

The Clinical and Translational Science Awards (CTSA) Consortium Governance Manual

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Clinical and Translational Science Awards (CTSA) Consortium Governance

Part 1. Overview and Goals of the NIH CTSA Consortium

A. Background

The National Institutes of Health (NIH) engaged in a series of initiatives collectively known as the “NIH Roadmap for Medical Research” (<http://nihroadmap.nih.gov/>) that promote clinical and translational investigation and aim to improve health and prevent disease. The CTSA consortium was envisioned as an NCRP program that drew on the NIH Roadmap initiative to re-engineer the clinical and translational research enterprise. The consortium was launched incrementally starting in 2006.

B. CTSA Consortium Mission, Scope and Goals

The goal of the Clinical and Translational Science Award (CTSA) program is to improve human health by transforming the research and training environment thereby enhancing the efficiency and quality of clinical and translational research.

CTSA consortium institutions bridge basic, clinical and translational research to bring effective strategies and treatments into clinical practice more rapidly. A major goal of the CTSA program is to create an environment that will overcome challenges and impediments to clinical and translational science. The consortium works towards adopting and implementing agreed-on best practices, policies, procedures, and other measures to advance collaborative clinical and translational research while reducing burdens on individual investigators.

The CTSA consortium, when fully implemented, will link about 60 institutions to energize the discipline of clinical and translational science.

C. Cooperative Agreement Funding Mechanism

The National Center for Research Resources (NCRP) administers the CTSAAs as cooperative agreements. The cooperative agreement is an "assistance" funding mechanism (rather than an "acquisition" mechanism) in which substantial NIH programmatic involvement with the awardees occurs during the performance of the program activities. Under the cooperative agreement mechanism, the NCRP

stimulates, guides, coordinates or participates in project activities and is involved substantially with award recipients. The NIH supports and stimulates the awardees' activities by working jointly in a partner role, but does not assume direction, prime responsibility or a dominant role. The specific tasks and activities in carrying out project activities will be shared among the awardees and the NIH Project Scientists and/or NCRR Program Officials. Those aspects of the cooperative agreement partnership between the awardees and the NIH are also applicable to activities of the national CTSA consortium.

Part 2. CTSA Consortium Leadership and Decision-Making

A. Consortium NIH Advisory Bodies

1. NCRRC National Advisory Research Resources Council

Members of the National Advisory Research Resources Council (NARRC) along with additional *ad hoc* external consultants provide the NCRRC Director with advice and guidance on CTSA activities.

2. NIH Institute and Center (IC) Directors CTSA Advisory Board

The NIH IC Directors Advisory Board is a forum at which NIH leadership can communicate community and trans-NIH input concerning the CTSA Consortium to the NCRRC Director, and where CTSA functions, goals and budgets can be reviewed. Membership comprises five IC Directors, one of whom is chair, and two NIH Office of Portfolio Analysis and Science Policy representatives, *ex officio*. Members serve three-year terms with the possibility of reappointment. The Board meets at least quarterly.

B. CTSA Consortium Steering Committee Roles and Responsibilities

1. CTSA Consortium Steering Committee

The CTSA Consortium Steering Committee (CCSC) is the core governing and decision-making body of the CTSA consortium. The CCSC comprises the PIs of each CTSA site, trans-NIH representatives as voting members and non-voting NCRRC program staff. CTSA sites with multiple PIs are free to send all PIs to CCSC meetings, but only one is identified to vote for the institution. CCSC co-chairs are elected from among the non-Federal members by a simple majority vote of the CCSC for a one-year term of service. Co-chairs serve as co-chairs-elect for the first 6 months of office and then for a year as co-chairs. On retirement, they are invited to join the committee that nominates the next co-chairs-elect. New members enlarge the committee when additional CTSA sites are funded.

The CCSC proceeds by consensus when possible. For decisions requiring a vote, each CTSA has one vote (multi-PIs decide amongst themselves who should vote) while the fraction of NIH votes is adjusted to be one-third of the CCSC total. Passage of any voting issue (including those that are associated with resource ramifications) will require a 2/3 majority vote of the CCSC. Voting may be conducted at meetings or by teleconference, appropriate web tools and electronic or regular mail. The CCSC meets in person at least once a year. Each CTSA institution must agree to work toward adopting and implementing the policies and best practices that are approved by the CCSC.

The CCSC:

- Sets Strategic Goals and priorities, approves projects and ensures progress
- Works through the CTSA committees, including the Executive Committee, to identify and implement consortium plans and mission
- Refines consortium governance
- Discusses opportunities and impediments
- Identifies and addresses broad issues impeding clinical research
- Identifies and approves best practices and policies that will advance clinical and translational research as a discipline
- Facilitates collaboration and sharing among CTSA institutions and with other partners in clinical and translational research, e.g., industry, laboratories, hospitals
- Receives annual reports from CTSA Consortium Key Function Committees including identification of their respective topic Groups and responds to their recommendations for consortium-wide implementations

2. CTSA Consortium Executive Committee

The CTSA Consortium Executive Committee (CCEC) comprises the CCSC co-chairs and co-chairs-elect; ten CTSA member PIs, elected by simple majority vote to represent themselves as well as the other PIs; and three NIH members designated by the NCCR Director. The members serve for one year with the potential of re-election for two additional years. The CCEC is chaired by the co-chairs of the CCSC.

The purpose of the CCEC is to enhance the efficiency of interactions between the CTSA PIs, the NIH/NCRR and other committees. The CCEC takes the lead on timely action of emergent CCSC issues and reports to the CCSC. Executive functions delegated to the CCEC by the CCSC provide this group with the authority to act upon recommendation from Strategic Goal Committees (SGC) or Key Function Committees (KFC) and to ensure that relevant aspects of the Strategic Goals are implemented by either a KFC or by a multi-disciplinary group (described further below). Voting may be conducted at meetings or by teleconference, electronic or regular mail and requires a 2/3 majority vote of the CCEC.

The CCEC:

- Monitors and manages strategic priorities
- Makes decision on committee membership
- Identifies need and sources for resources
- Responds to day-to-day issues
- Reports to the CCSC

3. CTSA *ad hoc* Governance Group

A subgroup of the CCSC, comprising four PIs, two NIH representatives and *ad hoc* members may meet twice yearly as needed to review CTSA consortium governance and to report recommendations regarding updates and amendments to the CCSC. The Governance Group advises the CCSC regarding CTSA committee structures, CTSA committee meeting frequencies, CTSA committee evaluation criteria including criteria for dissolution of committees, and generation of CTSA policy.

4. PI Liaisons

The CCSC identifies PIs who serve as liaisons to KFCs and their constituent Groups for one to two years, and this appointment is renewable indefinitely. The selection may be based on volunteering or may involve election in the case that a large number of PIs wish to assume this role. In a liaison role, PIs function as a sounding board for KFCs and their Groups, sharing the CCSC's priorities with members of the committees. They coordinate and integrate the activities and priorities of the KFCs or their Groups with those of the Strategic Goal Committees and the CCSC and should be available to participate in major meetings of the cognate KFCs or their Groups. They are included in all communications. The PI

liaisons are knowledgeable about KFC or Group activities, priorities and milestones and serve as their advocates in CCSC meetings. Initiatives emanating from the KFCs will be brought forward to the CCEC or full CCSC by the PI liaisons.

The CCSC identifies PIs who serve as liaisons to NIH ICs. In this liaison role, PIs serve as points of contact for IC leadership with questions or recommendations for the consortium and actively participate in IC functions such as Board and Council meetings to increase member knowledge about the goals and implementation of the consortium and its relevance to ongoing IC-funded research and new initiatives.

C. Cooperative Agreement Administration

1. Principal Investigator (PI) and Awardee Rights and Responsibilities

The CTSA Principal Investigators have the primary responsibility to define objectives and approaches of the CTSA and bear overall responsibility for that institution's participation in the CTSA consortium.

The primary responsibilities of the awardees are to:

- Support the key functions described in their applications
- Collaborate with other CTSA to work towards adopting and implementing the agreed on policies, procedures, best practices, or other measures established by the CTSA Consortium Steering Committee
- Provide information to the NCRP Program Official, staff advisor(s) and NIH Project Scientists concerning progress
- Maintain career development opportunities to encourage new investigators to work in clinical and translational science

Awardees will retain custody of and primary rights to their data and intellectual property developed under the award subject to current government policies regarding rights of access as consistent with current DHHS, PHS, and NIH policies. Principal Investigators and key personnel, as appropriate, are expected to participate in CTSA Consortium Steering Committee meetings.

2. NCRR CTSA Program and Grants Administration Teams

NCRR appoints a Program and Grants Administration Team to each CTSA that always comprises a Grants Management Specialist and a Program Official and may include a Project Scientist(s).

a. NCRR Grants Management Officers and Specialists

Grants Management Officers (GMOs), or designees, are responsible for the business administration of the CTSA's and for resolving non-programmatic questions including the applicability of DHHS and NIH grant policies. GMOs ensure that NIH and grantee staffs fulfill requirements of laws, regulations, and administrative policies. Also, the GMO or his/her designee with Program Officials and other staff may perform visits to CTSA organizations whenever necessary to carry out his/her responsibilities for evaluating and monitoring the business management practices of such organizations.

The GMO has sole responsibility to sign Notices of Award (NoA) or to change the funding, duration or other terms and conditions of award, including replies to requests for prior approvals. The GMO is responsible for providing clarification or enforcement of statutory, regulatory or administrative assistance policy requirements. The Grants Management Specialist (GMS) is the agent of the GMO. The GMS provides the business management expertise for an assigned portfolio of CTSA's and works closely with the assigned Program Official. Certain tasks, such as responding to grant related correspondence, may be delegated by the GMO to the GMS.

b. NCRR CTSA Program Officials

NCRR Program Officials are scientists who provide the scientific expertise for the typical programmatic stewardship of assigned CTSA's and are named in the award notice.

Typical Program Official stewardship includes:

- Approval of awardee plans prior to award and review of performance after completion
- Evaluation of progress by reviews of technical or fiscal reports or by program visits, to determine that performance is consistent with objectives, terms and conditions of the award; this may include external reviewers

- Technical assistance requested by awardees, or correcting programmatic or financial deficiencies in awardee performance
- Scientific and technical discussions with awardees, or actions to facilitate or expedite interactions between awardees; e.g., organizing and holding meetings of investigators

Additionally, the NCRRTS CTSA Program Officials may recommend the termination or curtailment of an investigator or project/program (or an individual award) in the event the partnerships fail to evolve within the intent and purpose of this initiative. The Program Official and the GMO function in concert to provide overall stewardship of the CTSA.

NCRRTS Program Officials:

- Participate as non-voting members of relevant CTSA committees
- Serve as coordinators of KFCs and/or SGCs, providing liaison to NCRRTS, supporting committee activities and meetings, and coordinating approaches, projects and programs between CTSA committees
- Assist the partnership efforts by facilitating access to fiscal and intellectual resources provided by NIH, industry, private foundations and federal funding agencies
- Ensure that activities proposed for development or implementation at CTSA do not overlap or duplicate activities supported by Research Centers at Minority Institutions Infrastructure Grants, Minority Biomedical Research Support Grants or other peer-reviewed funding mechanisms
- Interact with each CTSA, coordinate approaches between CTSA, and contribute to the adjustment of projects/programs or approaches as warranted
- Provide assistance in reviewing and commenting on all major transitional changes of an individual CTSA's activities prior to implementation to ensure consistency with the goals of this RFA
- Link the approaches developed from these partnerships to each other and to other NCRRTS-supported Centers and Consortia to ensure that information is shared and utilized on the widest basis possible
- Monitor institutional commitments and resources to ensure that the partnership receives the maximum chance of stabilization and success

c. NCRR CTSA Project Scientists

NCRR Project Scientists have substantial scientific involvement during the conduct of this activity, through technical assistance, advice, and coordination beyond normal program stewardship for grants. One or more Project Scientists may be assigned by the NCRR to each CTSA.

NCRR Project Scientists:

- Coordinate activities at the designated CTSA with other ongoing studies supported through NCRR to avoid duplication of effort and encourage sharing and collaboration in the development of new clinically useful agents and methodologies
- Review and comment on critical stages in the implementation of the program
- Assist in the interaction between the awardee and investigators at other institutions to promote collaborations
- Coordinate access to other resources available through CTSA including access to specialized technology cores
- Assist with technical monitoring to permit kinds or directions of work
- Participate on committees as voting members as needed or in other functions to guide the course of long-term projects or activities
- Retain the option of recommending termination of support if technical performance or implementation falls below acceptable standards, or when specific key resources cannot be effectively implemented in a timely manner
- Retain the option to recommend additional infrastructure support within the constraints of the approved research and negotiated budget
- Coordinate activities for the CTSA institutions to participate in the national program evaluation and work with NIH evaluation officials and other evaluation staff
- Call additional meetings/workshops of CTSA to address emerging areas of high priority
- Are not involved in normal programmatic stewardship

3. NIH Staff Advisor Roles and Responsibilities

NIH staff advisors are trans-NIH representatives to the CTSA program who provide technical assistance, advice and coordination beyond normal grant stewardship, through the CCSC, the KFCs and their topic Groups. One or more NIH staff advisors may be assigned by the NCRR to each CTSA Key Function Committee (KFC). A number of NIH staff advisors on a KFC will be designated voting members; the fraction of NIH votes is adjusted to total one-third of the committee. A given individual may serve on more than one CTSA committee. To help carry out these duties, NIH staff advisors may consult with non-NIH experts in the field.

NIH staff advisors:

- Participate as members of the CTSA Consortium Steering Committee (CCSC), KFCs and their topic Groups
- Coordinate activities at academic institutions having CTSA with the priorities of the CTSA Consortium Steering Committee (CCSC) to avoid duplication of effort and encourage sharing and collaboration
- Review and comment on the implementation of consortium SGs and KFC recommendations

NIH CTSA staff advisors are recommended by NIH IC Directors for two-year terms, renewable, with additional membership to ensure adequate scientific expertise and representation for FDA, CDC and other relevant organizations, agencies and bodies, as required. All NIH CTSA staff advisors, Project Scientists, Program Officials and points of contact for evaluation, budget, and grants management can be NIH representatives to the CTSA program. Meetings of the NIH CTSA staff advisors and committee coordinators can be called annually; all-hands meetings of NIH staff advisors to the CTSA program are coordinated by co-chairs comprising an NCRR staff member and another IC representative. Additional meetings or conferences are called by the co-chairs or membership as required. The meetings serve as a forum in which CTSA program operations and evaluations are discussed NIH-wide and in which recommendations are formed by majority opinion. Interactions between the NIH CTSA staff advisors and CTSA awardees occur through NCRR Program Officials and the CTSA Consortium Steering Committee and KFCs.

4. Arbitration Process

Disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to arbitration. An Arbitration Panel composed of three members will be convened. It will have three members: a designee of the CTSA Consortium Steering Committee chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two. In the case of individual awardee disagreement with NIH, the first member may be chosen by the individual awardee. This special arbitration procedure in no way affects the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulations 42 CFR Part 50, Subpart D and DHHS regulations 45 CFR Part 16.

Part 3. CTSA Consortium Activities

A. Consortium Strategic Goals

The CTSA consortium encourages cooperative enterprises that promote clinical and translational science, the training and career development of clinical researchers. Through a stepwise approach, the CCEC identifies, defines, refines and updates Strategic Goals for the CTSA consortium. This is a dynamic process that directly reflects the dynamic nature of the consortium and its mission.

B. NIH CTSA Meetings and Workshops

Scientific workshops and *ad hoc* meetings related to and in support of CTSA clinical and translational research and resources may be proposed by NIH Project Scientists, staff advisors or Program Officials, the CCSC, SGCs or KFCs. Proposed meetings and workshops will be considered and must receive approval by two-thirds of the CCSC if consortium resources, e.g., such as travel funds, faculty staff effort, etc, are to be used.

C. Strategic Goal Committees

The primary focus of the CTSA consortium is achieving the Strategic Goals identified by the CCEC. Consortium-wide resources will be directed to the Strategic Goals to ensure that the CTSA organization has identifiable timelines, objectives, milestones and outcomes. Strategic Goal Committees (SGC) will be identified and will have responsibility for the achievement of Strategic Goals identified by the CCEC via coordination with appropriate Key Function Committees and their topic Groups. SGC representatives will report to the CCEC during their regular teleconferences.

Two PIs, one of whom is a CCEC member, lead each SGC. Three non-Federal members of the CTSA Administration Committee are appointed as members of each SGC. NIH staff advisors equal to one-third of the non-Federal voting membership are also appointed to the SGC. Each SGC is coordinated by an NCR staff member who typically is also coordinator of the primary KFC that supports the SGC.

SGC PIs work with the CCSC, CCEC and content experts to devise a charge with deliverables for each of the goals and are guided as needed by the implementation steps delineated in the strategic planning process.

SGCs incorporate input and expertise from relevant KFCs and other expertise as needed. These subject experts may serve as members of each SGC. Communications and interactions between SGCs and KFCs are bi-directional.

The existing committee structure will be continuously undergoing systematic examination so that it is optimized to support the Strategic Goals of the consortium while also providing important networking and synergizing functions to improve and support local CTSA operations. The SGCs may charter working teams that are created to address a defined issue and disband upon accomplishment of their goals

The SGCs:

- Provide clarification and definition to goals, priorities and projects that have been identified by the CCEC/CCSC.
- Oversee progress in meeting identified Strategic Goals
- Identify resources needed to achieve Strategic Goals
- Create working groups as needed
- Discuss opportunities and impediments
- Periodically reassess and reprioritize components of Strategic Goals
- Report to the CCSC and CCEC

D. Child Health Oversight Committee

The Child Health Oversight Committee (CHOC) provides a unique national forum for CTSA investigators and NIH scientists to identify collaborative opportunities to facilitate pediatric and translational research. The CHOC identifies barriers and collaborative solutions to address the unique challenges in pediatric research. The CHOC recommends strategies that can be implemented across the CTSA program to the CCSC. Each CTSA can be represented and the CHOC includes NIH membership of up to 33%.

The CHOC may meet yearly in the Washington, D.C. area or in conjunction with major national meetings and each CTSA should be invited. NIH staff are active members of each of the CHOC and facilitate communication among the CTSA's with support services, which could include teleconferences, a Listserv and/or an interactive web site. Summaries of CHOC meeting proceedings are posted to the CTSA web site within one month of each meeting. Each CHOC member should report on Committee activities to the PI and key function directors at their home CTSA institution. The CHOC may elect subgroups of members that include NIH

staff to serve on an Operations Group that will take the lead on timely action of emergent Committee issues and operations.

The CHOC may form subgroups that coordinate activities with SGCs and the CCSC such as:

- Rare Diseases
- Metrics of Success
- Pediatric T2 Research
- Pediatric Drugs and Devices
- Pediatrics Research Ethics
- Pediatric-Adult Life Span
- Clinical Research Networks

E. Key Function Committees and their Topic Groups

The CTSA consortium aims are promoted through a series of CTSA Key Function Committees (KFC). A major purpose of the KFCs is to serve as a venue for sharing best practices and ideas between members. Each CTSA may be represented and each KFC includes NIH membership of up to 33%. KFCs have one or two non-Federal co-chairs who are elected by a process in which each CTSA and each NIH committee member has a single vote. Two or more NIH staff members serve as coordinators, at least one of whom is an NCRR staff member.

KFCs are created and charged by the CCSC and the SGCs. KFCs provide written reports through their PI liaisons to the CCSC and SGCs every 6 months and may be invited to provide special oral updates on major policy issues or activities to the CCSC, CCEC or SGCs.

Within each of the KFCs, topic Groups may be formed to work on specific focused areas. If a KFC identifies an activity or action that has consortium-wide ramifications, they should bring the topic forward to the CCSC through their PI liaisons to get feedback from the CCSC or CCEC. The KFCs may also be charged by the CCSC (or CCEC) with specific tasks. Charges to KFCs may include the implementation of aspects of the Strategic Goals. Members of KFCs and their topic Groups are an important source for members of the SGCs.

KFCs may meet yearly in the Washington, D.C. area, as approved by the CCSC, or in conjunction with major national meetings, and each CTSA is be invited. NIH staff are active members of each of these Committees and facilitate

communication among the CTSA's with support services, which could include teleconferences, a Listserv and/or an interactive web site. Summaries of KFC meeting proceedings are posted to the CTSA web site within one month of each meeting. Each KFC member should report on Committee activities to the PI and key function directors at their home CTSA institution. KFCs may elect subgroups of members that include NIH staff to serve on Operations Groups that will take the lead on timely action on emergent Committee issues and operations. The terms of service and meeting frequency of these Operations Groups will be determined individually.

The KFCs:

- Disseminate ideas, best practices, experience and tools to improve CT research at CTSA sites
- Contribute subject matter knowledge and content expertise to SGCs and CCEC as requested by the SGC leadership
- Develop best practices and disseminate by meetings, publications, et cetera as approved or requested by the SGCs, CCEC and/or CCSC
- Generate new initiatives for the consortium institutions and identify funding opportunities to be vetted through the appropriate PI liaisons with the CCSC or CCEC for review and final approval

Examples of CTSA KFCs and their respective topic Groups include the following:

Administration: Comprised of high level administrators from participating institutions that support the activities of CTSA Principal Investigators and provide administrative direction for program execution

- Grants Management
- Annual Progress Report

Biostatistics/Epidemiology/Research Design: Forum for the exchange of information on current approaches to the integration of biostatistics, epidemiology, and research design into clinical and translational science research programs within and across CTSA institutions

- BERD Online Resources and Education
- BERD Evaluation

Clinical Research Ethics: Supports collaborative clinical ethics research, expands the use of best practices of clinical research ethics and facilitates the

access to and exchange of clinical research ethics educational materials and useful templates

- Consultation
- Ethics Educational Materials

Clinical Research Management: Reviews protocol processing issues from initial protocol development to the point of subject enrollment on clinical trials; addresses methods of improving clinical research management at CTSA sites; coordinates and interacts with all other KFCs to maximize the value of workshops and publications

- Contracts
- IRB
- Pilot and Metrics

Communications: Forum for CTSA representatives and NIH participants to share local CTSA communications activities and experiences, identify national CTSA communication needs, and generate ideas to address these needs

- Media/Public Relations
- Communication Systems and Information Management

Community Engagement: Ensures the successful implementation of a broad community engagement plan among the CTSA sites by sharing knowledge, expertise and resources

- Regional Workshop Planning
- Educational Competencies
- Community-based Academic and Practice Partnership
- Resource

Education and Career Development: Forum for the advancement of integrated and interdisciplinary education, training, and career development in the clinical and translational sciences and serve as a clearing house for novel concepts, methodologies and approaches in curriculum development, program development, and clinical research training and recruiting

- Education Competency

Evaluation: Coordinates institutional evaluation efforts with the national CTSA consortium evaluation

- Definitions and Measurement
- Social Network Analysis

- Shared Resources
- IRB Issues in Evaluation

Informatics: Ensures successful implementation of informatics support for all CTSA functions by sharing knowledge, expertise, and resources

- Data Repositories
- Inventory Resources
- User Needs
- Education
- Standards and Interoperability
- Human Studies Database
- Informatics versus Information Technology
- Collaboration Facilitation

Participant and Clinical Interactions Resources (PCIR): Fosters an environment that promotes participation in clinical and translational research by assuring the availability of personnel and facilities for safe, cost-effective research

- Resource allocation models
- Nutrition and exercise
- Shared resources

Public-Private Partnerships: Facilitates the implementation of partnerships with industry, other academia and patient advocacy groups and others to support and conduct medical research, research training and the dissemination of information

- Aggregating Intellectual Property and Resources
- Agreements
- Education

Regulatory Knowledge: Promotes the protection of human subjects and facilitate communicating shared regulatory compliance issues and improvements

- Alternative IRB Model Pilots
- Clinical Trial/Study Registration Tracking
- CMS Regulations Impact
- Research Subject Advocacy
- Research Coordinators
- IND/IDE Support

Translational: Develops infrastructure to facilitate advancements of novel translational research and technologies through the CTSA consortium in collaboration with NIH

- CTSA Imaging

Part 4. Glossary of Terms

Child Health Oversight Committee: Forum for CTSA investigators and NIH scientists to identify collaborative opportunities to facilitate pediatric clinical and translational research through the CTSA program

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

Collaborative Research: Continuum of shared research resources ranging from investigator teams, pooled expertise, shared capabilities, technologies and databases, leveraging of institutional resources within and between institutions

Consortium: An agreement, combination, or fellowship formed to undertake an enterprise beyond the resources of any one member

Cooperative Agreement: An administrative and funding instrument used for the CTSA program, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities; the Principal Investigator(s) retain the primary responsibility and dominant role for planning, directing, and executing the proposed project, with NIH staff being substantially involved as a partner with the Principal Investigator

CTSA Consortium Executive Committee (CCEC): Member-elected subgroup of the CTSA Consortium Steering Committee comprising CTSA members and NIH staff advisors, to take timely action on emergent CCSC issues

CTSA Consortium Steering Committee (CCSC): Comprises PIs of each CTSA and NIH representatives; core governing and decision-making body for the CTSA consortium

Demographics: Population (trainee, mentor, research participant, public) characteristics that include age, sex/gender, race/ethnicity, location of residence or location of academic appointment, socioeconomic status, educational attainment, employment or tenure status

Discipline: Field of study defined by shared theories, accepted methods, preferred conceptualizations and values; monodisciplinary research is restricted to one research discipline and to one branch or specialization within a research field; people working within one discipline study the same research objects, share the same paradigm, use common methodologies, and speak the same "language"

Generations of CTSA Grantees: CTSA awardees funded during the first and the subsequent annual funding cycles of the CTSA program

IC: NIH Institutes and Centers

Interdisciplinarity: Cooperation of members from different disciplines to work jointly from each disciplinary perspective, removing disciplinary barriers to address questions of mutual interest to participants

Investigators: Researchers who observe or study by close examination and systematic inquiry

Key Function Committees: Consortium-wide forums for communication and sharing best practices across areas of clinical and translational research including Clinical Research Ethics, Participant and Clinical Interaction Resources, Communications, and Biostatistics/Epidemiology/Research Design, and others as established

Mentors: Accomplished investigators in a research area with a track record of success, having trained individuals in postdoctoral positions who then have gone on to become independent investigators

Monodisciplinarity: Restricted to one research discipline and to one branch or specialization within a research field ; investigators working within one discipline study the same research objects, share the same paradigm, use common methodologies, and speak the same "language"

Multidisciplinarity: Forming coordinated environments and/or team(s) with members from multiple disciplines to work independently or sequentially to address questions of both mutual and separate interest to participating members

NARRC: National Advisory Research Resources Council providing input, advice and guidance to the NCRR Director

NCRR: National Center for Research Resources, NIH

NCRR Program Officials: NCRR scientific staff responsible for the programmatic stewardship of a CTSA award

NCRR Project Scientists: NCRR scientific staff responsible for the scientific coordination of a CTSA award

Networks: Social structures that bring together a broad selection of professionals and resources that complement and enhance each other's endeavors; nodes are the individual actors in the networks, and ties are the various relationships between the actors

NIH Staff Advisors: NIH representatives to the CTSA program who provide technical assistance, advice and coordination through Steering and Oversight Committees, Subcommittees and other workgroups, beyond normal grant stewardship

NIH IC Directors Advisory Board: Five IC Directors, one of whom is chair, and two Office of Portfolio Analysis and Strategic Initiatives (OPASI) representatives, ex officio, who provide advice to the NCRR Director on the CTSA consortium

Return on Investment: Impact of invested time, resources and funding on speed, efficiency and effectiveness of translation of research throughout the clinical and translational research continuum and resulting improvements in health

NIH Roadmap for Medical Research: NIH blueprint for building the medical research enterprise of tomorrow with initiatives focused in three main areas: new pathways to discovery, research teams of the future, and re-engineering the clinical research enterprise

Strategic Goal Committees (SGC): Comprise three PIs and three members of the Administration Committee; responsible for the achievement of each Strategic Goal identified by the CCSC in coordination with appropriate Key Function Committees

Transdisciplinarity: Integrating or blending knowledge and techniques from different disciplines to address questions of mutual interest beyond the purview of individual disciplines; a form of interdisciplinarity in which boundaries between and beyond disciplines are transcended and knowledge and perspectives from different scientific disciplines are integrated

Translational continuum: Spans, bi-directionally, basic science discovery, early translation into Phase I/II trials, late translation into Phase III/IV trials and regulatory approval, health services research, dissemination to providers and communities, and adoption by providers, patients and the public

Translational Research: Transforms scientific discoveries arising from laboratory, clinical or population studies into clinical applications to reduce morbidity and mortality and improve population health