of Awardees
05/10/23	If applicable, completed materials sent to NCATS for approval (Appendix V)
07/01/23	Project Start Date
06/30/24	Project End Date

CTSI Resources Available to Support Investigators

Several resources are available in the CTSI to help submit a strong application; while they are not required as part of the submission, investigators are highly encouraged to seek out additional assistance. All services can be requested through the [CTSI Service Request](#) form.

- **Grant Proposal Editing:** have an expert medical editor review your proposal prior to submission. They will offer suggestions on how to refine your writing and thinking. Your proposal will be edited in “track changes” so that you can easily accept or reject edits (free to everyone).
- **Biostatistical Support:** meet with a statistician to develop your study design, measurement, and statistical analysis plans prior to submission (free to everyone).
- **Research Studio:** meet with a multi-disciplinary panel of experts to work through specific aims, hypotheses, or ways to address the generalizable requirement (free to everyone).
- **CTSI Faculty Consultation:** meet with a CTSI faculty member (clinician, basic scientist, or behavioral scientist) to talk through project ideas or to find research/clinical partners (free to everyone).
- **Informatics:** optimization of the EMR to extract data for research purposes (free or fee-for-service, depending on need).

Application Procedure

1. Letter of Intent Deadline: 10/14/22, 11:59 pm

Letters of Intent (LOI) (2 pages max) require the following:

- A brief abstract, including specific aims.
- A clear statement of how the project will overcome translational barriers that impede advancement of research translation, and a statement of what makes the project generalizable to other populations or disease mechanisms. Study methods and feasibility of projects should also be included.
- A list of study team members for the proposed project. All team members should have agreed.

The LOI should be submitted through the [ePilot electronic submission system](#) by the deadline noted above.

Review Criteria and Process for Letters of Intent

1. An Administrative Review will be completed to verify all required components were submitted and formatting guidelines followed (e.g. does not exceed page limit).
2. Letters of Intent that pass the Administrative Review are reviewed by the WF Intramural Research Support Committee (IRSC); a Dean-appointed committee of selected expert faculty. Reviewers at this stage will be looking for whether proposed projects can help catalyze translation of discoveries to treatments or the delivery of care and to ensure the project is responsive to the RFA.

3. An invitation to apply for a full application, or notification if you are not selected, will be communicated via e-mail by 11/15/22.

2. Full Application Deadline: 12/14/22, 11:59 pm

Investigators invited to apply will receive an e-mail by 11/15/22 with a link to submit a full by **12/14/22**. **Applications received after 12/14/22 will not be reviewed.** Application instructions are included in the ePilot system and summarized below.

Applications that do not comply with these guidelines will not be considered for review.

Format Specifications

- Arial font and no smaller than 11 point
- Margins at least 0.5 inches (sides, top and bottom)
- Single-spaced lines
- Consecutively numbered pages

Submission/Applicant Information

- Project Title
- Submitting Principal Investigator, Co-Investigator(s), and other Key Personnel information

Abstract (300 words max)

Research Strategy (6 pages max, all items below are required components)

- Specific Aims
- Research Plan:
 - Significance
 - Innovation
 - Approach
 - Study Team
- Study milestones and anticipated outcomes (e.g. publication, presentation, grant submission, patent) with timeline (see [Appendix VI](#) for examples)

References (no page limit)

Information Regarding Human Subjects

Address the following if the project **involves human subjects**.

- IRB Approval Status (please note: IRB approval is not required for full application submission)
- Clinical Trial Classification Questions
 - If your project requires an IND/IDE submission or exemption, please consult with Issis Kelly Pumarol at ikellypu@wakehealth.edu for support and to discussion timelines. The timelines can impact your full project timeline and should be considered in the project plans.
- Protection of Human Subjects
 - Needs to clearly describe risk, protections, benefits, and importance of the knowledge to be gained by the revised or new activities as discussed in Part II of NIH competing application instructions
- [Inclusion of Individuals Across the Lifespan](#)
- Inclusion Plans for Women, Minorities, and Children, if applicable
- Recruitment and Retention Plan
- Targeted Enrollment Table (using [NIH Targeted Enrollment Table](#))
- Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable

- If you are unsure how much safety monitoring your study will need, please contact the CTSI DSMB Administrator, Issis Kelly Pumarol, at ikellypu@wakehealth.edu.

Information Regarding Live Vertebrates

Address the following if the project **involves live vertebrates**.

- IACUC Approval Status (please note: IACUC approval is not required for full application submission)
- IACUC approval will be required (as 'just in time' information) for implementation of projects with live vertebrate animals

Budget and Justification (budget template plus 1 page justification)

- Complete the [budget template form](#) and a brief justification for the funds requested. Please explain how other resources may be leveraged to support the project. If the proposed research will be done on more than one campus/institution, please include details in the justification.
- If salaried effort is not included in the budget for key study personnel, please explain.
- Sub-awards to other institutions are permissible, provided that most of the pilot project's activities and dollars spent occur within WF or one of its affiliates.

NIH-style biographical sketch for all Key Personnel

Review Criteria and Process for Full Proposals

1. An Administrative Review will be completed to verify all required components were submitted and formatting guidelines followed. **Applications that do not comply with guidelines will be automatically disqualified and will not be considered for review.**
2. Proposals that pass the Administrative Review are peer-reviewed by the WF Intramural Research Support Committee (IRSC) using NIH review criteria and scoring. Budgets will be reviewed by both CTSI Administrators and IRSC for appropriateness. There will be separate review discussions for clinical science and basic science proposals.
3. Final award approval will be at the recommendation of CTSI Leadership.

Reviewers will score applications from 1 to 9 based on:

1. Significance of the problem to be addressed
2. Innovation of the proposed solutions
3. Strength and breadth (interdisciplinary nature) of the investigative team
4. Methodological rigor and feasibility, with clear milestones
5. Generalizability: Likelihood the innovation will be broadly applicable and impact translational research or delivery of care
6. A reporting plan, whether the study yields positive or negative results
7. The likelihood that the investment will lead to external funding, publication, or a licensable innovation; early-career faculty involvement, race/gender inclusiveness of the research team; and inclusion of women, minorities, older adults, and children as potential study participants.

Budget Guidelines

The project is one year beginning 07/01/23 and ending 06/30/24. Up to \$40,000 in direct costs may be requested.

Grant funds may be budgeted for:

- Salary support for the PI or faculty collaborators (using NIH salary cap)
- Research support personnel (including undergraduate and graduate students)
- Travel, if necessary to perform the research
- Small equipment, research supplies, and core lab costs
- Other purposes deemed necessary for the successful execution of the proposed project

Grant funds may not be budgeted for:

- Office supplies or communication costs, including printing
- Meals or travel, including to conferences, except as required to collect data

- Professional education or training
- Computers or audiovisual equipment, unless fully justified as a need for the research
- Capital equipment
- Manuscript preparation and submission
- Indirect costs

Awarded funds must be used to conduct the work proposed. All direct charges to this award must adhere to federal regulations and requirements regarding the use of CTSA funds. The CTSI reserves the right to revoke funding if it is determined that funds were not spent in accordance with the approved protocol. The general criteria for determining allowable direct costs on federally sponsored projects are set forth in 2 CFR Part 200: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (The Uniform Guidance).

Program Expectations

Prior to funding, awardees will be assigned to a Research Navigator to: 1) assist with study initiation; 2) convene an initial meeting with the project PI, CTSI administrative personnel, and a senior CTSI leader to discuss the project and how CTSI resources can be leveraged for the pilot grant; and 3) monitor progress throughout the life of the study. If any significant issues arise, the study team will be required to work with the CTSI to determine solutions so that the study can be successfully completed (or in rare cases, terminated).

Specific Deliverables

- Participation in the study initiation meeting
- A formal progress report at 6 months
- Upon completion of the project:
 - Close-out report, with plans for implementing and disseminating innovations
- Presentation of findings at requested events (i.e. CTSI Seminar Series, Service Line Meeting, CTSI's annual External Advisory Committee meeting)
- Manuscript submitted within one year of the end of the pilot award
- Disclosure of 1) how results will be implemented and/or disseminated; 2) applications for extramural funding beyond the pilot grant; 3) what subsequent notification of funds occurred; and 4) related publications or significant collaborations resulted from the project, for a minimum of 4 years after completion of the award.

Other Guidelines

1. Prior to receiving funds, research involving human subjects must have appropriate approval from the IRB. Either an IRB approval letter or an IRB response to a "Determination Whether Research or Similar Activities Require IRB Approval" must be submitted to the CTSI prior to funds being released. Human subjects must be reviewed in accordance with the institution's general assurances and HIPAA. All key personnel must have certification of training in the protection of human subjects prior to the start of the grant period.
2. Research involving human subjects must also have approval from the National Center for Advancing Translational Sciences (NCATS). NCATS has defined human subjects research (HSR) categories and determined the approval procedures per category. NCATS submission will be facilitated by the CTSI. Note: The study cannot be submitted to NCATS until **after** IRB approval has been given.
 - a. **Category 1:** Greater Than Minimal Risk studies and all [NIH-defined Clinical Trials](#)
 - i. Category 1 studies/trials require approval from NCATS to begin.
 - b. **Category 2:** Minimal Risk and Exempt Studies
 - i. HSR study is exempt and/or considered minimal risk by the IRB
 - ii. Category 2 studies must be submitted to NCATS, but do not require formal approval.
3. Prior to receiving funds, research involving live vertebrates must have appropriate approvals from IACUC. Either an IACUC approval letter or documentation on why activity does not require IACUC approval must be submitted to the CTSI prior to funds being released.
4. CTSI staff will work closely with funded teams throughout the grant period to monitor progress and, when necessary, provide assistance. A six-month interim progress report and a final progress report will be required. We expect PIs to report over the lifetime of the work the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations, and patents.

5. All publications that are the direct result of this funding must reference: “Research reported in this publication was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR001420. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.” Publications must also be registered in PubMed Central.
6. Any awardee who leaves his or her position should contact the CTSI to discuss plans for the project.

Grant Administration

The Principal Investigator is responsible for the administration of grant funds.

Contacts

Questions about your research project or the ePilot electronic submission system should be directed to Brittney Patterson at britjack@wakehealth.edu.

Appendix I: Academic Learning Health System

Quality, safety, and outcomes could be markedly improved if demonstrated best practices were universally adopted. However, the traditional health care system does not promote a culture of institutional learning to improve practices, apply research principles, evaluate change, or share best practices between systems to rapidly and widely disseminate innovations.¹ WF is transforming from a traditional structure to a new structure as an academic Learning Health System. In such a system, responsibility for improvement is shared among all stakeholders, who are organized both to deliver care and to continuously improve it. **A Learning Healthcare System integrates the clinical and research enterprises, and emphasizes real time learning, continuous improvement and translating “what we know” into “what we do”.**² This vision aligns with the national CTSA program’s intent to promote and facilitate the evolution of CTSA hubs to the learning healthcare system model. Wake Forest CTSI defines an *academic* Learning Health System as “science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience.”

The academic Learning Health System Pilot Award is designed to incentivize and support a broad range of research (exploratory studies, QI projects, evaluations of interventions, evaluations of barriers to implementing interventions) that either answer questions about how to create an academic Learning Health System, or where and how research is an intentional element in the transformation to an academic Learning Health System. Thus the purpose of this RFA is to stimulate *innovative research ideas that can transform the way we deliver care.*

Definitions:

A **Learning Healthcare System** is defined, by the Institute of Medicine, as a system in which, “science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience.”³

Translational science, as defined by the NIH, “represents each stage of research along the path from the biological basis of health and disease to interventions that improve the health of individuals and the public. **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 Science** is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.”⁴

Projects that address the academic Learning Health System topic and are both generalizable and translational are strongly encouraged. These include, but are not limited to projects that:

- **Move QI / system change projects into publishable and generalizable research.** Examples: Test whether process changes that worked at WF also work at other hospitals; implement a tested quality improvement method at WF; increase the reliability of quality improvement initiatives by incorporating prospective non-randomized controlled trial designs or quasi-experiments (enhanced observational study designs), using staggered implementation, risk adjustment, or case matching approaches.
- **Import practices from other healthcare systems.** The challenges we face as a healthcare system are certainly not unique. We should learn from others who have managed the same challenges. Example: Import features of other healthcare systems -national or international- and adapt them for use in our system.
- **Test ways to engage clinicians in research.** Bringing together clinicians (who can identify healthcare delivery problems) and researchers (who can develop and test research questions) can lead to an evidence-based pipeline that moves clinicians’ ideas into research and then back into clinical practice. Examples: Embed a researcher into a service line to find healthcare delivery problems we need to address with research. Invite clinicians to bring the top two clinical issues they have observed to a meeting with researchers (“Which process issues you have observed? What do you notice every time you deliver care to a certain group of people? Which questions would you test if only you could pull the data from the EMR?”). Test strategies to bring clinicians into clinical trials or other ongoing studies. The success of the clinician-researcher interactions might be measured via process measures such as the

number of ideas generated, or whether a clinical issue is turned into a research question that is explored further (e.g., results in a ticket to WakeOne for a data pull).

- **Engage patients and other healthcare stakeholders to influence research and improve care.** Example: Engaging non-traditional research partners and incorporating perspectives beyond those of the research team – from topic selection to outcome selection and study design to conduct and dissemination of the results – can improve the utility of research for patients and providers. For example, one approach could involve capturing ideas from patients (or parents of patients) treated within our healthcare system, asking them about their concerns, and then rank ordering them (using the Delphi method). Items could be ranked as most pressing or most testable (e.g., medication list is not current on the patient printout; test results are shared with the patient through myWakeHealth before the clinician interprets them).
- **Test ways to change culture / form identity so that all faculty and staff understand that they are part of a Learning Healthcare System.** Example: Strategies could focus on education about research or evidence-based practice, institutional campaigns, or group discussions. For example, one approach might be to ask staff at department meetings to list how they are contributing to a LHS and to conduct a pre/post-test of clinicians and staff identifying as researchers after the intervention. Test strategies to develop and maintain a continuous learning culture, or strategies to align healthcare delivery incentives to support the Learning Healthcare System goals.

Appendix II: Health Disparities

Although scientific and technological discoveries have improved the health of the US population overall, some population subgroups continue to experience a disproportionate burden of disease. A **Health Disparities** project will focus on one or more health disparity populations, which include Blacks/African Americans, Hispanics/Latinos, American Indians/Alaska Natives, socioeconomically disadvantaged populations, and rural populations. This focus can be on health disparity populations as a whole, a single health disparity population, or a specific subgroup within a health disparity population.

Projects that merely focus on diseases or conditions that happen to be more prevalent or associated with greater morbidity/mortality in one or more health disparity populations, without the proposed work itself being directly focused on improving health disparities (i.e., specific risk/protective factors, disease progression, treatment response, or health outcomes for a particular health condition in one or more health disparity populations) are not a priority.

Successful proposals will focus on racial/ethnic minority populations, socioeconomically disadvantaged populations, and/or rural populations and explain how the proposed project advances Health Disparities research or our delivery of care to underserved populations.

Appendix III: Biomedical Informatics

The primary focus of a **Biomedical Informatics** project is to address gaps in knowledge or other barriers to translational research problems by leveraging one or more Informatics tools and methods.

A project focused on biomedical informatics is intended to evaluate strategies in one of the following areas:

1. Creation, evaluation, and implementation of Clinical Decision Support Systems;
2. Improving and evaluating electronic information capture and data flow of both clinical and patient derived data;
3. Development of improved analytical methods for clinically derived data;
4. Creation of informatics tools to improve population health management;
5. Creation, evaluation, or implementation of Biomedical Informatics tools and algorithms.

The project must be translational in nature and should help to close the gaps in establishing a true Learning Healthcare System.

Successful proposals will create, evaluate, or implement Biomedical Informatics tools and algorithms while providing a rationale for local relevance and potential for generalizability, explaining how the proposed project advances research in Biomedical Informatics, and identifying translational roadblocks that the proposed project will address and the anticipated benefits of overcoming them with the informatics.

Appendix IV: Implementation Science

The primary focus of an **Implementation Science** award is support the development of methods to promote the dissemination, adoption, integration, and/or effectiveness of promising practices, strategies, and/or technologies in clinical and/or community settings. Implementation scientists are committed to closing the gap between “what we know” as scientists and “what we do” as practitioners. A pilot focusing on implementation science is intended to elicit proposals that evaluate different strategies for closing the research-to-practice chasm through the development and testing of tailored implementation frameworks, identification of organizational and community levers to facilitate translation, determination of the feasibility of new implementation models, identification of strategies for scale-up, and/or development of strategies to disseminate knowledge or practices to a broad audience.

Successful proposals should test a practice, strategy, or technology that can be used to foster the translation of “what we know” to “what we do”.

Appendix V: NCATS Approval

Projects that meet the definition of human subjects research will require prior approval from the National Center for Advancing Translational Sciences (NCATS), the funding source of the CTSA grant. This means that no funds will be released to the award recipient until NCATS has provided approval.

The following items are needed for the NCATS submission by 05/10/23 (if an investigator is not ready to submit to NCATS by 05/10/23, their project timeline will not be altered to accommodate):

- Project Information (i.e. submitting investigator, project title)
- IRB Approval
 - We do not require an initiated IRB application/approval by the Full Application Deadline; however, in order to submit for NCATS approval, certification of IRB approval is required. Therefore, we encourage draft protocols/consent documents be created as far in advance as possible. Notifications of funding will be sent by 3/08/23.
- Project Abstract
- IRB Approved Protocol
- IRB Approved Consent/Assent/waiver
- Protection of Human Subjects
- Inclusion of Individuals Across the Lifespan
- Inclusion of women, minorities, and children
- Recruitment and Retention Plan
- Targeted Enrollment Table
- Biosketches (PI and Key Personnel)
- Documentation of CITI certification
- Data and Safety Monitoring Plan
- IND/IDE Documentation, if applicable
- Budget and Budget Justification

Please note: additional documentation will be required if project is classified as a Clinical Trial.

Appendix VI: Study Milestone Examples

Below are examples of study milestones, outcomes, and timelines. However, these formats are not required.

Example 1:

- **Milestone 1 (0-1.5 months):** Milestone 1 Details **Outcome:** Outcome 1 Details
- **Milestone 2 (1.5-4 months):** Milestone 2 Details **Outcome:** Outcome 2 Details
- **Milestone 3 (4-6 months):** Milestone 3 Details **Outcome:** Outcome 3 Details
- **Milestone 4 (6-12 months):** Milestone 4 Details **Outcome:** Outcome 4 Details
- **Milestone 5 (8-12 months):** Milestone 5 Details **Outcome:** Outcome 5 Details

Example 2:

Timeline and Milestones												
Month	1	2	3	4	5	6	7	8	9	10	11	12
Activity/Aim/Milestone 1	X	X	X	X								
Activity/Aim/Milestone 2	X	X										
Activity/Aim/Milestone 3		X	X	X								
Activity/Aim/Milestone 4					X	X	X	X	X	X		
Activity/Aim/Milestone 5					X							
Activity/Aim/Milestone 6						X	X					
Activity/Aim/Milestone 7								X		X		
Activity/Aim/Milestone 8											X	X

Example 3:

Aim	Milestone	Month 1-3	Month 4-6	Month 7-9	Month 10-12
1	Milestone 1	X	X		
	Milestone 2		X		

Aim 1 Anticipated Outcomes: Detail

Aim	Milestone	Month 1-3	Month 4-6	Month 7-9	Month 10-12
2	Milestone 1		X	X	
	Milestone 2		X		
	Milestone 3			X	

Aim 2 Anticipated Outcomes: Detail

Aim	Milestone	Month 1-3	Month 4-6	Month 7-9	Month 10-12
3	Milestone 1			X	
	Milestone 2			X	X

Aim 3 Anticipated Outcomes: Detail

References

1. IOM (Institute of Medicine). Best care at lower cost: The path to continuously learning health care in America. Washington, DC: The National Academies Press; 2012.
2. IOM (Institute of Medicine). The CTSA program at NIH: Opportunities for advancing clinical and translational research. Washington, DC: The National Academies Press; 2013. p.36
3. IOM (Institute of Medicine). The Learning Healthcare System: Workshop Summary. Olsen L, Aisner D, McGinnis JM, eds. Washington, DC: National Academies Press; 2007.
4. NIH (National Institutes of Health) / NCATS (National Center for Advancing Transactional Sciences. Translational Science Spectrum. NCATS 2015: <https://ncats.nih.gov/translation/spectrum>