**National Institutes of Health**

# Clinical and Translational Science Awards Program

## National CTSA Process Evaluation Feasibility Study

**Final Report**

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# Glossary of Terms

| Term | Definition |
|---|---|
| *Clinical Research* | Studies and trials in human subjects meeting the National Institutes of Health (NIH) definition in the PHS 398 instructions. |
| *Cohorts of Clinical and Translational Science Awards (CTSA) Institutions* | CTSA institutions funded during the first and subsequent funding cycles of the CTSA program. |
| *Consortium* | An agreement, combination, or fellowship formed to undertake an enterprise whose achievement is beyond the resources of any one member. |
| *Process Evaluation* | A type of program evaluation that focuses on whether a program has been implemented in the manner intended, how it has been implemented, and whether and to what extent it is reaching the target population(s) that it is meant to serve. This evaluation is also called implementation analysis. |
| *Scholars* | Individuals with a research or health professional doctoral-level degree or equivalent who are receiving support while beginning and establishing their independent research careers. |
| *Science* | The discovery of new knowledge about health and disease prevention, preemption, and treatment as well as the methodological research to develop or improve research tools. |
| *Trainees* | Individuals receiving support and education at the predoctoral level enrolled in graduate education. |
| *Transdisciplinarity* | Integrating or blending knowledge and techniques from different disciplines and transcending disciplinary paradigms to a new level of understanding to address questions conceptualized beyond the purview of the individual disciplines. It is a specific form of interdisciplinarity in which the boundaries between and beyond disciplines are transcended and the knowledge and perspectives from different scientific disciplines, as well as nonscientific sources, are integrated. |
| *Translational Research* | Translational research includes two areas of translation. The first area is the process of applying the discoveries generated during research in the laboratory and, in preclinical studies, refers to the development of trials and studies in humans. The second area concerns research aimed at enhancing the adoption of best practices in the community. |

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# 1. INTRODUCTION AND OVERVIEW

## Clinical and Translational Science Awards Program

Of the three initiatives identified through the NIH Roadmap process, restructuring the clinical research enterprise in the United States is clearly the most ambitious. The Clinical and Translational Science Awards (CTSA) program is the primary programmatic vehicle for accomplishing this restructuring process. Through this program, the National Institutes of Health (NIH) is providing resources that will enable 60 academic health centers to create an academic home for clinical and translational science activities and to recruit, train, and support the career development of the next generation of clinical and translational scientists.

In October 2005 the first Request for Applications for the Institutional CTSA program was released. In October 2006 the first 12 CTSA institutions received awards totaling $108 million. A second round of 12 CTSA awards was announced in September 2007. The program will be fully implemented with 60 CTSA institutions by 2012.

## Purpose of the National CTSA Process Evaluation Feasibility Study

The National CTSA Process Evaluation Feasibility Study is the first of a four-phase approach to designing and conducting the national evaluation of the CTSA program. The first (and current) phase is to design a methodology, including the questions to be answered and the qualitative and quantitative indicators needed to answer the questions, for a process evaluation of the National CTSA Consortium. Following acceptance of the recommended design and methodology for the evaluation, the second phase will include an initial pilot-testing of the instruments and data collection procedures for the process evaluation study. The third phase will be the full-scale implementation of the National CTSA Consortium Process Evaluation Study and a design for an outcome study. The fourth phase will include the implementation of the National CTSA Outcome Evaluation Study.

The National CTSA Process Evaluation Feasibility Study had four objectives:

- Develop a clear understanding of the CTSA program and its components.
- Refine the existing study questions and conceptual framework in concert with the NIH CTSA Project Team (which consists of representatives from NIH Institutes and Centers, National Center for Research Resources staff members, and senior NIH leaders).
- Based on a review of the relevant literature, interviews with biomedical professional organizations, informational visits to two CTSA institutions, and the consideration of existing program documents and data sources, offer recommendations for the design and implementation of a National CTSA Consortium Process Evaluation Study.

- Prepare the supporting materials to facilitate the implementation of the study, including the NIH Evaluation Set-Aside Funding application.

This National CTSA Process Evaluation Feasibility Study Final Report describes the CTSA program (Section 2); the methods and findings from the feasibility study (Section 3); a discussion of the implications of these findings for the national process evaluation (Section 4); and recommendations for the national process evaluation design and implementation, including study questions, key variables, data sources, data collection approaches, and data analyses (Section 5).

# 2. CLINICAL AND TRANSLATIONAL SCIENCE AWARDS PROGRAM

The Clinical and Translational Science Awards (CTSA) program is led by the National Center for Research Resources (NCRR) through a Cooperative Agreement funding mechanism. Under the CTSA Cooperative Agreement, each CTSA institution participates in the activities of a National CTSA Consortium through an established governance structure. Federal representatives participate as voting members on the various committees, subcommittees, and workgroups.

## CTSA Program Goals

The goal of the CTSA program is to " … transform the local, regional, and national environment for clinical and translational science, thereby increasing the efficiency and speed of clinical and translational research."[1] This goal will be achieved in two ways. At the institutional level, each CTSA institution is creating an "academic home" for clinical and translational science that includes faculty, programs, and resources that integrate clinical and translational science across multiple departments, divisions, schools, clinical and research institutes, and hospitals and other health care organizations. Within this academic home, the CTSA institution will establish a new discipline of clinical and translational science through the development of new degree programs and career pathways. At the national level, CTSA institutions will work with NCRR and other National Institutes of Health (NIH) Institutes and Centers (ICs) to create a National CTSA Consortium. The National CTSA Consortium will provide a mechanism for the development of a collaborative community that will identify impediments and barriers to clinical and translational science activities across institutions and will propose, disseminate, and implement "best practices" and new policies, procedures, standards, and systems that will remove common roadblocks and accelerate the pace of research activities.

## CTSA Program Structure

The CTSA program is designed to operate at both an institutional and a national level. The program thus includes two structural components: the CTSA institutions and National CTSA Consortium.

### CTSA Institutions

The basic "building block" of the CTSA program is the CTSA institution. Each CTSA institution includes a lead academic health center and one or more additional partnering organizations. Each CTSA institution will do the following:

- Create an academic home (defined by the Request for Applications as a specific center, department, or institute within the academic health center) for clinical and translational science.

- Provide opportunities for original research on novel methods and approaches to clinical and translational science.
- Provide the translational technologies and knowledge base for the spectrum of clinical and translational science, including all types and sizes of studies and specialties.
- Integrate clinical and translational science by fostering collaboration between the departments and schools of an institution and between institutions and industry.
- Provide a point of contact for partnerships with industry, foundations, and community physicians as appropriate.
- Provide research education, training, and career development leading to an advanced degree (master's or doctorate) for the next generation of clinical and translational scientists (including physicians, nurses, dentists, pharmacists, and other allied health professionals); conduct self-evaluation activities; and participate in a national evaluation of the CTSA program.[2]

Twelve institutions received CTSA awards in October 2006; these first 12 CTSA institutions are referred to as Cohort 1. Twelve additional institutions received CTSA awards in September 2007 (referred to as Cohort 2). The specific institutions included in these first two cohorts are identified in **Exhibit 1.**

**Exhibit 1.**
**Institutions Receiving Clinical and Translational Science Awards, 2006 and 2007**

| COHORT 1—2006 | COHORT 2—2007 |
|---|---|
| Columbia University | Case Western Reserve University |
| Duke University | Emory University |
| Mayo Clinic | Johns Hopkins University |
| Oregon Health & Science University | University of Chicago |
| Rockefeller University | University of Iowa |
| University of California, Davis | University of Michigan, Ann Arbor |
| University of California, San Francisco | University of Texas Southwestern Medical Center |
| University of Pennsylvania | University of Washington |
| University of Pittsburgh | University of Wisconsin |
| University of Rochester | Vanderbilt University |
| University of Texas at Houston | Washington University |
| Yale University | Weill Cornell Medical College |

The CTSA institutions enter the program with differences in existing research infrastructure, educational and training programs, and partnering organizations and with different strengths. These initial differences also mean that each CTSA institution will be undertaking its own unique set of activities designed to accomplish the major goals for the institutional component of the CTSA program. However, each applicant was encouraged to develop a set of key functional cores or resources as a part of its overall program. The Request for Applications identified nine functional cores (see **Exhibit 2**) as suggested focal areas, although applicants were permitted to modify this list or develop others as deemed appropriate.

**Exhibit 2.**
**Suggested Key Functional Cores for CTSA Institutions**

| NINE KEY FUNCTIONS IDENTIFIED IN THE REQUEST FOR APPLICATIONS |
|---|
| Development of Novel Clinical and Translational Methodologies |
| Pilot and Collaborative Translational and Clinical Studies |
| Biomedical Informatics |
| Design, Biostatistics, and Clinical Research Ethics |
| Regulatory Knowledge and Support |
| Participant and Clinical Interactions Resources |
| Community Engagement |
| Translational Technologies and Resources |
| Research Education, Training, and Career Development |

*Source: Institutional Clinical and Translational Science Award Request for Applications: RFA-RM-06-002.*

## National CTSA Consortium

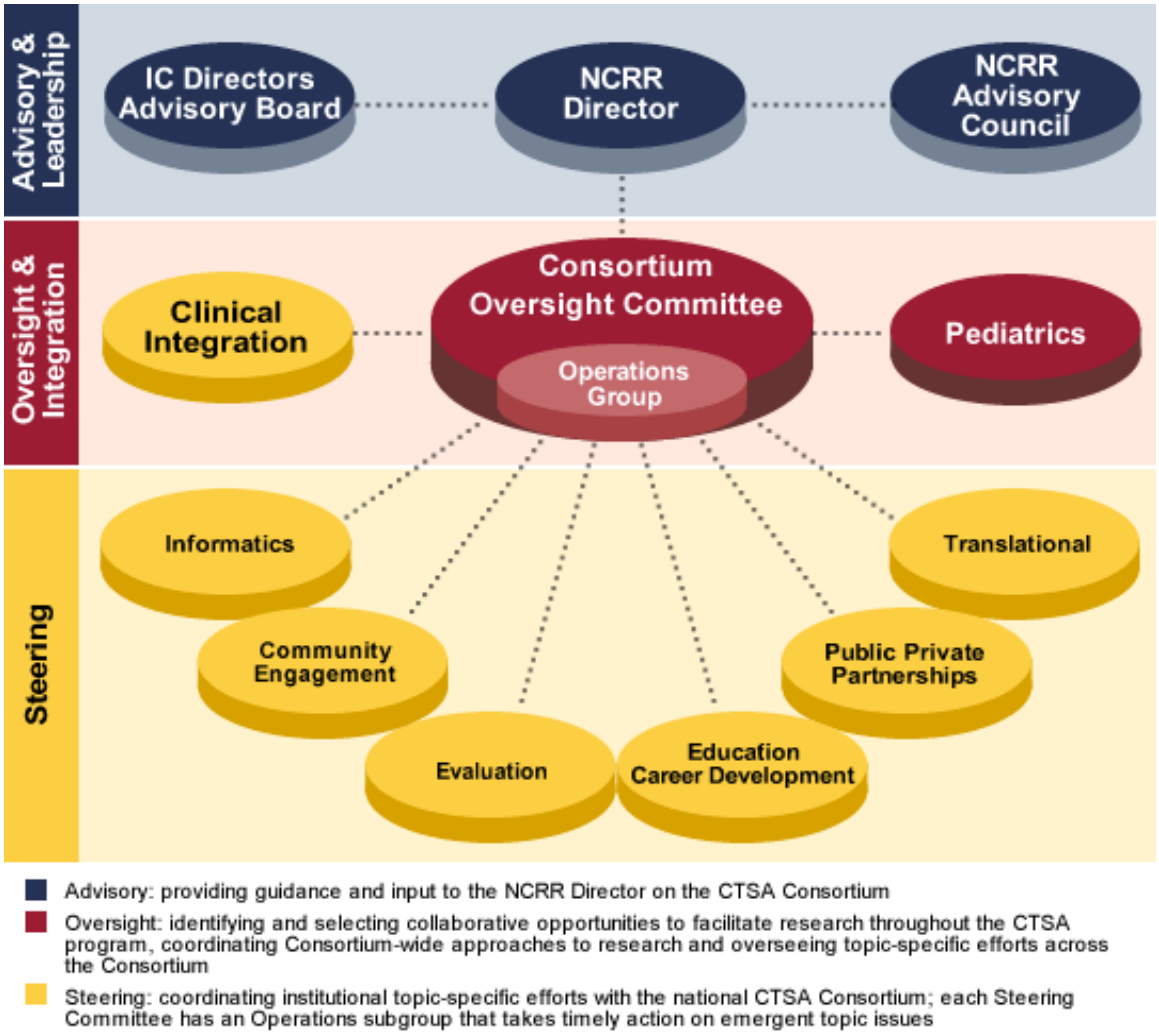
The National CTSA Consortium is composed of members from each CTSA institution and NIH. The National CTSA Consortium will do the following:

- Cooperatively identify and address the impediments and barriers to clinical and translational science.
- Adopt and implement agreed-on "best practices," policies, procedures, standards, and other measures to advance collaborative clinical and translational science and to reduce the burden on individual investigators at all institutions.
- Engage other Federal and non-Federal partners (e.g., biomedical professional, educational, and research organizations).
- Create a networked environment in which clinical studies can be expedited by their implementation across multiple institutions.

As these goals suggest, the activities and experiences of the CTSA institutions provide an important source of information for the National CTSA Consortium.

The National CTSA Consortium is organized around an evolving committee structure, depicted below in **Exhibit 3.** This committee structure has been designed to accommodate the addition of new topical areas (e.g., steering committees, workgroups) and new members as necessary. Details of the functions of the various committees, subcommittees, and workgroups are provided in the *CTSA Consortium Governance Manual* at www.ctsaweb.org.

**Exhibit 3.**
**Consortium Governance and Organization**




*Source: CTSA Governance Manual.*

Two additional elements of the National CTSA Consortium are relevant for the national process evaluation: the CTSA Web site and the emergence of collaborations among different CTSA institutions. The CTSA Web site offers several capabilities that will become increasingly important to the implementation and evaluation of the program. The Web site serves as a major communications channel and archive for the National CTSA Consortium. Its communications functions include announcements of upcoming CTSA committee and workgroup meetings; updates on relevant NCRR and other NIH news, activities, and special events; and a collaborative software (Wiki) feature that will facilitate collaboration among individuals at different CTSA institutions. The archival functions include lists of members of the CTSA committees and workgroups, articles and papers of interest to the members, and presentations and minutes from past meetings.

## Trans-NIH CTSA Program Conceptual Framework

The Trans-NIH CTSA Evaluation Subcommittee developed a preliminary conceptual framework for the CTSA program in 2006 (**Appendix A1**). Composed of interested evaluation experts from the various NIH ICs that are participating in the CTSA program, the Trans-NIH CTSA Evaluation Subcommittee serves as a resource and advisory group for the national evaluation effort. The conceptual framework connects various existing resources and NIH inputs with specific CTSA program activities and relates these to the attainment of short-term and long-term goals across six areas: (1) clinical and translational science research, (2) clinical and translational science training and mentoring, (3) clinical and translational science methods and technologies, (4) community relationships and human subject protection, (5) clinical and translational science partnerships, and (6) evaluation and quality improvement. The framework is important because it served as a starting point for the efforts to conceptualize the CTSA program and ways to structure the evaluation.

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[1] Zerhouni, E. (2003). The NIH Roadmap. *Science,* 302: 63-64, 72.
[2] National Center for Research Resources (207). *Institutional Clinical and Translational Science Award (U54) Request for Applications: RFA-RM-06-002.* Bethesda, Maryland: National Center for Research Resources.

# 3. METHODS AND FINDINGS FROM THE NATIONAL CTSA PROCESS EVALUATION FEASIBILITY STUDY

When conducting the National CTSA Process Evaluation Feasibility Study, six sources of information were used to develop a more complete understanding of the Clinical and Translational Science Awards (CTSA) program and to construct a design for the national process evaluation. These sources and informational objectives are summarized in Exhibit 4.

**Exhibit 4.**
**Sources of Information and Informational Objectives**

| Source | Objectives |
|---|---|
| 1. Review of literature on clinical and translational science, evaluations of research programs, and the application of specific evaluation methodologies | Identify evaluation designs, methods, and measures that have been used in other evaluations of research and development programs |
| 2. Review of recent NIH evaluation studies funded by the Evaluation Set-Aside program and interviews with NIH project directors of evaluation projects of similar magnitude and complexity | Identify evaluation designs, methods, and measures that have been used in other evaluations of the National Institutes of Health (NIH) research programs |
| 3. Interviews with representatives from biomedical professional organizations | Obtain the perceptions and perspectives of interested biomedical professional organizations about the CTSA program and its evaluation |
| 4. Two CTSA institutional informational visits | Obtain background information on CTSA institutional programs and identify important implementation factors |
| 5. Review of CTSA institutional self-evaluation plans | Explore how CTSA institutions plan to evaluate their local programs and whether there are common measures applied across the institutions |
| 6. Pilot data extraction from the CTSA Annual Progress Reports and the minutes of CTSA Steering Committee meetings | Examine the Annual Progress Reports and CTSA Committee minutes as sources of data for the national process evaluation |

Methods and findings for each of these data sources are discussed in more detail below.

## Review of Literature

The literature review focused on a broad range of topics relevant to evaluating the CTSA program, including evaluations of NIH Roadmap Initiatives, evaluations of clinical and translational science, evaluations of research programs, and specific evaluation methodologies.

## Methods

Initial literature search strategies were informed by a 177-item bibliography (dated July 2005) that was prepared for the Roadmap K12 Multidisciplinary Clinical Research Career Development Program and a related document that contained these same references in a format sorted by content area. The 31 content areas for the literature searches are listed in **Appendix A2**.

## Findings From the Literature Review

The literature pertaining to the evaluations of research and development programs is derived from multiple disciplines. There are several useful source documents that provide an entry point into this literature. *Evaluating R and D Impacts*[1] reviews the use of several evaluation approaches *circa* 1993; this book illustrates the variety of evaluation methods that have been used to study Federal, regional, and institutional research programs. More recent collections of papers include a publication produced by the Washington Research Evaluation Network (WREN)[2] and a report published by the National Institutes of Science and Technology.[3] Among the evaluation methodologies discussed in these sources are peer review, case studies, historical tracing, content analysis, surveys, bibliometric analysis, cost-benefit analysis and return–on-investment methods, benchmarking, input-output analyses, systems models, performance indicators, and network studies.

There are several publications that review the evaluation aspects of research and development programs. Of these, the most relevant in terms of the U.S. literature is a paper by David Roessner.[4] He notes that there has been an extensive history of the evaluation of research, technology, and development programs, much of it by economists. (Many of these economic studies are discussed in a second paper.[5]) For example, early studies during the 1960s and 1970s emphasized estimating the rates of economic returns from investments in research and the costs and benefits of basic versus applied research programs. Relatively few studies at that time explored the social (or noneconomic) benefits resulting from changes in technology. A second wave of evaluation studies, which appeared in the late 1970s and 1980s, was marked by the appearance of a broader range of evaluation approaches, notably bibliometric techniques. This period also saw increased interest in the noneconomic outcomes and benefits from research. The recent history of the evaluation of U.S. research programs has been heavily influenced by the passage of the Government Performance and Results Act (GPRA) in 1993. With the passage of GPRA (and later, the Office of Management and Budget's Program Assessment Rating Tool ), program evaluation across Federal agencies has increased as program managers strive to meet agency requirements.

Peer review has historically been the dominant type of noneconomic approach used in the evaluations of Federal research programs and has been the "gold standard" applied to the evaluations of specific Federal and institutional research programs.[6] This methodology may be more appropriate for assessing the outputs of research programs rather than outcomes.[7]

There has also been some consideration of the appropriate types of process, output, and outcome indicators for the evaluation of research and development programs.[8] Examples of typical process measures include employee retention, employee satisfaction, the indices of organizational culture, the quality of the supporting infrastructure, communications among research teams, and the degree to which scientists perceive that they are unhindered in their research but are subject to clear ethical regulation. Output indicators (defined as

tabulations, calculations, or other recording of activity or effort) typically provide short-run evidence that developments are occurring that can be expected to lead to ultimate goals. Examples of commonly used output indicators in the evaluations of research and development programs include the quantity of knowledge produced (often measured as the number of peer-reviewed publications, invitations to speak and present at conferences, awards, honors, and positions in professional societies); number of patents, devices, and software developed; number of students trained; number of users of scientific facilities; and level of satisfaction with the facilities. Outcome measures reflect the results produced by or from a program activity. Examples of outcome indicators include expert judgment about the quality of research and development, new discoveries and specific advances, new processes and products developed, citations of publications in journals, and patent applications.

One theme that runs through the literature is the lack of appropriate comparison groups for research and development programs. This often occurs because there are no natural analogs to these research and development programs.[9] As a result, one strategy often used is to compare the program against itself by examining the degree to which a specific program has stimulated new or additional research activities.

The evaluation of research and development programs faces several challenges. These include the need to develop better theory about using research programs to identify what types of outcomes are important to capture (with a particular emphasis on noneconomic benefits) and the need for more studies that provide detailed documentation of how the research activities produce social outcomes and benefits. An example of an approach that has been applied in both U.S.[10] and European[11] studies is the project-level survey. In this approach, a one-page questionnaire is sent to principal investigators or project directors who have completed a specific project. The questionnaire asks about specific outputs (e.g., papers and patents resulting from the project) and short-term outcomes (e.g., the project having led to additional grants, estimates of the potential impact of the project's findings). If the potential impact is viewed as great, the evaluation team sends a subsequent one-page questionnaire to the project director at 1, 3, and 5 years after the project's conclusion to monitor the specific commercial effects. Projects with documented high impact can be followed up more intensively through interviews with the investigator or through analyses of the economic impact.

## Review of NIH Evaluation Studies

The literature review was supplemented with a review of selected NIH evaluation studies funded by the NIH Evaluation Set-Aside Program and interviews with NIH project directors for evaluation projects similar in scope and complexity to the CTSA program.

### Methods

Two publications were key in identifying and characterizing NIH evaluation studies, *The Institute of Medicine (IOM) Report—NIH Extramural Center Programs: Criteria for Initiation and Evaluation* (IOM 2004)[12] and the *Report of the NIH Workgroup on the IOM Research Centers Report* (2005).[13] In addition, the Evaluation Branch (EB) of the Office of Portfolio Analysis and Strategic Initiatives posted a list of the 111 evaluation studies at NIH in March 2007 that had been funded by the Evaluation Set-Aside Program (http://opasi.nih.gov/desa/eb/intranet/setaside/fundedstudies.asp). Potentially informative reports were reviewed and, if appropriate, were printed. A senior member of the EB staff was interviewed to augment the list of evaluation studies to be pursued. NIH program staff members who

were directing the evaluations of the following three programs were also interviewed: (1) the process and outcome evaluations of the National Institute of Neurological Disorders and Stroke (NINDS)-funded Udall Centers of Excellence in Parkinson's Disease Research Program; (2) the third of three phases of the Evaluation of Research on the Prevention and Cure of Type 1 Diabetes, funded through the Balanced Budget Act of 1997 (a U.S. Department of Health and Human Services program for which the National Institute of Diabetes and Digestive and Kidney Diseases directed the evaluation); and (3) an evaluation of the Roadmap Interdisciplinary Research Training Initiative. This research training initiative consists of four programs: (1) an Institutional Training Grant (T32) program, (2) the new Training for a New Interdisciplinary Research Workforce (linked research education [R90] and research training [T90]) program, (3) a conference grant (R13) program for the development of short courses, and (4) an Academic Career Enhancement Award (K07) program for curriculum development. This evaluation was being funded through set-aside funds, and the Government Project Officer is from the National Institute on Drug Abuse. Interview questions focused on whether a literature review had been performed and, if so, the type, proposed evaluation design and methods, and lessons learned related to the methodologies and research strategies. At the suggestion of the National Center for Research Resources (NCRR), the study team also met with the Director of Planning and Analysis in the Office of Science at the U.S. Department of Energy (DOE), who has responsibility for research and development evaluation.

## Findings from Evaluations of NIH Research Programs and Initiatives

A summary of the specific NIH programs reviewed—their funding agencies, funding mechanisms, type of evaluation, purpose and goal of the evaluation, methodology and data sources used, and report examined—is provided in **Appendix A3**. This table shows that the evaluations of NIH Institute and Center programs range from simple program reviews to full-scale process and outcome evaluations. The most common evaluation approach was a program assessment that involved a group of internal and sometimes external reviewers who examined the program documents and data from the subject programs. The reports provided substantive information about the evaluation designs, including the methods, data sources, and indicators and a selection of comparison groups. In most studies, however, comparison groups were not used because an appropriate comparison for the program did not exist.

Interviews with NIH program staff members who directed or oversaw these evaluations highlighted the considerable variation in the degree to which program staff members were permitted to participate in the evaluation. For example, NINDS leadership felt strongly that such participation could be perceived as a conflict of interest. No NINDS leadership or staff member had access to the primary data collected by the evaluation contractor (with the exception of one working group member who is also an intramural researcher at NINDS). Likewise, they did not review the recommendations of the working group before the report was distributed to their advisory council.

The DOE interview yielded many valuable resources including those posted on the WREN Web site, which is a forum for the Federal research and development community (http://www.wren-network.net/resources.htm).

# Perceptions of Representatives from Biomedical Professional Organizations

Interviews with representatives of national biomedical professional organizations were used to assess the perceptions and expectations held by external organizations concerning the CTSA program and to obtain suggestions about the process and outcome measures considered relevant by these organizations.

## Methods

Twenty-three national biomedical professional organizations were identified on the basis of three criteria: (1) focus of the organization (e.g., science, health practice, community), (2) evidence of interest in the CTSA program as determined by previous communication with NIH or participation in NIH briefings, and (3) NCRR staff input. The co-chairs of the NIH CTSA Evaluation Subcommittee sent a preliminary e-mail to representatives of these organizations explaining the purpose of the interviews and inviting participation in a 30- to 45-minute telephone discussion. Following this introduction, members of the study team contacted the representatives to schedule and conduct the telephone interviews. The interviews followed a semistructured protocol that guided the discussion. The protocol served as a general guide for a conversation about the program and was not used as a structured interview. Representatives from 15 of the 23 organizations agreed to take part in the calls. The interview protocol is included in **Appendix A4**.

## Findings from Interviews With Biomedical Professional Organizations

The findings from the 15 interviews are summarized across two broad topic areas—(1) perceptions and expectations about the CTSA program and (2) important outcomes and impacts—and are discussed below.

### *Perceptions and Expectations Concerning the CTSA Program*

Representatives from the biomedical professional organizations interviewed welcomed NIH's interest in engaging external organizations in a dialog about the implementation of the CTSA program and the design of the national evaluation. Many organizations want to play a continuing role in the implementation structure of the program, either through their participation in an external advisory group, regular briefings and presentations on the program's status and accomplishments from NIH officials, and/or participation on existing CTSA Consortium committees and subcommittees. Respondents consider the www.ctsaweb.org Web site to be extremely informative, easy to use, concise, up to date, and an effective tool for informing the field about the activities and impact of the CTSA program and key scientific findings.

Overall, respondents believed that the specific aims of the CTSA are on target—"providing the infrastructure to develop the next cohort of clinical and translational scientists," "having health professionals work together and putting more evidence-based research into practice," "trying to remove the translational blocks in terms of clinical research and shorten the process and time that it takes to translate research into practice," and "creating a home in academia for clinical and translational research." Respondents sent a strong message that

they were fully supportive of the goals, intents, and intended outcomes of the CTSA program.

### *Suggestions Concerning Important Outcomes and Impacts of the CTSA Program*

Respondents offered their input on the design of the national evaluation and expressed a strong desire to receive information about specific aspects of the CTSA program's performance and focus. Areas of interest included information about the specific diseases and interventions being studied, how well evidence-based research is being adopted in practice, the proportion of projects that involve pediatric-specific research and/or include children, whether the proportion of clinical research (within biomedical research generally) is enhanced, the impact on the shortfall in the number of well-trained clinical and translational scientists, metrics on the populations that are the targets of CTSA research projects, and strategies that work to improve the research information technology and linkages with the community. In addition to understanding *what* works, respondents want to understand *why* it works.

Because pediatrics is a cross-cutting discipline, the pediatric aspects of the CTSA program are another important area of interest. The structure of the CTSA program (based in academic medical centers) is perceived as a potential challenge for pediatric research because of the limited geographic areas served by such centers. A specific concern is the ability to recruit sufficient numbers of children for studies of less common childhood illnesses.

The recommendations for possible measures to assess program impact focused on three levels: the CTSA institutions, National CTSA Consortium, and NIH. Within each level, respondents identified several measures they viewed as relevant and important to capture, which are shown in **Exhibit 5**.

**Exhibit 5.**
**Recommended Measures**

| CTSA Institution | National CTSA Consortium | National Institutes Of Health |
|---|---|---|
| • Increase in patents and protocols<br>• Increase in publications<br>• Centralized patient record systems<br>• Changes in prescribing patterns<br>• Improvements in the health statistics of populations in communities with CTSA institutions<br>• Use of core or shared facilities<br>• Community participation in clinical research | • Increase in degree of data-sharing across CTSA institutions<br>• Best practices for training translational scientists<br>• Linkages to improve research information technology<br>• Linkages occurring between CTSA institutions<br>• Interactions with other NIH programs | • Multidisciplinary CTSA review panels<br>• Involvement of other Federal agencies in the CTSA program<br>• NIH funding levels over time<br>• CTSA clinical investigators' success rates for NIH grants |

| CTSA Institution | National CTSA Consortium | National Institutes Of Health |
|---|---|---|
| • Institutional support for CTSA<br>• Number of (and changes in) lectures, courses, and degree programs<br>• Number of trainees in clinical translational science<br>• Increase in the number of investigators initiating clinical studies<br>• Faculty collaborations | | |

Several respondents offered views on the difficulty of selecting a comparison group for the national evaluation. One respondent expressed the commonly shared view that "the nature of the CTSA program is such that once you've seen one, you've seen one." Most interviewees who discussed this issue believed that the appropriate comparison would be to permit CTSA institutions to serve as their own comparison over time (i.e., preaward versus postaward progress).

## Informational Visits to CTSA Institutions

To obtain a more indepth understanding of the CTSA institutional programs and to explore the feasibility of conducting an institutional substudy as part of the larger process evaluation, the study team conducted two pilot institutional informational visits in June and July 2007. These visits had several objectives, including:

- Exploring the factors that shaped the local implementation process at the two institutions
- Exploring the extent to which the two selected institutions were actively collaborating with other Cohort 1 CTSA institutions and prospective CTSA applicants
- Assessing the overall value and feasibility of conducting a substudy of selected institutions as part of the broader national process evaluation study design.

### Methods

Planning for the two institutional informational visits began during April and May 2007, and the visits were conducted in June and July. The specific CTSA institutions were chosen on the basis of the following criteria: geographic diversity (East Coast versus West Coast), the size of the institution, the evaluation model used, and input from NCRR staff. The two institutions selected were the University of Pittsburgh and the Oregon Health & Science University. The duration of each visit was 2 days.

Through a local liaison staff person at each institution, interviews were scheduled with the Principal Investigator (and co-Principal Investigator if there was one), the program's administrative and fiscal staff members, leaders from as many of the functional cores as were available, and local evaluation staff members. Based on a review of the institution's Annual Progress Report and a set of factors believed to affect the local implementation

process, the study team developed discussion guides individually tailored to each respondent. A sample Discussion Guide is included in **Appendix A5.**

## Findings From Informational Visits

The two CTSA informational visits provided an indepth understanding of the scope and complexity of the CTSA program and its implementation at the CTSA institutional level. The visits also furnished information about the operations of CTSA institutions, factors that affected their capacity to implement the plans proposed in their original applications, degree and nature of the contacts and collaborations occurring among Cohort 1 CTSA institutions and with prospective CTSA applicants, and value and feasibility of incorporating an institutional substudy into the overall design of the national process evaluation. The main findings from the two visits are summarized below for two topics: (1) the identification of the factors that shaped the implementation process and (2) collaborations with other CTSA institutions.

### *Factors Affecting the Implementation Process*

The study team developed a list of factors that appeared likely to have either a positive or negative influence on the general implementation process based on a thorough review of the institutions' Annual Progress Reports and the general literature on systems implementation. Although these factors did appear to play a role in the implementation process at the two institutions, some factors appeared to be more localized (such as the placement of the CTSA program within the lead institution's organizational structure). The location of the CTSA initiative within the organizational structure of the lead institutions was important for securing institutional commitment and support. Other factors may have relevance across institutions and are therefore important from the perspective of the National CTSA Consortium. Examples of cross-cutting factors include communication within the CTSA institutional program, communication between the program and other entities within the institution or community, and the issue of "branding" (i.e., what is the image of the CTSA institutional program that will be conveyed to others). One issue not included in the original list proved to be especially interesting. This concerned "system navigation," that is, how the CTSA addressed the problem of connecting investigators with questions or problems to the portions of the research infrastructure where they could find assistance. The two CTSA institutions developed different approaches to this problem, and it would be useful to follow these approaches over time to assess their effectiveness.

### *Frequency of Collaborations With Other Cohort 1 CTSA Institutions and Prospective Applicants*

The informational visits highlighted the extent to which there has been considerable exchange of information between the Cohort 1 CTSA institutions and other institutions that are considering or applying for a CTSA award. These contacts include telephone conversations with counterparts at other institutions, visits by staff from one CTSA institution to others, the sharing of information and materials, and planning toward possible collaborative activities. Both the visited CTSA institutions were entering into joint activities with other CTSA institutions. Some of these collaborations emerged through discussions that took place during CTSA committee and subcommittee meetings, and it is important to note that the informal "networking" functions of these meetings can sometimes be more important for promoting collaboration than the formal discussions and activities of the meetings themselves.

# Review of CTSA Institutions' Self-Evaluation Plans

As a part of the CTSA application process, each CTSA institution submitted a proposed self-evaluation plan. A content analysis of these proposed plans was conducted to assess the extent to which the 12 Cohort 1 CTSA institutions proposed common metrics for assessing the implementation and results of their programs.

## Methods

Measures from each CTSA were examined for each key function and were classified as representing a process measure or an outcome measure. Process measures included measures that assessed the extent to which a functional core had been implemented or utilized or otherwise reflected the outputs of functional activities. Outcome measures represented the results of program activities and were further classified as short-term (1–3 years), intermediate (4–7 years), or long-term (more than 7 years).

The study team recognized that the self-evaluation plans proposed by the CTSA institutions as part of their initial applications might change to a considerable extent as the implementation process unfolded. New measures might be added to reflect changes or additions to the original initiatives. More likely, proposed measures might be dropped due to the lack of time or resources. Therefore, each CTSA was given an opportunity to review an Excel spreadsheet of its proposed measures and was asked to note any additions, deletions, or modifications. A second content analysis of measures was completed based on these revised measures. The same conventions described above were used for the second analysis.

## Findings from Review of CTSA Institutions' Self-Evaluation Plans

Under Section 11 of the Request for Applications (RFA) (*Tracking and Evaluation Plan*), CTSA institutions are directed to " … include a detailed self-evaluation plan to assess implementation of the short- and long-term CTSA goals, including implementing program activities and tracking trainees and scholars and their mentors, their pilot projects, and their involvement with multidisciplinary team research." The CTSA institutions were encouraged to establish internal monitoring and tracking systems, and their evaluation plans reflected this emphasis.

The review focused on two aspects of the self-evaluation plans: the type(s) of comparison strategies used in the self-evaluation designs and the types of measures proposed. All 12 CTSA institutions included some type of comparison strategy in the design of their self-evaluations. The most commonly used strategy was a pre-post comparison in which the progress was tracked against a baseline year. One institution proposed to compare its implementation progress against assigned dates or other scheduled milestones. Two institutions reported plans to utilize a benchmarking approach but did not describe how they proposed to develop their benchmarks. Three institutions proposed to develop specific comparison groups. Two of these institutions planned to conduct surveys with random samples of faculty who were and were not participating in the CTSA institutional program. The faculty would be assessed on such variables as the number of publications and grants, problems or delays in developing applications, level of satisfaction with the services provided. A third institution proposed to use a "delayed-cohort" design in which successive annual cohorts of scholars and trainees would be assessed on the same measures to track improvement over time.

As directed by the RFA, each CTSA institution organized its self-evaluation plan around key functional cores. For the most part, these key functional cores were highly similar to the nine suggested functional cores listed in the RFA, but there were some variations. Several institutions, for example, established separate functional cores for activities targeted at engaging the lay public and for engaging industrial partners. Within the key functional cores, each CTSA institution proposed a variety of measures. As part of the feasibility study analysis, these were classified as either process or outcome measures. Process measures included coverage or utilization of a service and its implementation and progress toward goals. The outcome measures reflected the results of activities and were further classified as short-term, intermediate, and long-term using the timeframes noted earlier.

**Exhibit 6** lists measures that 7 or more of the 12 institutions identified for specific key functional cores. In reviewing these measures, it should be noted that different institutions may define the same measure in different ways. The number of institutions planning to use each measure is provided in parentheses following the measure.

**Exhibit 6.**
**"Common" Measures Identified by Key Functional Core—Cohort 1 CTSA Institutions**

| Key Functional Core | Measure |
|---|---|
| Developing Novel Clinical and Translational Methodologies | • Number and characteristics of projects that received feasibility or developmental funding (7)<br>• Number of extramural grants developed from pilot projects (7) |
| Pilot and Collaborative Studies | • Number and characteristics of investigators and projects receiving pilot funding (12)<br>• Establishment of a pilot funding program (12)<br>• Number of pilot projects successfully completed (12)<br>• Number of extramural grants funded based on pilot projects (11) |
| Biomedical Informatics | • Number of training sessions held to facilitate biomedical service use and attendance (7)<br>• Number of investigators obtaining consultations on biomedical informatics issues and problems (7)<br>• Investigators' satisfaction with biomedical informatics consultations and services (10) |
| Research Design, Biostatistics, and Clinical Research Ethics | • Number and types of consultations provided on research design, biostatistics, and clinical research ethics (12)<br>• Number of investigators and/or projects receiving consultations on research design, biostatistics, and clinical research ethics (9)<br>• Number and types of courses and workshops taught by staff (7)<br>• Number of students, trainees, scholars, and fellows attending and completing these courses (7)<br>• Investigators' satisfaction with the consultation services (9) |

| Key Functional Core | Measure |
|---|---|
| Research Design, Biostatistics, and Clinical Research Ethics (Cont'd.) | • Number of publications for which research design, biostatistics, or clinical ethics staff were lead authors or co-authors (7) |
| Regulatory Knowledge and Support | • Number of regulatory consultations provided (7)<br>• Number of courses, lectures, and workshops provided by regulatory staff (7)<br>• Establishment or enhancement of regulatory consultation support services (9)<br>• Investigators' satisfaction with the consultation services (7) |
| Participant and Clinical Interaction Resources (PCIR) | • Number of investigators using new or expanded clinical facilities (7)<br>• Development or expansion of new or existing PCIR facilities (7)<br>• Investigators' satisfaction with new or expanded facilities (7)<br>• Number and dollar amounts of extramural grants using new or expanded facilities (7) |
| Community Engagement | • Number of community members attending community advisory board meetings (7) |
| Translational Technologies and Resources | • Number of investigators who are utilizing new translational technologies (7)<br>• Investigators' satisfaction with the availability and access to translational technologies (7) |
| Research Education, Training, and Career Development | • Number and characteristics of scholars, trainees, students, and fellows enrolled (10)<br>• Number of students, trainees, and scholars graduated from educational programs (8)<br>• Students', trainees', and scholars' satisfaction with the quality of mentoring (9)<br>• Students', trainees', and scholars' satisfaction with the quality of instruction (9)<br>• Career progressions and outcomes (9) |

## Review of Annual Progress Reports and National CTSA Steering Committee Minutes

To minimize the data collection burden on the CTSA institutions, the study team explored internal program documentation as potential primary data sources for the national process evaluation—Annual Progress Reports (APRs) and National Steering Committee Minutes.

### Methods—Annual Progress Reports

The APR reviews focused on three sections: the Core-by-Core Status Report; the Highlights, Milestones, and Challenges section; and where available, minutes from the External Advisory Group. The objective was to examine each section and to compile information on

the principle challenges identified in the implementation process for each of the functional cores. This process involved examining the three sections for each CTSA institution, recording the challenges and implementation issues identified for each specific institution, and summarizing the information across institutions for each functional core. The objective was to construct a national profile from these local materials.

## Findings—Annual Progress Reports

The findings from the APR analysis are presented in **Exhibit 7.** The review showed that the CTSA institutions reported implementation challenges in the following functional core areas: administration and governance; biomedical informatics; research design and biostatistics (but not clinical research ethics); regulatory knowledge and support; participant and clinical interactions resources; community engagement; translational technologies and resources; and research education, training, and career development. Only one institution reported issues associated with launching its pilot and collaborative studies program. The number in parentheses following each functional core represents the number of institutions reporting one or more implementation challenges.

**Exhibit 7.**
**Implementation Challenges by Functional Core**

| Functional Core | Type of Implementation Challenge |
|---|---|
| Administration and Governance (7) | • Aligning new CTSA administrative structure with existing departments<br>• Creating new administrative and other infrastructures while simultaneously using them<br>• Developing an effective self-evaluation program that supports continuous improvement<br>• Communicating within the program (at the local level) and with other entities within the institution<br>• Obtaining the appropriate buy-in from leadership, faculty, and staff members<br>• Overcoming the effect of considerable geographic dispersion among partnering institutions<br>• Avoiding the problem of creating new “silos” while old ones are being broken down<br>• Recruiting and training new staff |
| Research Design, Biostatistics, and Clinical Research Ethics (4) | • Knowing that the demand for consultation services is outstripping the time availability of staff<br>• Developing an adequate business model that allows charging for services formerly provided for free<br>• Organizing a new consultation service, which involves bringing together elements from several separate departments and which makes tracking services complex<br>• Reaching out to junior faculty in a widely dispersed geographic setting |

| Functional Core | Type of Implementation Challenge |
|---|---|
| Biomedical Informatics (4) | • Addressing IT needs while pursuing biomedical informatics research interests<br>• Developing an adequate business model that allows charging for services formerly provided for free<br>• Rapidly building a new comprehensive system while using it<br>• Hiring and training key personnel<br>• Realizing that the components of this core are widely dispersed across several departments and centers, creating problems around organization and communications<br>• Anticipating the longer time required to implement software that integrates protocol development and management, institutional review board (IRB) review, and monitoring and auditing |
| Community Engagement—Public and Health Professionals (4) | • Identifying and constructing profiles of all community-based research conducted<br>• Establishing the priorities and procedures that permit scientific research while not slowing down clinical care<br>• Stimulating research within the practice-based research network |
| Community Engagement—Industry (1) | • Losing a major organizational partner |
| Regulatory Knowledge and Support (5) | • Bridging the differences between IRB processes and systems at partnering institutions<br>• Hiring qualified staff<br>• Establishing consultation services for this functional core despite duplicate services being provided elsewhere on campus<br>• Communicating within a geographically dispersed set of partners |
| Participant and Clinical Interactions Resources (6) | • Developing effective transition plans for the integration of General and Clinical Research Centers (GCRCs)<br>• Providing support for new initiatives while continuing to fund past initiatives to which funds are encumbered<br>• Including the new functions and new personnel who require additional budget support beyond what is provided in the award<br>• Integrating new PCIR activities within existing services and designing an effective means of communication for all involved<br>• Developing an adequate business model<br>• Developing a flat budget in the face of negotiated salary rate increases for the nursing staff<br>• Assessing the cost savings measures that have diminished the ability of junior faculty to build careers in translational science<br>• Changing the culture and focus of GCRC staff and administration<br>• Promoting a multidisciplinary focus |

| Functional Core | Type of Implementation Challenge |
|---|---|
| Translational Technologies and Resources (3) | • Hiring qualified staff<br>• Helping investigators track down needed equipment<br>• Knowing that the demand for consultations and time from technology experts may exceed their available time and may compromise their own research activities |
| Research Education, Training, and Career Development (3) | • Rapidly implementing the educational programs, which has outpaced their capacity to arrange suitable research rotations<br>• Breaking down the walls between certain educational programs has led to realignments of resources and staff, creating steep learning curves for these staff members<br>• Hiring qualified staff<br>• Moving into a new physical space—how to keep all programs operating and to provide uninterrupted service to students, trainees, scholars, and faculty members during the transition<br>• Knowing that the time constraints, service obligations, funding, and adequate mentoring have proven to be barriers to the involvement of residents in research |

Based on the information found in the APRs, the functional cores that proved most challenging for the greatest number of CTSA institutions to implement during year 1 are administration and governance (7 institutions), participant and clinical interactions resources (6 institutions), and regulatory knowledge and support (5 institutions).

The various implementation challenges described by the Cohort 1 CTSA institutions appear to fall into two general categories. First, there are local issues that may be unique to a specific CTSA institution. These issues include such challenges as planning for relocation into a new physical space or losing a major organizational partner. Second, there are broader problems that many of the CTSA institutions have to face, such as establishing local communications systems, aligning the new administrative structure of the CTSA program with existing clinical departments, integrating the GCRCs into the CTSA program, and breaking down ”silos” within the CTSA institution. These are problems that many CTSA institutions are likely to face, and they may become topics of discussion at the National CTSA Consortium level.

## Methods—Review of National CTSA Steering Committee Minutes

One source of information on the activities of the National CTSA Consortium is the minutes and work products of the various CTSA Consortium Steering Committees and workgroups. These documents were examined to explore their contents and to assess the level of committee activity, participating CTSA institutions, main discussion topics, and actions taken. Posted minutes were reviewed from the following National CTSA Steering Committees: Community Engagement; Education/Career Development; Informatics; and Translational.

## Findings—Review of National CTSA Steering Committee Minutes

The four Steering Committees reviewed varied considerably in the number of meetings held through September 30, 2007. Of the four, the Community Engagement Steering Committee held eight meetings; the Education/Career Development Steering Committee held two meetings; the Informatics Steering Committee held four meetings; and the Translational Steering Committee held two meetings. However, the number of meetings held is not necessarily a good gauge of committee activity and effort. The Informatics Steering Committee held a 2-day workshop on September 27–28, 2007.

The review indicated that the four Steering Committees were clearly identifying and acting upon specific focal areas. For example, the Community Engagement Steering Committee has begun to compile information on the CTSA institutions' community advisory boards, needs assessment activities, and community-based research projects. The Committee is also developing a forum for sharing resources and instruments and is seeking suggestions for the development of a trans-CTSA educational curriculum on community engagement. The Committee has also begun to collect and disseminate information on funding opportunities and participation in special workshops and conferences. The Informatics Steering Committee has created the following working groups: Inventory of Existing Informatics Projects, Integrative Data Repository, Standards and Interoperability, Research Knowledge and Dissemination, and Research Education. The Education/Career Development Steering Committee has identified the transition from K award to R01 award support as the most susceptible time at which to lose clinical research investigators, an important step in developing the strategies to retain clinical researchers. Its priorities include establishing national core competencies in clinical and translational science, organizing a mentor development program, improving scholar retention, and taking part in an annual national meeting with the Association for Clinical Research Training. The Translational Steering Committee also established several priorities for future activities, including developing a working definition of translational science, creating an inventory of translational cores and other resources available at member institutions, identifying the issues and barriers to T1 research, and encouraging collaborative processes and the dissemination of information among the CTSA institutions. A common theme across the priorities of these four Steering Committees is the need to develop a detailed inventory of the relevant activities and projects within the purview of each Committee. As this effort grows, it could provide a useful resource for the national process evaluation.

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# 4. IMPLICATIONS OF FINDINGS FOR THE NATIONAL CTSA CONSORTIUM PROCESS EVALUATION DESIGN

This section considers the implications of the feasibility study findings for the overall design and methods of the National CTSA Consortium Process Evaluation Study.

## Special Considerations Affecting the National CTSA Consortium Process Evaluation Study

The Clinical and Translational Science Awards (CTSA) Feasibility Study results highlight the complexity of this national initiative and raise several overarching issues that need to be considered in the design and implementation of the process evaluation study, including defining key terms, transitioning from the former General Clinical Research Center (GCRC) model to the CTSA model, capturing relevant contextual variables, and determining the critical timeframes for assessing the results of program activities and their outcomes.

### Defining Key Terms

One important step that will need to be taken when implementing the process evaluation study will involve constructing operational definitions of terms, such as “translational science” and “transdisciplinary science.” Recognizing the complexity of these terms, the National Center for Research Resources (NCRR) has developed a glossary of terms, and some of those definitions have been incorporated into the Glossary of Terms for this report. However, it will be necessary to operationalize these definitions to be able to apply them to the problem of determining which research projects can be classified as translational science that involves a transdisciplinary team.

### Integrating General Clinical Research Centers Into CTSA Institutions

The CTSA program is intended to supplant the GCRC program that has operated for more than 45 years. The GCRC program is a national network of centers throughout the United States that provides research infrastructure, training, and clinical settings in which biomedical investigators can conduct interdisciplinary, primarily clinical, inpatient, and outpatient, research projects with both children and adults. All the CTSA institutions funded under Cohorts 1 and 2 operated at least one GCRC. The 12 Cohort 1 CTSA institutions operated 16 GCRCs, and the 12 Cohort 2 CTSA institutions operated 14 GCRCs. CTSA institutions that operated established GCRCs face the challenge of integrating their resources, personnel, and experiences into the larger CTSA structure. It will be important to monitor this process over time, identify the challenges faced in conducting this integration process and the strategies that have worked for earlier cohorts of CTSA programs, and share these with later CTSA cohorts.

### Capturing Relevant Contextual Variables

Contextual variables are factors that operate outside the control of those agencies and individuals who are implementing the program yet may have an important effect on the program's activities, outputs, and/or outcomes. A decision to fund the CTSA program according to the funding guidelines issued on September 18, 2007, may result in program revisions, changes in scope, and intersite collaborations as institutions seek ways to accomplish their goals within the funding limitations. NCRR has pledged to work closely with both cohorts to promote the sharing of resources through the National CTSA Consortium and modifications to the scope of individual awards as necessary. It will be important to monitor the types of changes in scope that occur across the CTSA institutions as a result of this reduction and to explore the extent to which this leads to the sharing of resources through the National CTSA Consortium.

### Timeframes for Short-Term, Intermediate, and Long-Term Outcomes

To frame the process evaluation study, the design incorporates Dr. Elias Zerhouni's definitions of the timeframes associated with different types of outcomes. Short-term outcomes are those likely to occur within 1–3 years following the program's inception, intermediate outcomes are those likely to occur within 4–7 years after inception, and long-term outcomes may require 8–10 years or longer to develop.

## Design of the National CTSA Consortium Process Evaluation Study

The findings support three conclusions that are relevant to the design of the National CTSA Consortium Process Evaluation Study. First, a review of the general literature on the evaluations of research and development programs and on recent National Institutes of Health (NIH) evaluations found that identifying external comparison groups for the evaluations of large-scale research programs is often difficult, given that such programs are often unique. Therefore, based on the literature review, interviews with representatives of national biomedical professional organizations, and feedback from CTSA institutions and National CTSA Consortium representatives, the study group concluded that the most appropriate comparison strategy for the National CTSA Consortium Process Evaluation Study would be to compare progress over time against a baseline—a pre-post approach that would monitor changes in the program over time and compare these against prior years. This approach is consistent with many of the evaluation designs found in the literature review.

Second, the effects of the CTSA program will occur at several levels, including scholars and trainees, clinical and translational science, CTSA institutions, the National CTSA Consortium, health practice, and the community and society. The two structural components—CTSA institutions and the National CTSA Consortium—are important for the National CTSA Consortium Process Evaluation Study to track. Because the CTSA institutions are charged with conducting their own self-evaluations to track progress toward individual institutional goals, the primary focus of the national evaluation efforts will be at the National CTSA Consortium level, with a particular emphasis on how the Consortium develops over time.

Third, examining program effects at these different levels will require the use of multiple data collection approaches and both quantitative and qualitative data. This conclusion is supported by the literature review and particularly by a review of selected NIH evaluations,

where the use of multiple data collection approaches was a common feature that strengthened the overall validity of the specific design.

## Data Collection Strategies for the National CTSA Consortium Process Evaluation Study

The feasibility study findings also have several important implications concerning the choice of data collection strategies for the process evaluation study. Four potential sources of data were examined: (1) CTSA Institutional Annual Progress Reports, (2) National CTSA Consortium Steering Committee Minutes, (3) CTSA Institutional Self-Evaluation Plans, and (4) case studies. Each of these sources had strengths and limitations as a primary source of data for the process evaluation study, as discussed below.

### *1. CTSA Institutional Annual Progress Reports*

The CTSA Institutional Annual Progress Report is a standardized progress report that each CTSA institution is required to submit electronically to NCRR annually. It includes information on personnel (investigators and career development personnel), publications, projected activities, program descriptions, several progress reports, and a Technology Transfer Report. The contents of these sections are described in **Exhibit 8**.

**Exhibit 8.**
**Contents of the CTSA Institutional Annual Progress Report**

| Annual Progress Report Section | Contents of Section |
|---|---|
| Personnel | *Investigators:* Individuals whose clinical or translational science was aided by the resources of the CTSA or who served as a mentor for an individual listed under Career Development.<br><br>For each investigator, the Federal Public Health Service (PHS) and Federal non-PHS grants (and dollar amounts) that benefited directly from CTSA resources must be included. |
| | *Career Development:* Individuals who received support from the CTSA grant during the reporting period and are in a training position. Includes three categories: (1) trainees (received support from TL1 grant), (2) scholars (received support from the KL2 grant), and (3) other career development (received support from the UL1 grant).<br><br>Note that the information collected here includes the name of the mentor (if any).<br><br>Includes aggregated information on the gender and ethnic and racial characteristics of each of the three categories, with separate information on applicants who applied, applicants interviewed, and applicants accepted into the respective programs. |
| Publications | All publications of research that benefited from the resources of the CTSA and are included in *PubMed*. |

| Annual Progress Report Section | Contents of Section |
|---|---|
| Projected Activities | Projected CTSA resource usage for the upcoming year for three categories of activities: *Clinical Trials*, *Pediatric Research*, and *AIDS Research*. Expressed as a percentage of all CTSA activities. |
| Program Descriptions | List of organizations and institutions, other than the institution receiving the CTSA grant, that are *partners* in the reporting CTSA. |
| Highlights, Milestones, and Challenges Report | Overview of the progress of the overall CTSA, including its accomplishments; challenges encountered; its future directions; the status of the program in meeting milestones; and any proposed changes in the direction, activity, programs, focus, modified milestones, or other aspects of the CTSA for the coming year. This report is limited to five pages. |
| Self-Evaluation Report | Information on the self-evaluation program at the CTSA, including its conceptual framework; a description of the objectives, milestones, the variables measured, and the types of measures; the type of data collected; human subjects protections; a summary of the findings; future timelines; and participation in the national evaluation. Limited to five pages. |
| External Advisory Committee Report | A list of members of the External Advisory Committee, the date of its review, and the complete and inclusive text of the committee's report. |
| CTSA Components Report | A report from each of the CTSA components or key functions that includes key personnel, goals, the process and progress, the major accomplishment(s) (related to a program component goal), activities within the National CTSA Consortium, and plans for the coming year (three pages per component or key function). |
| Technology Transfer Report | Completed if there is any technology transfer information to report and includes the number of INDs, IDEs, BLAs, NDAs, and patents. |

As a data source, the Annual Progress Reports offer several important strengths. First, the information on personnel, publications, projected activities, program descriptions, and the Technology Transfer Reports use standardized definitions; thus, it would be possible to create several counts of variables of interest from these data. For example, it would be feasible to create an aggregated count of the number of individuals who applied for and were accepted into each institution's TL1, KL2, and UL1 programs by gender and by ethnicity and/or race.

Information from other sections of the Annual Progress Report (e.g., the Highlights, Milestones, and Challenges Report; Self-Evaluation Report; External Advisory Committee Report; and CTSA Components Report) follow a common *format*. Thus, although the amount of detail may vary, the information is organized in a similar manner across CTSA institutions. To ascertain whether the level of information provided would be sufficient to use as a potential source of information, the study team examined the implementation

challenges and found that CTSA institutions varied in the extent to which they described the implementation challenges and in the amount of information provided.

### *2. National CTSA Consortium Steering Committee Minutes and Work Products*

As a primary data source, the National CTSA Consortium Steering Committee minutes have strengths and limitations. The minutes can provide measures of CTSA institutional participation and committee activity. The minutes also provide highlights of specific activities and records of specific presentations. Workgroup products will provide more detailed descriptions of specific issues and proposed actions. The study team concluded that minutes should be supplemented by interviews with committee chairs as a means of obtaining more detailed information about committee goals and achievements.

### *3. Review of CTSA Institutional Self-Evaluations*

The review of the proposed and revised CTSA self-evaluation plans found that the plans were diverse, without much useful overlap across specific measures for each key functional core. Where CTSA institutions reported using similar measures, it could not be determined whether these measures were defined in the same way. (For example, satisfaction with various types of consultation services could be defined in many different ways.) Many of these measures would clearly be of greater value for the self-evaluations than for the national process evaluation. However, it would be useful for the national process evaluation to examine the annual reports of the self-evaluations as part of the implementation analysis.

### *4. Case Studies*

The review of the evaluation literature on research and development programs found that the case study is an important methodological approach that has been used to investigate in detail a specific program, project, or technology to describe how and why developments of interest have occurred. For example, a case study could focus on a joint university-industry venture, describing how it was formed, how participants shared various research tasks, and whether (and why) the collaboration was successful. In some cases, the estimates of the economic effects of the program could be included as well.

There are several strengths associated with this approach. Case studies can provide a broader sense of the context and richness of detail than other data collection approaches; however, they are labor-intensive to conduct.

Based on the two informational visits conducted in the feasibility study, the study team identified three reasons for including case studies on the institutional implementation of the CTSA program as a part of the general design and methods for the national process evaluation. First, case studies can provide a richer picture of the implementation process than the narrative portions of the Annual Progress Reports. It is important for the national evaluation to be informed about this process because the degree to which each institution is able to implement its own program affects the National CTSA Consortium. This point is especially critical in light of the recently announced revisions in funding guidelines for the CTSA awards. Understanding how the CTSA institutions are revising their original plans, how these decisions are reached, and how they play out within the CTSA institutional programs are important contextual factors to capture in the process evaluation study.

Second, case studies can provide information on how collaborations among the CTSA institutions form and operate to achieve their goals. This point builds on the previous point, such that one possible implementation strategy to address the revisions in funding guidelines would be to form collaborations with other CTSA institutions.

Third, case studies can help document the process by which the policies, standards, and best practices formulated at the National CTSA Consortium level are adopted within the local CTSA institutions. The results from informational visits and the review of the narrative portions of the Annual Progress Reports emphasized the importance of support from institutional leadership in obtaining the political and financial support necessary to implement the local CTSA programs. Whether this support can be mobilized to implement the recommendations of the National CTSA Consortium at the CTSA institution level will be important for the process evaluation study to capture.

# 5. RECOMMENDATIONS FOR THE DESIGN AND IMPLEMENTATION OF THE NATIONAL CTSA CONSORTIUM PROCESS EVALUATION STUDY

This section presents recommendations for the design and implementation of the National CTSA Consortium Process Evaluation Study, which is a necessary preliminary step to a National Outcome Evaluation Study. The section also includes an overview, the national evaluation questions, a conceptual framework for the process evaluation study, and a discussion of the six proposed process evaluation substudies.

## Overview of the Design of the Process Evaluation Study

The full-scale evaluation of the Clinical and Translational Science Awards (CTSA) program consists of four phases: (1) a feasibility study, (2) a pilot of the National CTSA Consortium Process Evaluation Study, (3) the full-scale implementation of the National CTSA Consortium Process Evaluation Study, and (4) a National Outcome Evaluation Study. The feasibility study, described in this report, has been completed. The process evaluation study will be implemented in two phases and will establish the infrastructure on which the outcome evaluation study can be developed. The process evaluation study will focus on the extent to which the National CTSA Consortium is implemented and on the products and outcomes of its activities. It will be both retrospective and prospective and will include the CTSA cohorts funded from 2006 to 2010.

Three additional features of the design for the process evaluation study are discussed below.

### 1. Study Design

The process evaluation study will be restricted to the assessment of the National CTSA Consortium. Evaluations of the individual CTSA institutions will be performed separately. The study will focus on the development and short-term accomplishments of the National CTSA Consortium, local collaborations among CTSA institutions, and the aggregate accomplishments of the CTSA institutions. Based on findings from the literature review and interviews with biomedical professional organizations, the design of the evaluation will be longitudinal in nature, comparing the progress of the National CTSA Consortium each year with previous years.

Two options in study design were considered: a longitudinal (observational) study and a prospectively designed comparative study. Of the two, a prospectively designed comparative study, which has been controlled for factors that might bias the results, is generally considered to provide more valid information. After careful review, we were unable to find or establish a suitable control for the National CTSA Consortium. It is a unique program unlike other research networks. Advice from biomedical professional organizations and a literature review justified a longitudinal study. A weakness of this approach is that the study will not reveal the gains in clinical and translational science that might have occurred without the addition of the National CTSA Consortium. In addition, the study will not be free from biases intrinsic to its design.

### 2. Design Includes Six Substudies

Due to the complexity of the CTSA program and its multiple levels of activities, the recommended design includes six substudies that target the following areas: the National CTSA Consortium; the institutional implementation process; trainees and scholars; clinical and translational science; health practice; and public awareness.

### 3. Mixed Methods Approach

The process evaluation study will use a mixed-methods approach that includes both quantitative and qualitative data. The value of quantitative data in a study of this type is clear and needs little elaboration. The role of qualitative data is equally important because there is much to be learned about the innovative strategies and approaches used by the local CTSA institutions to achieve their goals that cannot be rendered in numbers. For example, quantitative data will be critical for showing where the National CTSA Consortium succeeds in promoting various forms of collaboration over time, but qualitative data will help explain how and why such collaborations occurred and the strategies that might be implemented nationally to encourage further growth in these collaborations.

## National Evaluation Study Questions

The study team worked to identify and refine a series of national evaluation questions. The study team began with a preliminary series of 48 questions. The team first agreed on a preliminary framework that defined the focus of CTSA national program activities and results in terms of six domains. These domains included the Individual, the Institution, the National CTSA Consortium, Clinical and Translational Science, Health Practice, and Society. With these six domains as an organizing rubric, and after reviewing and discussing the initial 48 questions, a final set of 11 questions was developed. These questions were then reviewed and approved by the Trans-NIH Evaluation Subcommittee and National Center for Research Resources (NCRR) senior management in June 2007. These 11 questions are listed below in **Exhibit 9**.

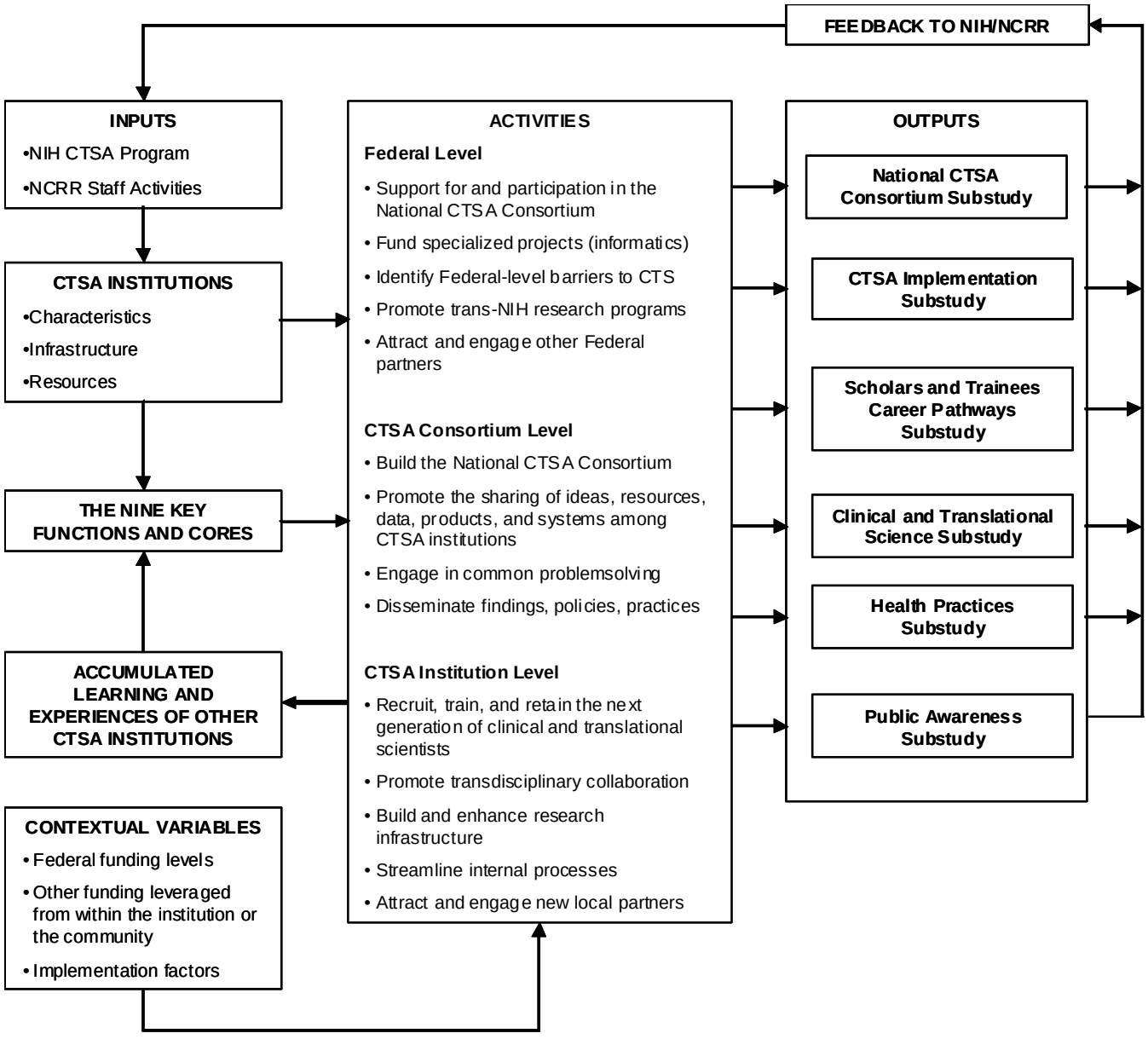
**Exhibit 9.**
**National Evaluation Study Questions**

| QUESTION # | DOMAIN | EVALUATION STUDY QUESTIONS |
|---|---|---|
| **1** | Individual | Does the CTSA program recruit, retain, and support the career advancement (promotion and tenure) of clinical and translational science investigators? If so, how? |
| **2** | Institution | Does the CTSA program effectively integrate clinical and translational science at the institutions? If so, how? |
| **3** | National CTSA Consortium | Have the CTSA institutions formed an integrated National CTSA Consortium? If so, how? |
| **4** | National CTSA Consortium | How effectively has the National Institutes of Health (NIH) participated in the National CTSA Consortium? |
| **5** | Clinical and Translational Science | Does the CTSA program accelerate the translation of basic research into clinical studies? If so, how? |
| **6** | Clinical and Translational Science | Does the CTSA program improve the speed and efficiency of the translation of clinical studies into community clinical practice? If so, how? |
| **7** | Clinical and Translational Science | Does the CTSA program improve the translation of feedback from clinical studies and community research back to basic research? If so, how? |
| **8** | Health Practice | Does the CTSA program accelerate the dissemination of new methods, tools, and resources into community clinical practice? If so, how? |
| **9** | Society | Does the CTSA program improve public knowledge of, support for, and involvement in clinical and translational science? If so, how? |
| **10** | Society | Has the CTSA program contributed to preventing and treating chronic and acute diseases? If so, how? |
| **11** | Society | What has been society's return on investment from the NIH funding of the National CTSA Consortium in economic terms and in quality of life? |

# Conceptual Framework for the National CTSA Consortium Process Evaluation Study

The conceptual framework for the Process Evaluation Study is shown in **Exhibit 10**.

**Exhibit 10.**
**Conceptual Framework for the National CTSA Consortium Process Evaluation Study**



## Design of the Process Evaluation Study

The process evaluation study includes six substudies that address the process aspects of the first nine national evaluation questions listed in **Exhibit 9.** The two remaining national evaluation questions concern program effects on the Nation's health and society's return on NIH's research investment in the CTSA program, neither of which can be answered meaningfully for several years after the program has been fully implemented at all 60 academic health centers. The six substudies that constitute the process evaluation study include the National CTSA Consortium Substudy, CTSA Implementation Substudy, Scholars and Trainees Career Pathways Substudy, Clinical and Translational Science Substudy, Health Practices Substudy, and Public Awareness Substudy. Evaluation of the impact of the Consortium on the Nation's health will be the subject of a separate evaluation. The relation of each of these substudies to the national evaluation study questions is shown below in **Exhibit 11.**

**Exhibit 11.**
**Process Evaluation Substudies in Relation to National CTSA Evaluation Study Questions**

| National Evaluation Study Questions | National CTSA Consortium Substudy | CTSA Implementation Substudy | Scholars And Trainees Career Pathways Substudy | Clinical And Translational Science Substudy | Health Practices Substudy | Public Awareness Substudy |
|---|---|---|---|---|---|---|
| 1 | | X | X | | | |
| 2 | | X | | X | | |
| 3 | X | X | | | | |
| 4 | X | X | | | | |
| 5 | | X | | | X | |
| 6 | | X | | | X | |
| 7 | | X | | | | |
| 8 | | X | | | X | |
| 9 | | X | | | | X |
| 10 | Long-Term Outcomes | | | | | |
| 11 | Long-Term Outcomes | | | | | |

# Six Process Evaluation Substudies

The study questions posed by the National CTSA Consortium Process Evaluation Study could potentially lead to the collection of a considerable amount of quantitative and qualitative data. Therefore, the process evaluation study will be implemented in two phases—a pilot phase and the full-scale implementation phase. The pilot phase will further refine the substudy design, substudy questions, choice of data sources, and analyses of the most important aspects of the National CTSA Consortium successes and challenges.

## 1. National CTSA Consortium Substudy

The National CTSA Consortium Substudy will describe and document the emergence and operation of the National CTSA Consortium. As discussed earlier, the primary structure of the National CTSA Consortium is its system of committees, steering committees, subcommittees, and workgroups, through which its members meet on a regular basis to identify common problems and formulate recommendations or solutions for resolution. Some of the CTSA institutions have begun to form collaborations with other CTSA institutions (and prospective CTSA institutions) to pursue common projects and interests. Based on discussions at various CTSA Steering Committee meetings, the emergence of these collaborations is expected to increase as new CTSA institutions join the National CTSA Consortium. It is possible that these collaborations may broaden in scope, from those organized around single projects or interests to those organized around multiple activities.

The National CTSA Consortium Substudy has five objectives that focus on both national and other levels of collaborative activities among CTSA institutions. The first objective is to describe and document the emergence and growth of collaborative activities among CTSA institutions. The second objective is to describe and document the activities of the National CTSA Consortium through its committees, steering committees, subcommittees, and workgroups. The third objective is to monitor the products that result from these national activities and to describe whether and how these products are disseminated (and to whom). The fourth objective is to assess the satisfaction of the CTSA Principal Investigators (PIs) with the structure and priorities of the National CTSA Consortium, the extent to which they participate, the perceived value of this participation, and the role of NIH as a partner in the National CTSA Consortium. As part of this objective the study team also recommends examining participant satisfaction regarding any collaborations among two or more CTSA institutions in which each PI participates. The fifth objective will explore user satisfaction with the CTSA national Web site and its communication tools. An important element of this objective is an analysis of how CTSA institutions utilize the Wiki communication tool, an innovation intended to facilitate collaborative communication, the exchange of ideas, and decisionmaking.

Substudy research questions, methods, data sources, and data analyses are summarized in **Exhibit 12.**

**Exhibit 12.**
**National CTSA Consortium Substudy**

| SUBSTUDY RESEARCH QUESTIONS |
|---|
| ***Collaborations*** |
| 1. What types of collaborations emerge among the CTSA institutions, and around which issues did these collaborations develop? |
| 2. How did the collaborations develop, and did they achieve their stated goals? |
| 3. What are the products or activities that result from these collaborations (e.g., research proposals, findings, other outputs)? How are these disseminated and to whom? |
| ***National CTSA Consortium*** |
| 4. What activities are undertaken by the National CTSA Consortium Steering Committees and workgroups? What products result from these activities (e.g., recommendations, model policies or procedures)? |
| 5. What objectives and priorities do the National CTSA Consortium Steering Committees establish, and did they meet these objectives? |
| 6. How do the CTSA representatives perceive the adequacy of the governance structure of the Consortium (e.g., their ability to present their ideas and suggestions, the size of the Consortium, the arrangements for establishing representation as the Consortium grows), the perceived value of participation in the Consortium's meetings and activities, its demands on their time, its priorities and focus, and the usefulness of the products resulting from its activities? How does NIH perceive the effectiveness of the National CTSA Consortium? |
| 7. How do CTSA representatives perceive NIH's role as a participant in the Consortium, NIH's responses to the emerging needs identified by the Consortium, and the changes made to NIH policies and procedures as a result of Consortium recommendations? |
| 8. How do the CTSA representatives perceive the CTSA Web site and communication channels, including the extent to which they use the Web site and its capabilities, the Wiki, other communications features, and suggestions for additional features? |
| ***Methods*** |
| 1. Monitoring of National CTSA Consortium Steering Committee activities and communication over the Wiki. |
| 2. Semistructured interviews with PIs, Steering Committee chairs, and NIH program staff members. |
| 3. Semistructured interviews with external organizations that become involved with the National CTSA Consortium's activities. |
| ***Data Sources*** |
| 1. Annual Web-based survey of the PIs. |
| 2. Review of the minutes and reports from the National CTSA Consortium committees, subcommittees, and workgroups. |
| 3. Content analyses of the Wiki. |

| ***Proposed Data Analyses*** |
|---|
| 1. Descriptive analyses of CTSA institutional collaborations.<br>a. What collaborations formed, which CTSA institutions were involved, and what were the stated purposes of the collaborations?<br>b. Which CTSA institutional collaborations achieved their stated aims, what did they produce, and how long did it take?<br>c. How satisfied were collaboration participants with the results?<br>d. Did successful collaboration on one issue or set of issues lead to efforts to collaborate on other issues?<br>e. Which CTSA collaborations led to the development of an organization as a formalized network or other entity? |
| 2. Descriptive analysis of the National CTSA Consortium.<br>a. Were the committees dissolved when they achieved all their stated objectives? Did the committees achieve their objectives within the projected timeframe?<br>b. What changes occurred to the Consortium governance structure to accommodate the increase in CTSA members over time.<br>c. What activities were conducted by the various Consortium committees, subcommittees, and workgroups, and what products were produced?<br>d. What were the results of the content analysis of the CTSA Web site Wiki?<br>(1) Utilization of the Wiki—by which CTSA institutions, how much, and for what purposes.<br>(2) Major themes and issues appearing in the Wiki. |
| 3. Perceptions of CTSA PIs and NIH staff members concerning their participation in the National CTSA Consortium.<br>a. Perceptions of governance structure and representation practices on Consortium committees, subcommittees, and workgroups.<br>b. Perceived burden (time demands) of participation in the National CTSA Consortium activities.<br>c. Perceived value of participation in the National CTSA Consortium activities.<br>d. Appropriateness of focus and priorities underlying the National CTSA Consortium activities.<br>e. Usefulness of the products resulting from Consortium activities.<br>f. Suggestions for changes in the National CTSA Consortium structure and work processes. |
| 4. Perceptions of CTSA institutions concerning NIH's role and participation in the National CTSA Consortium.<br>a. Perceptions about NIH's role as a participant in the National CTSA Consortium.<br>b. Perceptions about NIH's responses to emerging needs identified by the Consortium.<br>c. Adequacy and appropriateness of changes made to NIH policies and procedures as a result of Consortium recommendations.<br>d. Adequacy of the logistical and management support provided to the National CTSA Consortium committees, subcommittees, and workgroups and their activities.<br>e. Suggestions for additional ways that NIH could support or assist the Consortium. |
| 5. Perceptions of CTSA institutions about the CTSA Web site and communication channels.<br>a. Extent to which CTSA institutions utilize the Web site, Wiki, and communication features.<br>b. Satisfaction with the Web site and its capabilities.<br>c. Extent to which the CTSA institutions communicate with each other outside the CTSA Web site.<br>d. Suggestions for improving and/or upgrading the Web site. |

## 2. CTSA Implementation Substudy

Implementation is a critical precursor to the success of the CTSA program at both the institutional and national levels; for this reason, two of the six substudies address implementation issues at different levels within the CTSA program. The CTSA Implementation Substudy focuses on implementation issues occurring *across* the CTSA institutions, whereas the National CTSA Consortium Substudy will address the National CTSA Consortium.

At the institutional level, each CTSA planned to reorganize some existing resources and to create new ones that will enable it to construct an "academic home" for the emerging discipline of clinical and translational science. Each CTSA faces three sets of challenges in building this home. First, the CTSA lead institution must work with one or more outside partnering institutions and organizations whose organizational cultures may differ in important ways from that of the lead institution. These differences can lead to many political, administrative, and fiscal issues that may prove difficult to resolve. Second, the CTSA institutions will face the challenge of how to best integrate any existing General Clinical Research Centers (GCRCs) into the new CTSA internal structure. For some institutions this may involve integrating two or more existing GCRCs. This integration process may involve significant structural and procedural changes in these GCRCs. Finally, each CTSA will face the need to collaborate across departments and disciplines through the restructuring and dissolution of organizational "silos" or "stovepipes."

The CTSA Implementation Substudy focuses on the implementation process occurring among the CTSA institutions and the effects that this has on the activities and plans of the National CTSA Consortium. The major focus of the CTSA Implementation Substudy is on *how* the CTSA institutions create their academic homes for clinical and translational science. This substudy has five objectives. First, we will create an initial baseline "snapshot" for the CTSA institutions by constructing an initial profile based on the original grant application descriptions of existing resources. A sample of a possible CTSA "snapshot" template is shown below as **Exhibit 13**.

**Exhibit 13.**
**Partial List of Elements for a CTSA "Snapshot"**

| | | | | |
|---|---|---|---|---|
| **Name of CTSA Program:**<br>**Web Site Address:** | | | | |
| **Cooperative Agreement #**<br>**Cohort #**<br>**Project Start Date:** | | | | |
| **Principal Investigator:**<br>**Organizational Location of PI:** | | | | |
| **Co-Principal Investigator(s) (if any)**<br>**Organizational Location of Co-PI:** | | | | |
| **Key Functional Cores:** | | | | |
| **GCRCs** | | | | |
| **Partnering Organizations/ Institutions** | | | | |
| **External Advisory Committee Members** | Institution/Department/Organization | | | |
| **Scholars Supported in Year 1** | Discipline | Previous Pubs | Previous Grants | Mentors |
| **Trainees Supported in Year 1** | Discipline | Previous Pubs | Previous Grants | Mentors |

Second, the substudy will describe the general challenges and facilitating factors affecting the initial implementation phase across CTSA institutions. Because the implementation process often involves the need to modify or adapt the original plans to changes in local conditions, we will also identify the types of modifications and strategies that were necessary to move the implementation process forward.

Third, the substudy will conduct longitudinal case studies on a small sample of six CTSA institutions, focusing on the process of how these CTSA institutions were able to create an academic home for clinical and translational science and on the internal and external variables that shaped the implementation process.

Fourth, the case studies will examine the success of the CTSA institutions in implementing the recommendations about best practices from the National CTSA Consortium. The case studies will involve structured site visits and followup telephone contacts to selected institutions, thereby allowing for the observation and documentation of both the implementation process and subsequent development.

Finally, the substudy will identify innovative activities and programmatic elements created by the CTSA institutions, with a particular emphasis on three areas: (1) changes to the institutional review process, (2) changes to the project management process, and (3) collaborations with industry and the local community.

One objective shared by the individual CTSA institutions involves streamlining the institutional review process. There is considerable variability in the amount of time required to complete an institutional review board (IRB) review of a new research proposal across the different CTSA institutions. Although some of this variability arises from the complexity of the proposal and the level of risk to potential participants, much of the variability can be

attributed to differences in the structure and process of the IRB system at each institution. The study team recommends that the duration of this review process be tracked across CTSA institutions for different types of proposals. Developing a taxonomic framework for grouping comparable proposals is a task that should be pursued in collaboration with the Institutional Review Subcommittee of the CTSA Consortium Oversight Committee.

The substudy research questions, methods, data sources, and proposed data analyses are shown below in **Exhibit 14.**

**Exhibit 14.**
**CTSA Implementation Substudy**

| **SUBSTUDY RESEARCH QUESTIONS** |
|---|
| 1. Which functional cores are implemented across the National CTSA Consortium? |
| 2. Are specific institutional characteristics associated with the successful implementation of each CTSA institution's functional cores? |
| 3. What are the barriers to implementation for each key functional core, and what strategies are evolving to overcome these barriers? |
| 4. How have the CTSA institutions succeeded in reducing the amount of time from protocol generation to implementation? |
| ***Methods*** |
| 1. Construction of a "CTSA snapshot" describing the salient characteristics of each CTSA institution at the time of award and at the end of years 1 and 3. |
| 2. Case studies of selected institutions visited during year 2 and institutional representatives interviewed during subsequent years, with site selection based on size and other characteristics of the academic health center (large versus small). |
| ***Data Sources*** |
| 1. CTSA grant applications. |
| 2. CTSA Annual Progress Reports. |
| 3. Case study visits and followup telephone contacts. |
| 4. Interviews with NCRR program officers. |
| ***Proposed Data Analyses*** |
| 1. Descriptive analyses of the characteristics of CTSA cohorts at the time of award.<br>a. Development of a qualitative coding manual for CTSA applications and Annual Progress Reports.<br>b. Frequencies of institutional characteristics at the time of award (e.g., size of CTSA institution, number of GCRCs, number and types of partners, types of training programs, location of the academic home within the university).<br>c. Implementation status for each key functional core at the end of year 1. |
| 2. Analysis of efforts to reduce the average time required to obtain local IRB approval for and implementation of the research projects.<br>a. Development of a taxonomy of the types of studies by risk status for various types of research proposals (with IRB subcommittee).<br>b. Average time by CTSA institution for local IRB review and decision by type of study or risk status by year.<br>c. Average time required by CTSA institutions to establish and approve contracts or subcontracts by year. |

| ***Proposed Data Analyses (Cont'd.)*** |
|---|
| d. Average time from NIH grant award to the recruitment of the first subject by CTSA by year.<br>e. Changes made to the IRB review process and the project implementation process at CTSA institutions. |
| 3. Qualitative analysis of CTSA case studies.<br>a. Differences in implementation issues between large and small CTSA institutions.<br>b. Major implementation challenges experienced and how these were addressed. |

## 3. Scholars and Trainees Career Pathways Substudy

A basic goal of the CTSA program is to enhance the discipline of clinical and translational science by recruiting, training, and retaining the next generation of clinical and translational research scientists. The Scholars and Trainees Career Pathways Substudy has two objectives: to document the extent to which these policy changes occur at the institutional and national level and to describe and monitor the career progression of the scientists who choose to acquire training in clinical and translational science programs. For the purposes of this substudy, scholars are defined as "individuals with a research or health professional, doctoral-level degree (or equivalent) who are receiving support while beginning and establishing their independent research careers," and trainees are defined as "individuals receiving support and education in research at the predoctoral level enrolled in graduate education."

We will monitor the activities of the National CTSA Consortium Education/Career Development Steering Committee. In a recent presentation about its goals, the Committee's chairperson indicated that the Committee will focus on developing national curricula on clinical and translational science and on defining the standards and competencies required for specific degrees and groups of learners. One result of this work will be efforts to create Web-based modules for core education to promote consistency across CTSA institutions. The Committee (in collaboration with NIH) scheduled a workshop in January 2008 to discuss core competencies in clinical and translational science. It will also be designing a Mentor Development Program. The Committee will hold an annual national meeting in collaboration with the Association for Clinical Research Training (ACRT). As part of the effort to monitor these activities, the process evaluation study will conduct semistructured interviews with ACRT representatives to obtain their perspectives on the Committee's activities, priorities, and accomplishments.

**Exhibit 15** summarizes the Scholars and Trainees Career Pathways Substudy research substudy questions, methods, data sources, and proposed data analyses.

**Exhibit 15.**
**Scholars and Trainees Career Pathways Substudy**

| SUBSTUDY RESEARCH QUESTIONS |
|---|
| 1. What are the demographic and professional characteristics of the scholars and trainees enrolled in clinical and translational science training programs? How demographically diverse are the scholars and trainees? |
| 2. What demographic and professional individual characteristics are associated with the successful completion of programs by scholars and trainees? |
| 3. What changes have created a clear career pathway for clinical and translational scientists? |
| ***Methods*** |
| 1. Review the aggregated annual statistics on the numbers and characteristics of trainees and scholars recruited and enrolled in educational programs. |
| 2. Monitor education- and training-related goal attainment in the CTSA institutional Annual Progress Reports. |
| 3. Monitor the accomplishments and plans for the National CTSA Consortium Education/Career Development Steering Committee. |
| ***Data Sources*** |
| 1. Scholars and trainees identified through the Annual Progress Reports. |
| 2. CTSA Institutional Annual Progress Reports. |
| 3. National CTSA Steering Committee Minutes for the Education/Career Development Steering Committee. |
| 4. Semistructured interviews with ACRT representatives. |
| ***Proposed Data Analyses*** |
| 1. Descriptive analysis of the demographic and professional characteristics of entering scholars and trainees. |
| 2. Descriptive and bivariate analyses of training program completion status.<br>a. Proportion of scholars and trainees who successfully complete their training program.<br>b. Association between individual-level scholar/trainee demographic and professional characteristics and the successful completion of training program and/or the attainment of the first institutional pilot study and NIH-funded grant.<br>c. Association of programmatic characteristics (e.g., extent and type of mentoring) with the successful completion of training program and/or the attainment of the first institutional pilot study and NIH-funded grant. |
| 3. Qualitative analysis of the types of national-level changes in the policies enacted to support the development of career pathways for scholars and trainees. |

## 4. Clinical and Translational Science Substudy

A goal of the CTSA program is to increase the amount of clinical and translational science that is conducted, with a particular emphasis on research that is conducted in community settings and on research conducted by transdisciplinary research teams. The Clinical and Translational Science Substudy is designed to construct an annual profile of clinical and translational science through a review of the funded clinical and translational science grant applications, with a more intensive focus on those funded by NIH.

The Clinical and Translational Science Substudy has three objectives. The first objective is to construct a profile of the funded clinical and translational science projects by funding source (e.g., NIH, other Federal agencies, non-Federal sources). For NIH-funded projects, this profile will show the NIH funding Institute or Center (including projects funded by two or more Institutes and Centers [ICs]), disease category, and target populations (especially pediatric populations). The second objective is to examine how NIH-funded clinical and translational science investigators are moving into community settings by assessing whether the proportion of these studies increases over time. To accomplish this, it will be necessary to establish a clear definition of "community-based settings" in collaboration with NCRR. The third objective is to determine whether NIH-funded CTSA investigators are collaborating on transdisciplinary research teams, both within and across CTSA institutions.

The specific substudy research questions, methods, data sources, and proposed data analyses are presented in **Exhibit 16**.

**Exhibit 16.**
**Clinical and Translational Science Substudy**

| **SUBSTUDY RESEARCH QUESTIONS** |
|---|
| 1. What proportion of the funded CTSA clinical and translational science (CTS) projects are funded by NIH? What other Federal agencies and non-Federal organizations fund CTS proposals? |
| 2. What are the populations, diseases, and conditions targeted by NIH-funded proposals, and by which ICs are these proposals funded? How many proposals are funded jointly by two or more ICs? |
| 3. What proportion of NIH-funded projects are conducted in community settings? |
| 4. What proportion of CTSA institutional resources are allocated to clinical trials, pediatric research, and AIDS-related research? |
| ***Methods*** |
| 1. Descriptive study of funded clinical and translational science proposals, with specific focus on NIH-funded projects. |
| 2. Longitudinal comparison of grant characteristics from CTSA institutions at years 1 and 3 of the substudy (changes over 2 years). |
| ***Data Sources*** |
| 1. CTSA Annual Progress Reports (to identify grant applications; peer-reviewed publications; and the percentage of resources allocated to clinical trials, pediatric research, and AIDS-related research. |
| 2. Computer Retrieval of Information on Scientific Projects (CRISP) database. |
| ***Proposed Data Analyses*** |
| 1. Descriptive analysis of the projects funded by NIH, other Federal agencies, and non-Federal sources. |
| 2. Descriptive profile of projects funded by NIH.<br>a. Proportion of NIH-funded projects meeting the definition of clinical and translational science by ICs.<br>b. Proportion of NIH-funded clinical and translational science research projects that include pediatric target populations.<br>c. Proportion of NIH-funded CTS projects by disease category. |

| ***Proposed Data Analyses (Cont'd.)*** |
|---|
| 3. Descriptive profile of the community-based settings in which NIH-funded projects will take place.<br>a. Proportion of funded NIH CTS projects by type of setting (e.g., community, inpatient settings).<br>b. Proportion of NIH-funded projects in which community-based physicians, practice-based research networks, or other community-based health care providers participate as investigators or co-investigators on the research team.<br>c. Changes in time in these proportions. |
| 4. Descriptive analyses of the percentage of CTSA institutional resources allocated to clinical trials, pediatric research, and AIDS-related research. |

## 5. Health Practices Substudy

Another goal of the CTSA program is to increase and accelerate the diffusion of best practices and products developed by the National CTSA Consortium to the health professional community. As used here, the term health professional community includes health care providers (e.g., physicians, nurses, dentists, allied health workers). This substudy has two main objectives: (1) to describe the specific products developed by the National CTSA Consortium for the health care provider community and (2) to describe the National CTSA Consortium's dissemination activities (including how various Consortium products were disseminated and to which groups). One focus of this substudy concerns the identification of "best clinical practices" and the ways that the practices labeled as such by the National CTSA Consortium were determined to be the best clinical practices.

The specific substudy research questions, methods, data sources, and proposed data analyses for the Health Practices Substudy are summarized in **Exhibit 17**.

**Exhibit 17.**
**Health Practices Substudy**

| **SUBSTUDY RESEARCH QUESTIONS** |
|---|
| 1. What "best clinical practices" did the National CTSA Consortium identify, and what process was used to determine that they were best practices? How were these disseminated and to whom? |
| 2. What approaches or strategies does the National CTSA Consortium develop for persuading health care providers to adopt best clinical practices or specific drugs or devices? What approaches does the National CTSA Consortium develop to persuade health care providers to engage more actively with academic health centers? |
| ***Methods*** |
| 1. Annual Web-based survey of PIs. |
| 2. Document review. |
| 3. Semistructured interviews with representatives of biomedical professional organizations. |
| ***Data Sources*** |
| 1. Annual Web-based survey of PIs. |
| 2. Annual Progress Reports (especially noteworthy accomplishments for the year). |
| 3. Minutes and reports of Consortium committees, subcommittees, and workgroups. |
| 4. Representatives from relevant biomedical professional organizations. |

| ***Proposed Data Analyses*** |
|---|
| 1. Descriptive analyses of best clinical practices.<br>a. Specific best clinical practices identified by the National CTSA Consortium, the diseases and target populations for which they are applicable, and the methods used to determine the best clinical practices.<br>b. The process of how these best clinical practices were disseminated and to what groups.<br>c. Proportion of CTSA institutions that adopted the best clinical practices. |
| 2. Descriptive analysis of National CTSA Consortium strategies for engaging health care providers and for increasing the adoption of best clinical practices.<br>a. Efforts by the National CTSA Consortium (especially the Community Engagement Steering Committee) to develop strategies to increase the awareness and adoption of best clinical practices.<br>b. Presentations by members of the National CTSA Consortium on topics related to specific best clinical practices and efforts to engage health care providers in clinical and translational science. |

## 6. Public Awareness Substudy

The sixth substudy addresses National CTSA Consortium activities directed toward the general public. The CTSA program seeks to build public knowledge and understanding of clinical and translational science, improve public support for research, and increase public participation in national and local research projects. The objectives of the Public Awareness Substudy include (1) documenting the initial (baseline) community outreach activities conducted by the CTSA institutions at their time of entry into the National CTSA Consortium (and identifying those that appear to be promising strategies), (2) describing and documenting the roles of local organizations and community groups that partner with the CTSA institutions and tracking the addition of new partners on an annual basis, (3) monitoring the changes in community recruitment and retention rates reported by the CTSA research projects over time (and identifying target population groups that have proven especially challenging to engage), and (4) describing and documenting the activities that the National CTSA Consortium has conducted to increase public awareness of and support for clinical and translational science.

Substudy research questions, methods, data sources, and proposed data analyses are summarized in **Exhibit 18**.

**Exhibit 18.**
**Public Awareness Substudy**

| SUBSTUDY RESEARCH QUESTIONS |
|---|
| 1. What activities or strategies has the National CTSA Consortium developed to increase public awareness of clinical and translational science? |
| 2. Are there specific population groups or disease-specific groups that the National CTSA Consortium has identified as challenging to recruit or retain in clinical and translational science studies? What strategies and approaches has the National CTSA Consortium developed to assist CTSA institutions in recruiting and/or retaining the specific populations for which it has adopted best practices? |
| 3. What community-based organizations, State and local programs, and other groups do CTSA institutions engage as partners? What national and professional organizations does the National CTSA Consortium engage as partners, and what roles do these groups play? |
| ***Methods*** |
| 1. Annual Web-based survey of PIs. |
| 2. Document review. |
| ***Data Sources*** |
| 1. Annual Web-based survey of PIs. |
| 2. Annual Progress Reports (especially noteworthy accomplishments for the year). |
| 3. Minutes and reports of Consortium committees, subcommittees, and workgroups. |
| 4. Interviews with representatives of national and professional organizations. |
| ***Proposed Data Analyses*** |
| 1. Descriptive analyses of National CTSA Consortium (especially the Community Engagement Steering Committee) public awareness strategies. |
| 2. Identification of specific population groups or disease-specific groups from the Annual Progress Reports and Community Engagement Steering Committee minutes.<br>a. Types of groups identified by CTSA institutions.<br>b. Types of CTSA institutional strategies identified.<br>c. Special focus on pediatric populations. |
| 3. Descriptive analyses of CTSA institutional partnerships.<br>a. Partnering organizations at entry into CTSA and each year thereafter.<br>b. Barriers to developing partnerships and how these are addressed.<br>c. Description of partnerships with industry.<br>d. Roles that partnering organizations play. |
| 4. Descriptive analysis of National CTSA Consortium relationships with national and professional organizations.<br>a. Types of relationships with national and professional organizations.<br>b. Perceptions of national and professional organizations toward the National CTSA Consortium. |

## Data Sources for the National CTSA Consortium Process Evaluation Study

The proposed data sources for the six substudies reflect our desire to minimize the burden that data collection would impose on the CTSA programs. Wherever possible, the design utilizes existing data collection activities, such as the CTSA Annual Progress Reports; minutes and work products from the National CTSA Consortium committees,

subcommittees, and workgroups; and CTSA institutional self-evaluations. Other sources reflect data that are routinely compiled for certain CTSA activities by NIH (e.g., the IMPAC II database on research projects). **Exhibit 19** identifies the specific data sources listed in **Exhibits 12, 14, 15, 16, 17, and 18**.

**Exhibit 19.**
**Data Sources Proposed for the Six Substudies**

| Data Sources | National CTSA Consortium Substudy | CTSA Implementation Substudy | Scholars And Trainees Career Pathways Substudy | Clinical And Translational Science Substudy | Health Practices Substudy | Public Awareness Substudy |
|---|---|---|---|---|---|---|
| Annual Progress Reports | X | X | X | X | X | X |
| IMPAC II Database and CRISP Database | | X | | X | | |
| National CTSA Consortium Minutes and Reports | X | | X | | X | X |
| CTSA Local Evaluation Reports | | X | | | | |
| Case Study Visits | | X | | | | |
| Annual Web-Based PI Survey | X | | | | X | X |
| Semistructured Interviews With National CTSA Consortium Committee Chairs and NIH Staff Members | X | | | | | |
| Semistructured Interviews With Biomedical Professional Organizations | | | X | | X | X |
| CTSA Web Site and Wiki | X | | | | | |
| PubMed | | | | X | | |

These data sources are briefly described in **Exhibit 20** below.

**Exhibit 20.**
**Summary and Description of Proposed Data Sources**

| Proposed Data Source | Description Of Data Source |
|---|---|
| *Annual Progress Reports* | The Annual Progress Report submitted by each CTSA to NCRR. Sections of the report from which data will be collected include information on investigators, scholars, and trainees; CTS Publications; Program Description; Highlights, Milestones, and Challenges Report; External Advisory Committee Report; Self-Evaluation Report; CTSA Components Report; and Technology Transfer Report.<br>Quantitative data will be aggregated across CTSA institutions to provide national totals as appropriate. |
| *IMPAC II Database and CRISP Database* | The NIH IMPAC II database will be used as a source of data on research proposals submitted for review by an NIH initial review group, summary statements, and funding decisions.<br><br>The CRISP database will be used as a source of data for obtaining the project abstracts. |
| *National CTSA Consortium Minutes and Reports* | Minutes, reports, and other documents generated by the National CTSA Consortium committees, subcommittees, and workgroups will be reviewed and coded for information on the number of participants, activities conducted, reports produced, and other actions taken. |
| *CTSA Local Evaluation Reports* | Each CTSA is required to conduct and report the results from a local evaluation of its program. These reports are included with the Annual Progress Report. The content of these reports will be monitored on an annual basis, and findings from the reports will be compiled, analyzed for content, and coded for use in the process evaluation study. |
| *Case Study Visits* | Case studies will be conducted based on a sample of CTSA institutions. Specific CTSA institutions will be selected based on the size of the program (large versus small) and other characteristics that may affect the implementation process. Discussion guides will be prepared for each CTSA visited and for followup telephone contacts. |
| *Annual Web-Based PI Survey* | The annual Web-based survey of the Principal Investigators will include questions concerning their perceptions about the National CTSA Consortium and about the activities conducted by the Consortium oriented toward the health care provider community. |
| *Semistructured Interviews With National CTSA Consortium Committee Chairs and NIH Staff Members* | Annual semistructured interviews will be conducted by telephone with the chairs of the National CTSA Consortium committees and NIH staff members to obtain information on committee goals, priorities, accomplishments, and satisfaction with the process. NIH staff members will also be questioned concerning their perceptions about the effectiveness of the National CTSA Consortium structure and activities. Discussion guides will be used for these interviews. |

| Proposed Data Source | Description Of Data Source |
|---|---|
| *Semistructured Interviews With Biomedical Professional Organizations* | Annual semistructured telephone interviews will be conducted with representatives from various biomedical professional organizations to examine their perspectives on the National CTSA Consortium activities and their effects on national clinical and translational science issues. Discussion guides will be used for these interviews. |
| *CTSA Web Site and Wiki* | The CTSA Web site and its Wiki represent important communication channels for the CTSA institutions. The Wiki will be monitored on a regular basis, and thematic coding will be carried out to track the types and numbers of uses made of the Wiki by CTSA institutions. A brief user survey will also be conducted annually regarding the CTSA Web site to obtain users' perceptions about the Web site and its features. |
| *PubMed* | The CTSA Annual Progress Reports will provide a list of peer-reviewed publications that included a CTSA institution's investigators, trainees, and/or scholars who received support from the CTSA institution. PubMed will be used as the primary data source for tracking the peer-reviewed publications of CTSA investigators, scholars, and trainees. |

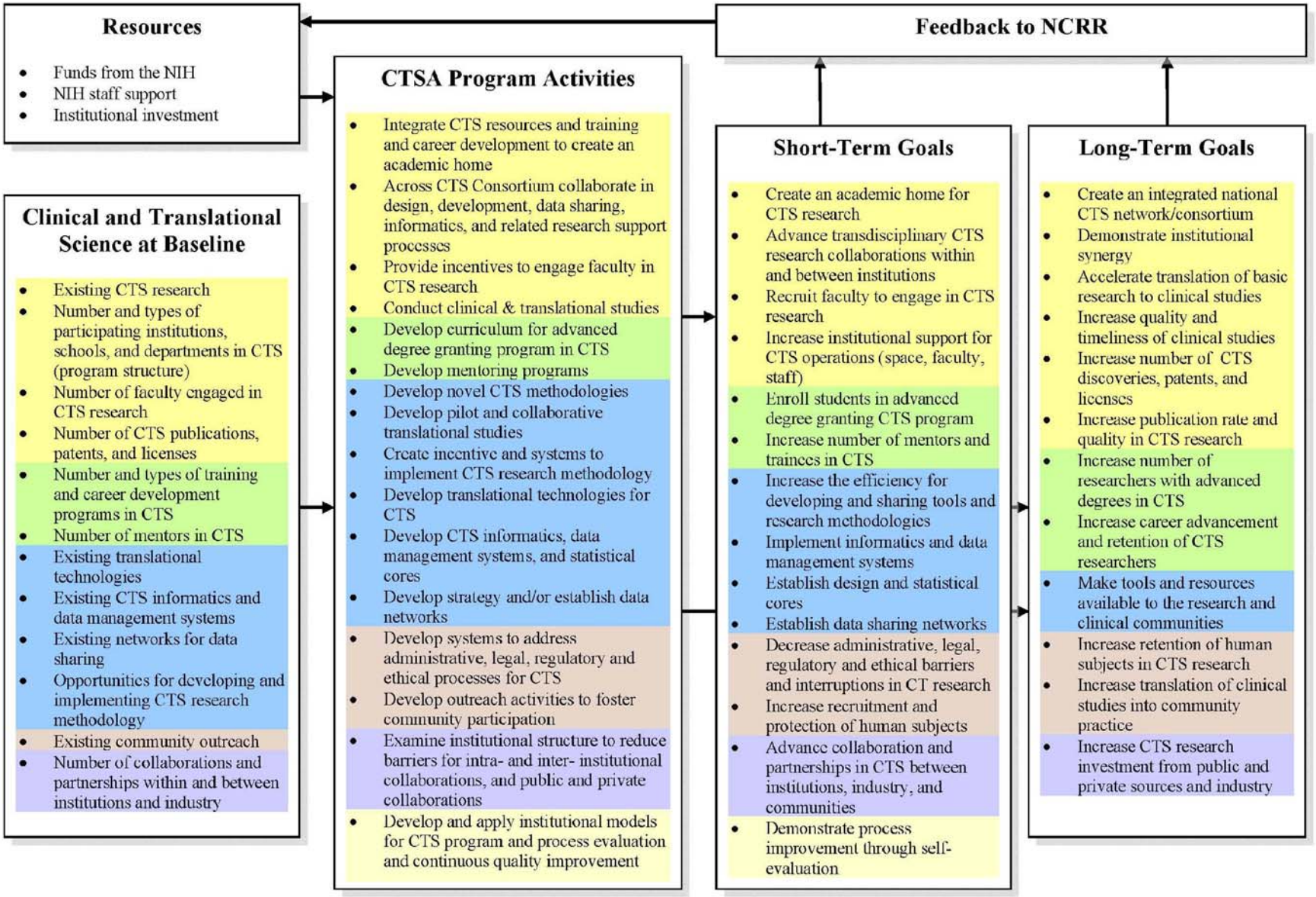
Although the proposed design utilizes existing reports and materials as data sources wherever practical, there are several issues that are not adequately covered by the Annual Progress Reports and other documents. Therefore, we recommend that certain information be collected annually through semistructured interviews and a Web-based survey. We recommend that several distinct groups of individuals be interviewed annually, including the Principal Investigators, chairs of the various National CTSA Consortium committees, and representatives from various biomedical professional organizations. The content of the interviews will be different for each group, as shown below in **Exhibit 21**.

**Exhibit 21.**
**Content of Proposed Data Collection Protocols**

| Respondent | Type of Instrument | Proposed Content |
|---|---|---|
| *Principal Investigators* | Web-based survey | • Perceptions about and satisfaction with the structure and activities of the National CTSA Consortium<br>• Participation in and satisfaction with collaborations with other CTSA institutions, including why and how the collaboration developed, the goals sought, whether these were achieved, the results of the collaboration, whether it continued on to include additional activities, and the level of satisfaction with the overall collaborative process<br>• Perception of NIH's role in the National CTSA Consortium<br>• Use of national communications tools and any suggestions for improvement |

| Respondent | Type of Instrument | Proposed Content |
|---|---|---|
| *Chairs of National CTSA Consortium Steering Committees* | Semistructured telephone interview guides | • Main goals and accomplishments of the Steering Committee during the past year<br>• Results achieved and satisfaction with these results<br>• Perceptions about and satisfaction with the structure and activities of the National CTSA Consortium |
| *NIH Staff Members* | Semistructured telephone interview guides | • Main goals and accomplishments of the Steering Committee during the past year<br>• Results achieved and satisfaction with these results<br>• Perceptions about and satisfaction with the structure and activities of the National CTSA Consortium |
| *Representatives From Biomedical Professional Organizations* | Semistructured telephone interview guides | • Perceptions of the CTSA program and the National CTSA Consortium, including its priorities, effects on other organizations and programs, and perceived effectiveness<br>• Nature of any joint activities conducted with the National CTSA Consortium<br>• Satisfaction with the role this organization is currently playing with the National CTSA Consortium<br>• Suggestions for improvement |

# APPENDIX A1: Draft Conceptual Framework of the National CTSA Consortium




Color Code Legend: **Yellow** – CTS Research; **Green** – CTS Training and Mentoring; **Blue** – CTS Methods and Technologies; **Tan**: CTS Community Liaison and Human Subjects Protection; **Lilac** – CTS Partnerships; **Light Yellow** – Evaluation and Quality Improvement

Note – NIH will also need to demonstrate how pediatric research is addressed in the CTSA Program

# APPENDIX 2: Topical Categories for Searches for Literature Review

## Background Topics

NIH Roadmap
Clinical & Translational Research
Industrialization of Medicine and Medical Research

## Methodology Topics

Evaluating Public Research & Development Programs
Evaluating Research Consortia
Evaluation Design: Frameworks for Evaluating Research Consortia
Evaluation of Specific Research Programs
Feasibility Studies for Designs of Outcome Evaluations
Measuring Race & Ethnicity
Measuring the Performance of Research Consortia
Research Productivity/Citation Analysis
Social Network Analysis
Use of Curriculum Vita as a Research Tool

## Other Relevant Topics

Academic Mentoring
Accelerating the Pace of Translation--Development Cycle Times
Community Engagement
Community-based Participatory Research
Collaborative Research (Scientists' Level)
Creativity
Diffusion & Adoption of New Technologies
Factors Affecting Career Trajectories
Interdisciplinary/Multidisciplinary
Pediatric Populations
Pediatric Research Consortia
Practice-based Research Networks
Public Attitudes toward Medical Research
Quality-Adjusted Life Years
Research Consortia & Partnerships
Research Subject Recruitment & Retention--Factors Affecting
Returns on Investment in R&D Programs
University-Industry Collaborations

# Appendix 3: Selected Evaluations of NIH Center Programs

| Program/Funding Institute(s) | Funding Mechanism(s) | Type of Evaluation | Purpose/Goals of the Evaluation | Methodology and Data Sources | Report |
|---|---|---|---|---|---|
| NIH General Clinical Research Centers (GCRCs), NCRR | M01 | Retrospective Evaluation | • To evaluate the effectiveness of the program after 30 years of operation<br>• To determine how the program can be improved. | • Review of extensive NIH files—GCRC Annual Progress Reports, GCRC CAP Applicant File, GCRC Funding Summary File, CGAF, TFF, IMPAC.<br>• Survey of NIH-funded clinical investigators at GCRCs.<br>• Survey of GCRC Principal Investigators.<br>• A follow-up survey of recipients of NIH career development awards.<br>• Interviews with NIH program staff and other officials.<br>• Panel to Formulate Recommendations | NCRR, 1996, Evaluation of the NIH General Clinical Research Centers (GCRC) Program: Final Report |
| Multipurpose Arthritis and Musculoskeletal Diseases Centers (MAMDCs); specialized Centers of Research (SCORs); and Skin Diseases Research Centers (SDRCs) | P60<br>P50<br>P30 | Program Assessment | • To review the existing Centers programs and to develop recommendations regarding the future structure of the Centers programs and their relative place among the Institute's various funding mechanisms. | • Working Group I comprised investigators affiliated with NIAMS Centers and non-affiliated investigators.<br>• Review of program materials describing the history and features of the various Centers funding mechanisms.<br>• Two meetings of Working Group II to review questions posed by Working Group I and background materials provided by NIAMS staff.<br>• Briefings by representatives from other NIH institutes regarding the nature of Centers programs in those settings, including NIDR, NEI, NIA, NIDDK, and NCI.<br>• Questionnaire sent to all NIAMS Centers Directors and non-Center affiliated investigators. | NIAMS, 1997. Executive Summary, Report to the Institute Director of the Centers Working Group II. |

| Program/Funding Institute(s) | Funding Mechanism(s) | Type of Evaluation | Purpose/Goals of the Evaluation | Methodology and Data Sources | Report |
|---|---|---|---|---|---|
| NICHD, Population Research Centers Program of the Demographic and Behavioral Sciences Branch, NICHD | P30<br>P50 | Program Assessment | • To evaluate the way in which NICHD has shaped the program over the last few decades through program guidelines and administrative actions and to explore strategies for the future.<br>• To assess how the Centers Program is meeting the needs of population research today, and whether there are different ways of structuring and competing the program to better serve the future of the science. | • Review of data summarizing the fiscal and scientific scope of the Centers Program.<br>• Interviews with key constituencies<br>• Review of comments received by the Branch regarding the Centers Program.<br>• Review of information on alternative models of structuring infrastructure support programs in the behavioral and social sciences.<br>• Request of comments posted on the Branch web-page.<br>• Review of historical data about the grant submissions and funding histories of NICHD-funded and non-funded population Centers. | NICHD. 1999. Report of the Demographic and Behavioral Sciences Branch Population Centers Review. |
| Centers for AIDS Research (CFAR) Program, NIAID, NICHD, NCI, NIMH, NIDA, NHLBI | P30 | Program Review | • To address the role of CFAR within the NIH AIDS research portfolio, the size of the program (e.g. number of Centers and total funding), the criteria to be considered in determining funding levels, the milestones for its evaluation.<br>• To determine what changes may further improve the CFAR program. | • A single focus group of external consultants, including: scientists representing a broad range of disciplines and experience with research Centers, scientists from Europe and Africa, a nonscientist member of the AIDS Vaccine Advocacy Coalition, discussants who were engaged in CFAR-related research activities, and two CFAR directors. | OAR, 1999. Report to the Director, Office of AIDS Research, of the Focus Group to Review the Centers for AIDS Research (CFAR) Program |
| Research Centers in Minority Institutions Program, NCRR | | Full-Scale Evaluation | • To measure the extent to which RCMIs improved in three areas: (1) competing for Public Health Service research grants, (2) publishing in peer-reviewed scientific journals, and (3) institutionalizing their research capacity. | • Survey of participating RCMIs<br>• Analysis of the correlation between RCMI activities and overall success. | NCRR, 2000. Evaluation of the Research Centers in Minority Institutions Program: Final Report 2000. |

| Program/Funding Institute(s) | Funding Mechanism(s) | Type of Evaluation | Purpose/Goals of the Evaluation | Methodology and Data Sources | Report |
|---|---|---|---|---|---|
| Specialized Centers of Research (SCOR) Programs, NHLBI | P50 | Program Review | • To review the SCOR mechanism, discuss its strengths and weaknesses, and develop recommendations to enhance the clinical focus and utility in SCOR programs. | • Review by an NHLBI extramural staff SCOR Reinvention Committee. | NHLBI, 2001. Report from the Committee to Redefine the Specialized Centers of Research Programs. |
| Research Centers Program, NCCAM | P50 | Program Review | • To determine whether modifications to the Research Centers organization and funding is merited.<br>• To consider the role that Research Centers have played in advancing NCCAM's mission and how that role should change in the future.<br>• To determine important characteristics for future NCCAM research Centers.<br>• To consider the most suitable funding mechanisms for various types of Centers conducting complementary and alternative medicine research. | • Expert panel review of the program.<br>• A single expert panel meeting considered input from Center Directors, NIH staff, and NCCAM staff. | NCCAM, 2002. NCCAM Research Centers Program Expert Panel Review. |
| Alzheimer's Disease Centers, NIA | | Program Review | • To consider what worked well during the first 20 years of the ADCC program and what had not.<br>• To determine whether the configuration of the Centers program is the best one for the foreseeable future.<br>• To suggest changes that would improve center operations and Alzheimer's disease research. | • Meeting of scientists from inside and outside the existing Centers to review and discuss descriptions of research in existing Centers and background material about the program.<br>• A second meeting of outside experts. | NIA, 2002. Report of the Alzheimer's Disease Centers External Advisory Meeting. |

| Program/Funding Institute(s) | Funding Mechanism(s) | Type of Evaluation | Purpose/Goals of the Evaluation | Methodology and Data Sources | Report |
|---|---|---|---|---|---|
| Research Centers: Exploratory Centers and Core Centers | P20<br>P30 | Center Self-Evaluations | • To determine whether the Centers are meeting their stated objectives and goals and to document what they have accomplished that they would not have been able to do without center awards. | • A plan for evaluating progress towards aims and/or goals of the Center is a requirement of the RFAs. | Findings from Center evaluations reported to the NINR Advisory Council.<br>NINR, 2002. Minutes of the Advisory Council of May 21–22, 2002. |
| Alcohol Research Centers, NIAAA | P50 | Feasibility Study | • To design a study to assess: the research productivity of Centers; the quality and merit of research conducted at the Centers; the advantages and disadvantages of specific center mechanisms; and the value added of Centers vs. independent research projects. | • Review of NIH and NSF center grant programs to ascertain comparison groups utilized and output measures examined.<br>• Review of NIAAA administrative records, IMPAC II, NSF awards database, citation database (ISI).<br>• Interviews of investigators<br>• Survey of PIs/administrators of Centers | NIAAA, 2002. Alcohol Research Center Program Evaluation Design. |
| Cancer Centers Program and Specialized Programs of Research Excellence (SPOREs), NCI | P30<br>P50 | Program Assessment | • To examine the P30 and P50 award mechanisms in terms of how they might best be positioned to support and facilitate increased discovery and translation of research into the future.<br>• To assess the current status and accomplishments of the cancer center and SPORE programs, plot directions for future growth, evaluate management and budgetary policies, and explore mechanisms for enhancing interactions between NCI, cancer Centers, SPOREs, and other critical partners in cancer research. | • Six Ad Hoc P30/P50 Working Group meetings over a six-month period.<br>• Review of data on the history, budget, and operations of the cancer center and SPORE programs.<br>• Testimony from a variety of NCI and federal agency personnel, cancer Center directors, and representatives of state, professional, and scientific organizations.<br>• Survey of P30 cancer Center directors designed with input from the Association of American Cancer Institutes (AACI) | NCAB, 2003. Advancing Translational Cancer Research: A Vision of the Cancer Center and SPORE Programs of the Future. Report of the National Cancer Advisory Board Ad Hoc P30/P50 Working Group. |

| Program / Funding Institute(s) | Funding Mechanism(s) | Type of Evaluation | Purpose / Goals of the Evaluation | Methodology and Data Sources | Report |
|---|---|---|---|---|---|
| NINDS, Udall Parkinson's Disease Research Centers | P50 | Feasibility Study | • To ascertain the feasibility of identifying the most relevant measures for tracking future progress, developing strategies to improve the program's effectiveness, and improving program management<br>• To determine the optimal design of the full-scale evaluation | • Review of IMPAC II (including CGAF and TFF), CRISP, center applications and annual progress reports, annual budgets, Thompson ISI, PubMed, Udall center websites, RFAs and Pas, NIH Parkinson's Disease Research Agenda, Morris K. Udall Parkinson's Disease Research Act of 1997.<br>• Surveys of Center staff, NINDS staff, NIH staff managing other center programs, panel of Parkinson's Disease experts, leaders of organizations promoting Parkinson's disease research. | NINDS, 2005, Final Report: A Feasibility Study for the Evaluation of Parkinson's Disease Research Centers: Assessment of Approaches and Development of an Evaluation Plan. |
| Centers for AIDS Research (CFAR) Program, NIAID, NICHD, NCI, NIMH, NIDA, NHLBI | P30 | Feasibility Study | • To determine whether an outcome evaluation of CFAR is warranted and feasible.<br>• If warranted and feasible, to make recommendations regarding the design of an outcome evaluation. | • Consultation with CFAR stakeholders including NIAID program staff, CFAR Steering Committee Members and CFAR Principal Investigators (PIs) (two focus groups of PIs were convened.).<br>• Development of a provisional logic model.<br>• Review and analysis of existing data on CFARs and potential comparison groups including previous program reviews of CFAR; meeting minutes, RFAs, and other historical documents; Funded Research Base (maintained by OAR/NIH); Medline publication list of CFAR-affiliated personnel; and Annual Progress Reports submitted by CFAR PIs. | Science and Technology Policy Institute for NIAID, 2006. Feasibility Study for an Evaluation of the Centers for AIDS Research |

| Program/Funding Institute(s) | Funding Mechanism(s) | Type of Evaluation | Purpose/Goals of the Evaluation | Methodology and Data Sources | Report |
|---|---|---|---|---|---|
| NINDS, Udall Parkinson's Disease Research Centers | P50 | Full-Scale Evaluation (Process and Outcome Evaluation) | • To determine the degree to which the program operated as intended and met the goals stated in the 1997 and 1998 RFAs.<br>• To determine the extent to which predictor variables impacted the short- and long-term goals of the program. | • Primary data collection through semi-structured interviews with PIs and project/core leaders and web-based surveys of Center investigators and comparison group (R01) investigators<br>• Thematic analysis of qualitative data<br>• Secondary data collection and analysis of application materials, publications (PubMed), and grant funding histories (IMPAC II, CGAF)<br>• Working Group of Advisory Council to inform design and conduct of the evaluations and make recommendations to NINDS | NINDS, 2007, Evaluation of the NINDS Morris K. Udall Parkinson's Disease Research Centers of Excellence Program—Data Report<br><br>NINDS, 2007, Report of the Working Group of the National Advisory Neurological Disorders and Stroke (NANDS) Council: Recommendations for the Udall Centers of Excellence in Parkinson's Disease Research Program. |

# APPENDIX 4: CTSA Interviews with Biomedical Professional Organizations

## INTERVIEW PROTOCOL

1. How familiar are you with the CTSA Program? What has been your involvement (if any) with the Program?

2. What information has your organization received on the CTSA Program?

3. From your perspective what is the CTSA Program trying to accomplish?

4. As you learned in the email you received from NCRR, The Madrillon Group, under contract with NCRR, is designing a national evaluation of the CTSA Program. The goals of this evaluation are to determine the impact of the CTSA program in transforming the following six domains/categories: scientists; academic research institutions; the CTSA Consortium; clinical and translational science; health practice; and community and society. Which of these areas are most important to the mission of your organization?

5. From your perspective what are the key issues and challenges in designing an evaluation of the CTSA Program?

6. From your perspective, what are the most important measures in terms of determining the impact of the program on:

   - Clinical and translational science?

   - Health practice?

   - The community and society?

7. What kinds of information would you like to receive on the Program's performance?

8. How would you like to receive this information? Written reports, website, news briefs, oral briefings, presentations at national conferences?

9. How would you use this information?

10. Is there anything I haven't covered that you would like to mention?

# APPENDIX 5: Sample Discussion Guides For Informational Visits

**Sample Discussion Guides for the Principal Investigators at each of the two sites are presented. Specific guides were developed for each individual with whom the team met.**

**DISCUSSION GUIDE**
**PRINICPAL INVESTIGATOR AND ADMINISTRATION, SITE #1**

Good Morning.

What we would like to do during the next hour is to explore with you several structural and organizational factors and processes that may have had an effect on the overall implementation of the Clinical and Translational Science Institute here at Pitt.

Let's begin with Organizational Structure.

1. Now let's talk about your Organizational Structure. One of the interesting themes you outlined in your Annual Progress Report had to do with an internal debate you were having about locating the CTSI in a single physical center versus establishing more of a "CTSI corridor", with various functions or cores clustering together. Can you tell us what the arguments are on either side, and where this issue stands at present?

    a. How would your organizational structure adapt under either model?

    b. What problems or challenges have you faced this year in creating the organizational structure you are working toward? How have you handled them?

    c. In what ways has the internal organizational structure of the University affected your implementation efforts?

    d. How have you been able to reach out to schools beyond the School of Medicine (for example Nursing, Dentistry, Public and International Affairs) through your organizational structure?

    e. How has your organizational structure helped you or hindered you in implementing the other parts of the CTSI?

2. The next area we'd like to explore is Organizational Culture. Is there an "organizational culture" within the biomedical research community here at Pitt? For example, what are the norms here for data sharing within a department? A school? Across schools? Do investigators consider sharing data between Universities? Is trans-disciplinary collaboration common here, or is it something that is going to have to be carefully cultivated and nurtured?

    a. What aspects of this organizational culture have helped you to implement the CTSI? What aspects have been more challenging to address? How have you done that?

    b. To what extent do "silos" exist here at the University? What are some of these silos? What have you done during this first year to open them up?

3. It's clear from reading your Annual Progress Report that you have been very successful in eliciting institutional commitment and support from the University—can you tell us about some of the ways this support has been shown, and tell us how you have been able to do that? Why you think you have been so successful in this area?

    a. To what extent do you believe that your position as Vice Chancellor for Clinical Research Health Sciences has helped in eliciting support from the University?

b. Are there any areas where you are not getting the degree of institutional support and commitment you would like? How are you handling that?

c. How has this support and commitment affected your ability to implement other portions of the CTSI?

4. Another topic we'd like to discuss is how the CTSI relates to other centers and major programs here at the University. Can you tell us about what you had hoped to accomplish in connecting to other programs here?

   a. What kinds of relationships have you been able to form with these other programs? Are these relationships collaborative? Competitive? Totally detached from these other centers?

   b. What effects have these relationships had on your implementation process?

5. The last major area we'd like to explore with you has to do with the 'branding" of the CTSI—how well you have been able to create the organizational identity you want with the administration and staff at Pitt, the surrounding community, and other stakeholders.

   a. In terms of creating this understanding and awareness of your existence and mission, what had you hoped to accomplish during the first year? How have you set about doing it?

   b. Which groups are you still trying to reach?

   c. How did the retreat you held earlier this spring fit into this effort—can you tell us more about that?

   d. Thinking about public attitudes toward medical research, how do you think the public regards clinical and translational research at Pitt?

6. Finally, what would you say have been some of the most important lessons you've learned this year about implementing the CTSI program here?

**DISCUSSION GUIDE**
**CO-PRINCIPAL INVESTIGATOR**

Good morning.

What we would like to do during the next half-hour is to explore with you the role that several structural and organizational factors may have played in shaping the implementation of the ___.

1. Let's begin with Organizational Structure. How did the ____ come to partner with the ___?

    a. What is the Principal Investigator's position here? What is your position here? Have you worked together before (and on what?)

    b. To what extent do you believe that your respective positions have contributed to the success you have had in implementing the ___?

    c. What kinds of collaborations had taken place between ___ and ____ in the past, and how does this initiative fit into that history?

    d. What are some of the challenges your respective institutions have faced in bringing this partnership together?

2. One of the points noted in the Annual Progress Report concerned the differences in the research organizational cultures between ____ and ____. Tell us about the research organizational cultures in these two institutions; how they are alike or dissimilar?

    (For example, to what extent do researchers here tend to collaborate across disciplinary lines?)

    a. Are there some specific elements of the organizational culture at ____ and ____ that have helped you implement the ____? What are these?

    b. Are there some specific elements of the organizational culture at ____ and ____ that will need to change in order for the ____ to become what you envisioned it to be?

    c. How are you working to change these elements in order to implement the ____?

    d. To what extent do "silos" exist at ____ and ____? What strategies are you employing to eliminate these silos?

3. How successful do you feel that the ____ has been in obtaining the institutional recognition, support, and commitment that you need to implement the program?

    a. What factors do you feel have contributed to (or impeded) your gaining the institutional recognition and commitment to the ____?

    b. To what extent have you been successful in leveraging additional support (funding, space, other resources) from other parts of the ____ and ____ organizations? What do you feel accounts for this?

**DISCUSSION GUIDE**
**PRINCIPAL INVESTIGATOR**

Good afternoon.

What we would like to do during this final hour is to explore with you the role that several structural and organizational factors may have played in shaping the implementation of the ____.

**Note: Because this is our final interview here, it is likely that there may be some questions we will want to ask that arise from what we have already heard from other interviewees. Those questions should receive precedence here. This is also a good opportunity to summarize and recap what we think we have heard and learned and ensure that we are getting this clearly.**

1. "Branding" of the ____. Let's begin by talking about the "brand" of the ____—how well you have been able to create the organizational identity you want within ____ and ____ (administration, faculty, staff) and the surrounding community.

    a. What was your original vision for the ____—what do you hope that it will accomplish?

    b. To what extent have you been successful during this first year in creating that organizational identity?

    c. What challenges have you encountered in creating this identity?

    d. Have you changed your vision of the ____ in any ways over this first year? How (and why)?

    e. Are there any groups that you feel you have not adequately reached yet, and what are your plans for connecting with them?

2. Institutional commitment and support. How successful have you been in obtaining the institutional commitment and support you want for the ____ during this first year?

    a. What forms has this institutional commitment and support taken? To what extent have you been successful in leveraging additional support (funding, space, other resources) from other parts of the ____ and ____ organizations?

    b. What factors have helped you to do this? What factors have hindered your success?

    c. Are there any areas of the ____ for which you are not getting the commitment and support you want? What are these areas, and why do you think you are not getting this support?

3. Lessons Learned. Finally, what would you say have been some of the most important lessons you've learned this year about implementing the ____ program?

# Appendix 6: Bibliography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