

**ARIZONA UNIVERSITY SYSTEM
TECHNOLOGY AND RESEARCH INITIATIVE FUND (TRIF)**

**ARIZONA BIOMEDICAL RESEARCH COMMISSION
(ABRC)**

**PROPOSAL TO PROVIDE TECHNICAL
ASSISTANCE IN SUPPORT OF DEVELOPMENT OF ARIZONA'S
CLINICAL AND TRANSLATIONAL SCIENCE AWARD (CTSA)
PROPOSAL TO THE NATIONAL INSTITUTES OF HEALTH (NIH)**

BUSINESS PLAN

March 2007

TABLE OF CONTENTS

	Page
EXECUTIVE SUMMARY	1
1. CORE VISION/PROJECT DESCRIPTION	
1.1. Need for Broader Technical Assistance in Support of the Full CTSA Proposal Development	3
2. OPERATIONAL STRATEGIES	
2.1. Development and Production Not Applicable	3
2.2. Marketing and Promotion Not Applicable	3
2.3. Project Management	3
2.3.1. Steering Committee	3
2.3.2. Executive Committee	3
2.4. Sustainability	4
2.4.1. Anticipated funding sources for ongoing support	4
2.4.2. Timeline for transitioning away from TRIF support	4
3. GOALS/METRICS/OUTCOMES	
3.1. Tasks	4
3.1.1. Orientation	4
3.1.2. Assist in Facilitation of Proposal Development	4
3.1.3. Addressing Specific CTSA Program Functions	5
3.1.4. Development of a Tracking and Evaluation Plan	5
3.1.5. Governance Approaches	6
3.1.6. Packaging the Technical Proposal	6
3.2. Timeline for Achievement of Goals	6
3.3. Early Proof of Performance	7
4. PRO FORMA FINANCIALS	
4.1. Funding Request: Resources and Planned Expenditures	8

Executive Summary

The Clinical and Translational Science Award (CTSA) represents the next generation of funding support by the National Institutes of Health (NIH) to support translational and clinical research at academic health centers. It is a central element of the NIH Roadmap's goal to re-engineer the clinical research environment in an effort to address the national shortcomings in converting the enormous growth of biomedical research discoveries into cures and treatments for diseases, which was also noted in the FDA's *Critical Path* report.

The focus of the CTSA is on creating an "institutional home" for clinical and translational research science within academic health centers, placing it on an even basis with other major departments within an academic health center. CTSA's will be tailored to meet the context of each institution and its partners, with a broad range of activities permitted, including development of novel clinical and translational methodologies, pilot and collaborative studies, biomedical informatics, regulatory knowledge and support, participant and clinical interactions resources, community engagement, translational technologies and resources, and a strong emphasis on broader education, training, and career development activities. All CTSA's must involve a broad range of diseases.

Looking to the future, the significance of the CTSA goes well beyond the fact that it combines many existing NIH grants in support of clinical and translational research, such as the General Clinical Research Centers and support for physician researchers. CTSA's across the nation will form a national network of leading-edge research institutes garnering specialized resources and having opportunities to pursue development of specialized research activities with NIH support. Those institutions and states without a CTSA will be at a significant disadvantage in pursuing clinical and translational research.

Arizona's CTSA Planning Grant and Ongoing Efforts in Advancing a Translational Research Pathway

A broad consortium of Arizona institutions, led by an executive committee comprised of the Translational Genomics Research Institute (TGen), The University of Arizona, and Arizona State University, have developed an initial concept for clinical and translational research that would move the entire state toward a system-based incorporation of research discoveries in support of clinical development and community implementation of molecularly informed therapeutic decisions. The planning grant sets forth a bold and focused vision of how to advance a comprehensive translational research approach to personalized medicine. The planning grant submitted by the Arizona consortium was one of the top rated in the nation and was the ***only planning grant funded in the nation to advance a statewide approach***. While offering a statewide approach can allow Arizona to become a national model, it does pose special challenges in advancing collaboration and shared commitment and engagement across state partners.

The planning grant for the CTSA is highly consistent with the *Arizona Translational Research Pathway* advanced in response to identified needs for better harmonization, streamlining, and coordination to promote translational and clinical research activities in the state. This effort, sponsored by the Arizona Biomedical Research Commission (ABRC) and the Flinn Foundation, and guided by the input of leaders from Arizona's universities, nonprofit research institutions,

hospitals and medical centers, and broader stakeholders, advanced a vision that: “Arizona can become the first state to address translational research on a formalized statewide basis, and in doing so help to “brand” Arizona as a national leader in the biosciences.”

This proposal asks for a one-time award of \$250,000 for ABRC to engage Battelle Technology Partnership Practice to assist in the development of the Arizona statewide application for a National Institutes of Health Clinical and Translational Science Award. The Battelle team is in a unique position to support the efforts of the Arizona Board of Regents (ABOR), the Arizona Biomedical Research Commission (ABRC), and the Flinn Foundation in seeing this Arizona statewide CTSA proposal come together. Battelle has the experience of putting in place the analysis and facilitation for the overall statewide Arizona Biosciences Roadmap, including conducting statewide analysis of Arizona’s core competencies (which has just been updated, with the final report pending), facilitating statewide committees and preparing detailed Scientific Platform reports in six leading areas of biosciences research, and preparing the statewide Arizona Translational Research Pathway report and supporting its ongoing implementation through the Arizona Translational Resource Network (AzTranNet), a set of subprojects that advance translational research in Arizona and the Arizona Bioscience Roadmap.

1. Core Vision/Project Description

1.1 Need for Broader Technical Assistance in Support of the Full CTSA Proposal Development

From discussions with the project leadership of the Arizona CTSA planning process, the statewide approach that Arizona is advancing is inherently more difficult to prepare than a typical one-institution CTSA submission. After approximately a three-month period of experience, there is now an identified set of circumstances and needs emerging that call for greater involvement of ABOR, ABRC, and the Flinn Foundation to support the ongoing development of Arizona's full CTSA proposal to NIH.

As part of Battelle's ongoing work for ABRC in support of the Arizona Translational Resource Network (AzTranNet), it was recognized that many of the ongoing efforts to implement the Arizona Translational Research Pathway can be highly supportive to Arizona's full CTSA proposal to NIH. Many of the goals stated in the CTSA proposal are being undertaken through the Pathway pilot efforts, including efforts to address intellectual property policies, develop statewide models and standards for best practices, outreach to community physicians, IRB collaborations, emphasis on tissue resources, and collaborations with special populations. In recognition of these synergies, a minimal level of technical support was identified in the recent ABRC grant to Battelle to provide input into the CTSA planning process.

2. Operational Strategies

2.1 Development and Production

Not Applicable

2.2 Marketing and Promotion

Not Applicable

2.3 Project Management

2.3.1 A Steering Committee composed of the funding entities will meet monthly with the CTSA Executive Committee to review progress and provide project guidance. In addition, the Arizona Hospital and Healthcare Association will be invited to participate.

2.3.2 CTSA Executive Committee

The Executive Committee is composed of:

Jeff Trent, Ph.D.

President & Scientific Director

Translational Genomics Research Institute (TGen)

Keith Joiner, M.D., MPH
Vice Provost, Medical Affairs
Dean, College of Medicine

Vicki Chandler, Ph.D.
Director, BIO5 Institute, Regents' Professor, Plant Sciences and Molecular
& Cellular Biology, Carl E. and Patricia Weiler Endowed Chair for
Excellence in Agriculture and Life Sciences

Michael Tracy, D. Phil.
Deputy Director
Biodesign Institute at Arizona State University

The Executive Committee will meet monthly with the Steering Committee to review progress and provide project guidance.

2.4 Sustainability

- 2.4.1 Sources of project funding are: Arizona Board of Regents, Arizona Biomedical Research Commission, and Flinn Foundation.
- 2.4.2 This project requests one-time funding.

3. Goals/Metrics/Outcomes

3.1 Tasks

ABRC will extend its current activities with the Battelle project team to working on the Arizona Translational Research Pathway initiative to provide technical assistance leading to the development of Arizona's full CTSA proposal to NIH.

3.1.1 Orientation

The Battelle project team will meet with the CTSA Planning Grant Executive Committee to discuss and finalize several items, including the work plan, and content of the project, schedules, contact points, and other issues. One key topic is how other aspects of the proposal will be done in concert with Battelle's technical assistance, particularly the budget proposal and staffing plan, which are beyond the scope of Battelle's work.

3.1.2 Assist in Facilitation of Proposal Development

Under the direction of the Executive Committee and in collaboration with the CTSA Coordinating Committee, Battelle will assist in developing focused guidance to the working groups on the vision, goals, and objectives of the planning grant and the requirements of the Request for Applications (RFA) from

NIH. The Coordinating Committee will receive and integrate draft documents from the CTSA workgroups.

This will involve preparing instructions and coordinating with group leaders, monitoring the quality of drafts coming forward, and interacting with working group leaders to address issues relating to meeting both the requirements of NIH's RFA and the approach of the statewide Arizona CTSA set out in the planning grant.

Coordinating Committee members:

Jodi Black, Ph.D.
Vice President, Research Administration
TGen

Leslie Boyer, M.D.
Medical Director, Arizona Poison and Drug Information Center
The University of Arizona

Kathy Matt, Ph.D.
Assistant Vice President
Office of Clinical Partnerships
Arizona State University

3.1.3 Addressing Specific CTSA Program Functions

The NIH Request for Proposals sets out nine specific program functions that each CTSA applicant needs to consider. Four of these program functions are closely aligned with the ongoing activities of the AzTransNet, including:

- Regulatory Knowledge and Support
- Design, Biostatistics, and Clinical Research Ethics
- Participant and Clinical Interaction Resources
- Community Engagement and Research

Battelle proposes to assist in directly preparing these sections of the proposal in coordination with a working group drawn from researchers and administrators across Arizona.

3.1.4 Development of a Tracking and Evaluation Plan

As set out in the NIH RFA, tracking and evaluation is an integral component of the required proposal and one not being advanced by any current work group in the CTSA proposal development effort. Battelle will assist the Executive Committee in selecting a consultant, drawn from the ranks of Battelle's Health Sector or from outside Battelle, to assist in the development of the evaluation plan for the Arizona CTSA. Battelle will oversee the efforts of this evaluation plan

development consultant under the direction of the Executive Committee to ease its access to key researchers and administrators and to monitor its progress.

3.1.5 Governance Approaches

Battelle will identify and provide concepts for governance structures for the proposed CTSA that balance how the functions of the statewide entity are to be performed along with the spirit of being a statewide activity. For each of the concepts, Battelle will analyze its implications for addressing collaboration, management and financial administration, staffing, core functions of the CTSA, and intellectual property management.

Battelle has found that it is often helpful to provide this conceptual framework and then to have the Executive Committee select a specific option for more detailed operational planning. In the more detailed operational planning, Battelle will work to develop explicit parameters, agreements, and plans to carry out the option selected and how it translates into governance structures, staffing, sharing of indirects, management of intellectual property, etc.

3.1.6 Packaging the Technical Proposal

The technical approach for the CTSA proposal is a complex and comprehensive approach for managing a broad set of activities to further clinical and translational research. The packaging of this proposal into a coherent document that sets out a clear approach and explains how the pieces fit together is a critical success factor. Battelle will assist in this effort, working under the direction of the Executive Committee, to bring the various sections together into an initial draft of the complete CTSA technical proposal.

Battelle will provide guidance and input into the development of the staffing plans and the budget and financial aspects of the CTSA proposal that will be developed by the CTSA Executive Committee.

3.2 Timeline for Achievement of Goals

Schedule

Assuming timely authorization, we are proposing that the scope of services will be over a seven-month time period from mid-March 2007 to September 30, 2007. Due to the nature of this work, some tasks can be carried out concurrently, while other tasks cannot be undertaken until earlier tasks have been completed. The table below lays out the scope of work and time frame for this project.

Work Plan							
Task	Month						
	March	April	May	June	July	Aug	Sept
1. Orientation							
2. Facilitation							
3. Selected Function Write-ups							
4. Evaluation Plan							
5. Governance							
6. Packaging of Tech Proposal							

3.3 Early Proof of Performance

The ABRC has committed \$100,000 for this project, with \$50,000 from its ongoing \$493,000 contract with Battelle and an additional \$50,000 enhancement recently approved by ABRC. The Battelle contract primarily supports AzTransNet, a set of subprojects that advance translational research in Arizona and the Arizona Bioscience Roadmap.

The Flinn Foundation has committed \$25,000 for this project.

The planning grant submitted by the Arizona consortium to the National Institutes of Health was the top-rated application in the nation and was the only one funded in the nation to advance a statewide approach. Arizona received \$150,000 from NIH.

With continued support from ABRC, a broad set of initiatives under the banner of AzTransNet is going forward to provide Arizona with the capacity to facilitate and coordinate translational and clinical research activities in Arizona, particularly approaches for:

- Harmonizing clinical research policies.
- Developing shared infrastructure in common needs areas, such as training, access to Institutional Review Board (IRB) support, and outreach to physicians for clinical research.
- Establishment of a new culture of trust and cooperation by serving as an honest broker.
- These initiatives provide “proof of concept” in support of the CTSA application.

4. Pro Forma Financials

4.1 Funding Request: Resources and Planned Expenditures

- 4.1.1 Amount Requested: \$250,000
- 4.1.2 Other Funds: \$125,000
 - 4.1.2.1 ABRC \$100,000
 - 4.1.2.2 The Flinn Foundation \$25,000
- 4.1.3 Estimated Total Project Cost: \$375,000
- 4.1.4 Estimated Project Costs by Task as Outlined in Section 3
 - Task 1: Orientation Costs: \$7,000
 - Task 2: Facilitation Costs: \$49,000
 - Task 3: Selected Function Write-ups: \$95,000
 - Task 4: Evaluation Plans: \$95,000
 - Task 5: Governance Costs: \$49,000
 - Task 6: Packaging Costs: \$80,000