

Governance and Operational Guidelines for the CTSA Program Domain Task Forces

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Questions and comments regarding the governance and operational guidelines for the CTSA Program Domain Task Forces should be directed to Dr. Redonna Chandler, Deputy Director for the Division of Clinical Innovation (rchandle@mail.nih.gov).

Glossary:

DTF: Domain Task Force

CTSA: Clinical and Translational Science Award

SC: Steering Committee

WG: Working Group

Community Member: A member of the community that includes all stakeholders connected to clinical and translational research. Communities may include but are not limited to non-profit or industry entities engaged in translational research, and might include disease advocacy groups, local health providers, community-based organizations, and other national or local communities.

1. DTF Membership

• Lead Team

- Chair from DTF Lead Team: One elected individual that should be an existing DTF Lead Team Member;
- Co-chair from CTSA Program SC: One individual appointed by the Steering Committee;
- Up to three individuals from the existing DTF membership, who are nominated or, if necessary, elected by vote; (Note: an individual that has formerly held the DTF Co-Chair position may be on the lead team);
- One NCATS Program Staff Member appointed by NCATS.
- **CTSA Representatives:** Each CTSA hub is allowed to have one voting representative on the DTF. This member is appointed by the hub PI and is the primary point of contact for their hub for all matters relating to that DTF. (Note: DTF Members may invite others at their hub to listen in to regularly scheduled DTF calls, if that is considered to be helpful.)
- **Community Members:** Three community members, or four with justification, are recommended. Each DTF may decide on a nominating process for Community members. The SC must be informed of an addition of a Community Member to the DTF membership during regularly scheduled reports from the DTF to the SC. [See Appendix A: DTF Community Membership Reimbursement]
- **Other Members:** Program Staff from NCATS DCI, NIH Program Staff, FDA, PCORI, CDC, etc., are appointed and approved by DCI Leadership.

2. Duration of Terms

- Lead Team Co-Chair (SC): Determined by SC processes;
- Lead Team Co-Chair (DTF): One year, renewable for an additional year by a majority consensus by the Lead Team Members;
- Lead Team Member: One year, renewable for an additional year by a majority consensus by the Lead Team Members;
- CTSA Representative: At the discretion of the CTSA hub PI;
- Community Member: Each DTF may choose the length of term. However, a term of at least two years is preferable from an organizational/logistical standpoint.

- NCATS representative: Determined by NCATS DCI processes.
- Other Members: Determined by NCATS DCI processes.

3. **Elections:**

- Elections will take place during November-December of every year. Elections must be completed by December 31st and appointments begin January 1st.
- Elections may occur at an ad-hoc basis as needed to ensure continuity in the membership of the Lead Team.
- Election processes are supported by the CTSA Program Coordination Center. [See Appendix B: Election Processes provided by CTSA Program Coordinating Center]
- Co-Chair from the DTF Lead Team: Eligible candidates include Lead DTF Members. They may be nominated or nominate themselves. If more than one individual is nominated, an election will take place. If no existing DTF Lead Team Member is nominated, self-nominates or accepts the nomination, a DTF Member may be nominated or self-nominated. If more than one individual is nominated, an election will take place.
- Lead Team Member: Eligible candidates include DTF Members. They may be nominated or self-nominate themselves. If more than one individual is nominated, an election will take place.
- Individuals are elected by a simple majority vote by DTF voting members. [See Appendix B: Election Processes provided by CTSA Program Coordinating Center]

4. **Roles and Responsibilities:**

- DTF: Align with CTSA Program strategic goals and advance CTSA Program objectives through the following activities:
 - Review measurable objectives for the assigned Domain;
 - Perform gap analyses;
 - Develop plans for projects that fill identified gaps and/or further the Program Objectives;
 - Provide an open forum for broad domain focused discussions;
 - Focus on broad domain focused projects through the formation of workgroups.
- Lead Team: Vet and recommend workgroups to the SC for comments, and ensure that WGs have appropriate sunset criteria. [See Appendix C: Suggested guidelines for the creation, development and criteria for sunseting of working groups]
 - SC Lead Team Co-Chair: Regularly update the CTSA SC (monthly or as needed in verbal or written form as necessary or requested by the SC). If the SC Co-Chair is not available for an SC meeting, the Lead Team Co-Chair or another Lead Team member may present the update at the SC meeting.
- NCATS Program Staff Member (on Lead Team)
 - Facilitate and convene relevant discussions
 - Encouraging consistency with the strategic goals of the CTSA Program
- Steering Committee: Optimally situated to ensure broad alignment of the DTFs with the strategic goals of the CTSA Program, the SC performs the following functions:
 - Provide comments about WGs and activities when reported to the SC;
 - Ensure engagement of relevant experts in the working groups (including from other DTFs);
 - Ensure against redundancy among the DTF activities or the WGs;
 - Promote synergies among the activities of the DTFs.

- Working Groups: Perform distinct deliverables within timelines approved by the Lead Team, subject to the following guidance:
 - Up to five WGs can exist at any time;
 - Once a WG has met its assigned deliverable, that WG ceases to exist;
 - If a deliverable is not met within the timeframe outlined, the Lead Team will determine whether the WG should be extended or phased out. [See Appendix C: Suggested guidelines for the creation, development and criteria for sunseting of working groups];
 - WGs propose and deliver well-defined projects that fill identified translational gaps and/or further the CTSA Program Objectives as laid out by the Advisory Council Working Group;
 - Projects may result in such outputs as workshops, consensus on harmonization across CTSA hubs, white papers, or new collaborations;
 - Although no direct funding is provided, DTF and WG activities are supported by the CTSA Program Coordination Center;
 - WGs may not use DTF time or resources to develop a grant application;
 - If DTF or WG members determine that funding is necessary for project completion or product development, discussion of a proposal for funding may not use DTF time or resources supported by the CTSA Program Coordinating Center; If a project is funded, requests for feedback from the DTF is encouraged to further the goals of the developed and funded grant. Lead Team Members should vet such requests for consults from the DTF on their expertise.
 - WGs have the option to request liaisons from other DTFs and include non-DTF members (outside advisors) as the project requires;
 - The size of a working group should be held to a minimum, will depend on the project, and has to be approved by the Lead Team as large groups may be unwieldy in terms of meeting project goals.

5. CTSA Program Coordination Center Support:

- Assign one program manager to each DTF to provide support in such areas as teleconferencing, logistics, communication, membership roster management, and listserv maintenance. The program manager is not a voting member of the DTF.
- Provide teleconference and webinar support for monthly DTF meetings of the full membership and DTF lead monthly meetings.
- Provide logistical support for each DTF to conduct one face to face meeting each year.
- Implementation of surveys/databases in REDCap as requested by DTFs.
- Reimburse Community Members for expenses incurred during consultation with NCATS Program Staff [See Appendix A: DTF Community Membership Reimbursement].
- Provide support for elections [See Appendix B: Election Processes Provided by CTSA Program Coordinating Center]

Appendix

A. DTF Community Membership Reimbursement

NCATS and the CTSA Program greatly value partnerships with community members in improving the translation of research into treatments and cures. NCATS also recognizes that some community members engage in these activities on a voluntary basis that may be in addition to, or in place of, regular employment. These community members are eligible to receive an honorarium for their DTF-related activities depending on their individual circumstances.

- Honoraria should be offered to:
 - Community members who are volunteers and not working for an employer.
 - Community members who are working for an employer and their DTF activities are not considered part of their scope of work.
- Honoraria should be offered for all DTF-related work that includes active contributions as described below to phone conferences, workgroup projects, and F2F meetings, including travel support (unless considered part of their employment).
- Payments will be made by the CTSA Coordinating Center, C4 (Vanderbilt University), on behalf of NCATS, directly to community members.

NCATS recognizes that patient and community engagement is important to advancing translational science. For NCATS-sponsored meetings, we will follow NIH guidelines for reimbursement and honoraria for those meetings where we invite members of the community to participate in NCATS DTF efforts. These rules allow compensation for travel expenses and per diem allowances for travel to conferences, meetings, consultations, or other activities, but only if they are performing a direct service, i.e., making a presentation, advising in an area of expertise, etc., for the NIH. These guidelines support reimbursement for individuals that provide unique and valuable expertise.

NCATS recognizes the importance of including the community perspective and is considering approaches for including that perspective in all its translational science efforts.

The following websites provide specific information for payment:

<http://share.csr.nih.gov/SREA/Documents/SREA+Flat+Rate+Breakdown.pdf>

<http://public.csr.nih.gov/ReviewerResources/TravelAndExpenses/Pages/default.aspx>

B. Election Processes Provided by CTSA Program Coordinating Center

SOP: Domain Task Force Elections (DTF)

Description: The purpose of this SOP is to provide a process which will facilitate the regular and orderly rotation of leadership on and off of the Domain Taskforces.

Strategy: Elections will be held between November-December of every year. Elections must be completed by December 31st and appointments begin January 1st. Elections may occur at an ad-hoc basis as needed to ensure continuity in the membership of the Lead Team. For additional information please refer to the Governance and Operational Guidelines for the CTSA Program Domain Task Forces.

C4 will collect nominations which, will include candidate name, statement of intent to lead the DTF, and a brief biosketch. C4 will compile all nominations into a [REDCap survey](#) and distribute to the FULL DTF via the group's listserv. DTF members will be given 10 calendar days to vote for their preferred candidates. Following the 10 days, C4 will tally the votes and inform the current Leadership Team and the new Lead Team members of the results. Lead Team vacancies will be filled in order based on number of votes obtained. For example, if there are two vacancies on the Lead Team, the two candidates receiving the highest number of votes will fill those vacancies. In the event of a tie for the final available Lead Team position, a [runoff election will be held via REDCap](#). DTF members will be given 5 calendar days to vote in the runoff election. Once the new Lead Team members have confirmed acceptance of the position and the current Lead Team members have been informed, C4 will introduce the new Lead Team members to the FULL DTF via an email to the group's listserv.

Definitions and Abbreviations:

Abbreviation	Definition
C4	CTSA Consortium Coordinating Center
CTSA	Clinical and Translational Science Award
DCI	Division of Clinical Innovation – NCATS
DTF	Domain Task Force
NCATS	National Center for Advancing Translational Sciences
PM	Project Manager
SC	Steering Committee

Procedure:

Step	Action	Timeframe
1	C4 DTF Project Manager (PM) sends email to FULL DTF listserv requesting nominations for the Lead Team positions. Email will: <ul style="list-style-type: none"> • indicate who is rotating off the Lead Team and number of vacant positions • request candidate names, statement of intent to lead the DTF, and biosketch • nomination period will last for 2 weeks 	Early-/Mid-November
2	C4 PM will compile candidate information into a REDCap survey for distribution and voting by the FULL DTF. <ol style="list-style-type: none"> 1.) If the number of nominations received equals the number of vacant Lead Team positions, no election will be held. Candidates will assume their new leadership positions by default. 2.) If there are more candidates than available Lead Team positions, an election will be held. <ul style="list-style-type: none"> ○ DTF members will be given 10 calendar days to vote for their preferred candidates (or until quorum is achieved) ○ Each CTSA Hub gets to vote once for their candidates ○ Members vote for as many candidates as there are vacancies (ex. 2 Lead Team vacancies so members vote for their favorite 2 candidates) ○ A quorum vote is 50% of the FULL DTF membership – C4 will send reminders to members who have not voted until quorum is achieved 3.) In the event of a tie for the final available Lead Team spot, a REDCap survey will be used to hold a runoff election between the tie candidates only <ul style="list-style-type: none"> ○ DTF members will be given 5 calendar days to vote (or until quorum is achieved) ○ Each CTSA Hub gets to vote once for their candidates ○ Members vote for one candidate 	Early-December
3	Following elections, the C4 PM will confirm acceptance by the new Lead Team members, inform the rest of the Leadership Team, and announce the election results to the FULL DTF via the group’s listserv.	Mid-/Late-December
4	The new Lead Team members will assume their position	January 1

C. Suggested guidelines for the creation, development and criteria for sunseting of working groups

Statement of Purpose/Plan Format

- **Background:** A clear statement of the problem addressed by the IOM/ACWG identified recommendation with sufficient background that one may understand the need for change in the CTSA program. These SOP's will be developed by the WG and submitted to the Lead Team for approval.
- **Description of Proposed Idea:** The purpose of a Working Group (WG) should include the identification and recommendation of pragmatic tools and strategies for addressing a specific IOM/ACWG report recommendation. When the WG task is completed, the recommended tools will help individual research teams and CTSA's to gauge the effectiveness of the tools and strategies addressing the specific area of focus. The general SOP will be developed by the Lead Team and refined by the WG. WG chairs are encouraged to consider whether the statement of purpose informs a very specific goal(s) that is/are achievable and realistic. The WG chair should discuss the SOP with the Lead Team so that there is consensus on the scope of strategies to address the SOP e.g., a more narrow or broad initial focus.
- **Strategy:** The strategies used by the WG to achieve its goal(s) should be developed by the WG members. Having adopted clear, achievable, and realistic goals, the WG should then develop strategies, tactics, and milestones to reach the goal. Tactics might include a pragmatic literature review, conducting environment scans of strategies used across disciplines (including prior CTSA WGs developed for related but slightly different purposes), the engagement of outside experts (including stakeholders), crowdsourcing of candidate domains or questionnaires, and an array of other approaches.
 - **Key Objectives (s): List objectives**
 - **Key Deliverable(s): List key outcomes**
 - **Proposed Metrics**
- **Workgroup Membership/Needed Expertise:**
- **Timeline/milestones (including proposed start and end date)**
- **Sunset criteria**
- **Submitter's name, email address and institution**