Clinical and Translational Science Awards (CTSA) Consortium Governance

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Clinical and Translational Science Awards (CTSA) Consortium
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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 a National Center for Research Resources (NCRR) 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 Vision

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

C. CTSA Consortium Mission and Goals

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 initiative 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 initiative, when fully implemented, will link about 60 institutions to energize the discipline of clinical and translational science.
D. Cooperative Agreement Funding Mechanism

The NCRR 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 NCRR 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 CTSAA consortium.
Part 2. CTSA Consortium Leadership and Decision-Making

A. Consortium NIH Advisory Bodies

1. NCRR National Advisory Research Resources Council

Members of the National Advisory Research Resources Council (NARRC) along with additional *ad hoc* external consultants provide the NCRR 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 trans-NIH input concerning the CTSA consortium to the NCRR Director, and where CTSA functions, goals and budgets can be reviewed. Membership comprises seven IC Directors (or their designee), one of whom is chair, one NIH Division of Program Coordination, Planning, and Strategic Initiatives representative, *ex officio*, and one NIH Budget Office representative, *ex officio*. Members serve two or 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) comprises the PIs of each CTSA site and trans-NIH representatives. Two or more NIH staff members serve as coordinators, at least one of whom is an NCRR staff member. CTSAs 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. Co-chairs serve for a one-year term and may not succeed themselves. Co-chairs serve as co-chairs-elect 6 months prior to transitioning to their year term as CCSC co-chairs. On retirement, they are invited to join the committee that nominates the next co-chair candidates.
The CCSC proceeds by consensus when possible. For decisions requiring a vote, each CTSA has one vote (multi-PIs decide amongst themselves who is the designated voting representative) and the fraction of NIH voting membership is up to one-third of the total committee voting membership. 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:

- Monitors and manages strategic goals
- Delegates responsibility of timely operational and activity management either to the CTSA Consortium Executive Committee (CCEC) or to specific Strategic Goal Committees (SGCs), as appropriate
- Receives items from the CCEC and SGCs when they are not able to achieve resolution within their groups (e.g., project affirmation) or when a vote is required
- Works through the CTSA committees, including the CCEC and SGCs, to identify and implement consortium plans and mission
- Discusses opportunities for and impediments to furthering the CTSA consortium mission or regarding 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., NIH ICs, industry, laboratories, hospitals
- Receives regular reports from the CCEC
- Receives regular reports from the SGCs
- Receives annual reports from CTSA consortium Key Function Committees including identification of their respective project groups and responds to their recommendations for consortium-wide implementations
2. CTSA Consortium Executive Committee

The CTSA Consortium Executive Committee (CCEC) is the core governing and decision-making body of the CTSA consortium. The CCEC comprises the CCSC co-chairs, immediate past co-chairs, and co-chairs-elect; five CTSA member PIs, elected by simple majority vote to represent themselves as well as the other PIs; the lead of each Strategic Goal Committee (SGC); the chair of the Child Health Oversight Committee; and NIH representatives, up to one-third of the CCEC total membership, designated by the NCRR Director. The elected members are self-nominated, and if elected, 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 such actions to the CCSC. The CCEC advises the CCSC regarding CTSA committee structures, CTSA committee meeting frequencies, CTSA committee evaluation criteria including criteria for dissolution of committees, CTSA committee operations, and generation of CTSA policy. Executive functions delegated to the CCEC by the CCSC provide this group with the authority to act upon recommendation from SGCs 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). Accordingly, the CCEC will meet annually, at the beginning of each calendar year, to review and update the strategic goals and assess how they are being conducted.

The CCEC may conduct votes, and when needed, makes recommendations to the CCSC for action. The CCEC proceeds by consensus when possible. For decisions requiring a vote, such as changes in governance, a quorum is 60% of CCEC members. Passage of any voting issue (including those that are associated with resource ramifications) will require a 2/3 majority vote of the CCEC. Voting may be conducted at meetings or by teleconference, appropriate web tools and electronic or regular mail.

The CCEC:
- Sets strategic goals and priorities and ensures progress
- Refines consortium governance
- Annually reviews and determines committee membership for the Publications Committee
- Identifies needs and potential resources
• Responds to day-to-day issues
• Provides regular reports to the CCSC

3. CTSA Publications Committee

The CTSA Publications Committee is a subgroup of the CCSC and comprises three CTSA PIs and an NCRR coordinator. The CTSA members serve two-year terms and are nominated by the CCEC. The purpose of the CTSA Publications Committee is to review publications submitted for consideration as a CTSA consortium publication, and to make recommendations to the CCSC for endorsement or rejection as a CTSA consortium publication.

4. PI Liaisons

PI Liaisons to CTSA KFCs: The CCSC identifies PIs who serve as liaisons to KFCs for one-year appointments, 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 project 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 SGCs and the CCSC and should be available to participate in major meetings of the cognate KFCs or their groups. They are included in KFC communications. The PI liaisons are knowledgeable about KFC or project group activities, priorities and milestones and serve as their advocates in CCSC meetings. Initiatives endorsed by the KFCs will be brought forward to the CCEC or full CCSC by the PI liaisons or their designee.

PI Liaisons to NIH Institutes and Centers: 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 their 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 CTSAs 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 NCRR Program Official, staff advisor(s) and NIH project scientists concerning progress

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 Officer (GMO), a Grants Management Specialist (GMS) and a Program Official (PO) and may include a project scientist(s).

a. NCRR Grants Management Officers and Specialists

GMOs, or designees, are responsible for the business administration of the CTSAs 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 applicable laws, regulations, and administrative policies. Also, the GMO or his/her designee with Program Officials and other staff may visit CTSAs as necessary to carry out his/her responsibilities for evaluating and monitoring the business management practices of awardees.
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 GMS is the agent of the GMO. The GMS provides the business management expertise for an assigned portfolio of CTSAs 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 Program Officials

NCRR Program Officials (PO) are scientists who provide the scientific expertise for the typical programmatic stewardship of assigned CTSAs and are named in the award notice.

Typical PO 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 NCRR CTSA POs 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 PO and the GMO function in concert to provide overall stewardship of the CTSAs.
NCRR POs:

- Participate as non-voting members of relevant CTSA committees
- Serve as coordinators of KFCs and/or SGCS, providing liaison to NCRR, 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 CTSAs do not financially 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 CTSAs, 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 the RFA
- Link the approaches developed from these partnerships to each other and to other NIH-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
- 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
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
- 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 project groups. One or more NIH staff advisors may be assigned by the NCRR to each CTSA KFC. NIH staff advisors on a KFC may be designated as voting members. 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 CCSC, KFCs and their project groups
- Coordinate activities at academic institutions having CTSAAs with the priorities of the CCSC to avoid duplication of effort and encourage sharing and collaboration
- Review and comment on the implementation of CTSA consortium strategic goals 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. Interactions between the NIH CTSA staff advisors and CTSA awardees occur through NCRR Program Officials and the CCSC, SGCs, 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 panel members. 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 and 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. Strategic Goal Implementation

The primary focus of the CTSA consortium is achieving the strategic goals identified by the CCEC. CTSA resources will be directed to the strategic goals to ensure that the CTSA consortium has identifiable timelines, objectives, milestones and outcomes. Strategic Goal Committees (SGCs) will be identified and will have responsibility for achieving progress towards strategic goals. SGC members will work with the CCSC, CCEC and content experts to devise a charge with deliverables for each of the goals. SGCs will not form project groups, but coordinate with and draw upon the expertise of the KFCs to accomplish projects. SGC representatives will report to the CCEC and CCSC during their regular teleconferences.

Membership on the SGCs consists of three PIs and three non-Federal members of the CTSA Administration KFC as appointed by the CCEC. Each PI serves a three-year term and functions as the lead PI and the SGC representative to the CCEC for the last of those years. Each SGC is coordinated by one or more NIH staff members who typically are also coordinators of the primary KFC that supports the Strategic Goal. Ad hoc participants may be appointed by the PI lead, with concurrence by the NIH coordinator, as needed to fulfill content expertise roles. Because of the continuous evolution of the participants in the CTSA consortium, SGC participation will be reassessed annually by the PIs and the NIH coordinator. The SGCs do not conduct votes, but when needed, make recommendations to the CCEC/CCSC for action or decision making.

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 potential resources needed to achieve strategic goals
• Discuss opportunities and impediments
• Periodically reassess and reprioritize components of strategic goals
• Report to the CCSC and CCEC
• Receive regular reports from CTSA consortium KFCs that align with the respective strategic goal

The current strategic goals are:

• Build National Clinical and Translational Research Capability
• Provide Training and Improving the Career Development of Clinical and Translational Scientists
• Enhance Consortium-Wide Collaborations
• Improve the Health of our Communities and the Nation
• Advance T1 Translational Research

SGC descriptions and participants can be found on CTSAweb.org at: http://www.ctsaweb.org/index.cfm?fuseaction=quicklink.showSGC

C. CTSA Consortium Management Group

The Consortium Management Group (CMG) is the operational arm of the CCEC. The CMG consists of one NCRR Supervisory Medical Officer, one NCRR staff from the NCRR Office of the Director, five CTSA administrators selected by PI nomination and NCRR approval, one NCRR senior management/operations official, and one project manager from the CTSA support contract.

The CMG oversees the project management functions of the consortium, assists with ongoing execution of the CTSA communication plan, makes recommendations concerning the analysis of the consortium’s portfolio of projects in collaboration with the CTSA PIs and NCRR staff, reviews with the CCEC the roles and responsibilities of committees, and participates with CTSA colleagues in the reporting of consortium progress.

D. CTSA Consortium-Child Health Oversight Committee

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

The CC-CHOC comprises representatives from each CTSA institution, with one representative designated as the voting member, and trans-NIH representatives as voting and non-voting members. Two or more NIH staff members serve as coordinators, at least one of whom is an NCRR staff member. The fraction of NIH voting membership is up to one-third of the total committee voting membership. The CC-CHOC has a non-Federal chair and a chair-elect who are elected by a simple majority vote; chair/co-chair terms are set by the membership of the CC-CHOC. Voting may be conducted at meetings or by teleconference, appropriate web tools and electronic or regular mail.

The CC-CHOC may meet yearly in the Washington, D.C. area or in conjunction with major national meetings. Each CC-CHOC member should report on Committee activities to the PI and Key Function directors at their home CTSA institution.

The CC-CHOC may elect subgroups of members that include NIH staff to serve on an Operations Group that will take the lead on timely action on emergent issues, guide operations, develop policies and procedures, periodically review functions, and facilitate discussions and communications. The terms of service and meeting frequency of this Operations Group will be determined individually.

The CC-CHOC may form project groups to work on specific focus areas and coordinate activities with SGCs, KFCs, and the CCEC. If the CC-CHOC identifies an activity or action that has consortium-wide ramifications, they should bring the proposed project forward through their PI liaisons, or their designee to the SGC that the project most closely aligns with, to get feedback from the CCSC or CCEC. CC-CHOC provides written annual reports through PI liaisons, or their designee, to the CCSC and SGCs and may be invited to provide special oral updates on major policy issues or activities to the CCSC, CCEC or SGCs.

The current CC-CHOC description, membership and project groups can be found on CTSAweb.org at: http://www.ctsaweb.org/index.cfm?fuseaction=committee.viewCommittee&com_ID=27&abbr=CCCHOC.
E. Key Function Communities/Committees and their Project Groups

The CTSA consortium aims are promoted through CTSA Key Function Communities/Committees (KFCs). A major purpose of the KFCs is to serve as a venue for sharing best practices and ideas between members and to carry out consortium projects. The KFCs comprise representatives from each CTSA institution, with one representative designated as the voting member and trans-NIH representatives as voting and non-voting members. Two or more NIH staff members serve as coordinators, at least one of whom is an NCRR staff member. The fraction of NIH voting membership is up to one-third of the total committee voting membership. KFCs have non-Federal chair/co-chairs who are elected by a simple majority vote; chair/co-chair terms are set by the membership of each KFC. Voting may be conducted at meetings or by teleconference, appropriate web tools and electronic or regular mail.

KFCs may meet yearly in the Washington, D.C. area or in conjunction with major national meetings. Each KFC member should report on committee activities to the PI and key function directors at their home CTSA institution.

Each KFC may select a subgroup of members that include NIH staff to serve on an Operations Group that will take the lead on timely action on emergent issues, guide operations, develop policies and procedures, periodically review functions, and facilitate discussions and communications. The terms of service and meeting frequency of these Operations Groups will be determined individually.

KFCs are created and charged by the CCEC. KFCs provide written annual reports through PI liaisons, or their designee, to the CCSC and SGCs 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, project groups may be formed to work on specific focused areas. If a KFC identifies an activity or action that has CTSA consortium-wide ramifications, they should bring the proposed project forward to the SGC that the project most closely aligns with through their PI liaisons, or their designee, to get feedback from the CCSC or CCEC. The KFCs may also be charged by the CCSC, CCEC, or SGCs with specific tasks. Charges to KFCs may include the implementation of aspects of the strategic goals. Members of KFCs and their project groups are an important source of expertise for the SGCs.
The KFCs:
- Disseminate ideas, best practices, experience and tools to improve clinical and translational research at CTSA sites
- Contribute subject matter knowledge and topical expertise to SGCs, CCEC, and CCSC as requested by the SGCs
- 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 and identify funding opportunities to be vetted through the appropriate PI liaisons with the CCSC or CCEC for review and final affirmation

The current KFCs, their descriptions membership, and project groups can be found on CTSAweb.org at:
http://www.ctsaweb.org/index.cfm?fuseaction=quicklink.showKFC.

F. 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 the CCSC, SGCs or KFCs, by NIH project scientists, staff advisors, program officials, or the NCRR leadership. 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 or faculty staff effort are to be used.
Part 4. Glossary of Terms

**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(s).

**CTSA Consortium-Child Health Oversight Committee (CC-CHOC):** Consortium-wide forum for CTSA investigators and NIH scientists to identify collaborative opportunities to facilitate pediatric clinical and translational research through the CTSA program.

**CTSA Consortium Executive Committee (CCEC):** Member-elected subgroup of the CTSA Consortium Steering Committee comprising CTSA members and NIH staff advisors; core governing and decision-making body for the CTSA consortium that takes timely action on emergent CCSC issues.

**CTSA Consortium Steering Committee (CCSC):** Comprises PIs of each CTSA and NIH representatives.
**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

**Key Function Communities/Committees (KFCs):** Consortium-wide forums for communication and sharing best practices across areas of clinical and translational research including Clinical Research Ethics, Community Engagement, Communications, Biostatistics/Epidemiology/Research Design and others as established

**KFC Project Groups:** Implementation groups developed from volunteer members drawn from the KFCs to initiate and carry out specified consortium projects such as developing resource networks, completing white papers, and others; groups will sunset on project completion

**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 Grants Management Officers:** NCRR grants management staff responsible for the business administration of the CTSAAs and for resolving non-programmatic questions including the applicability of DHHS and NIH grant policies
NCRR Grants Management Specialists: NCRR grants management staff responsible for providing business management expertise for an assigned portfolio of CTSA, working closely with the assigned Program Official

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 and other workgroups, beyond normal grant stewardship

NIH IC Directors Advisory Board: Seven IC Directors, one of whom is chair, one NIH Division of Program Coordination, Planning, and Strategic Initiatives representative, ex officio, and one NIH Budget Office representative, ex officio, who provide advice to the NCRR Director on the CTSA Consortium

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 (SGCs): Developed by consensus process of the CCSC; represented by three or more PIs and three members of the Administration Committee and subject matter experts drawn from the KFCs; responsible for the achievement of each Strategic Goal identified by the CCSC in coordination with appropriate KFC

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