National Center
for Advancing
Translational Sciences

NIH

Governance and Operational Guidelines for the CTSA Program Domain Task Forces

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General Notes

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

Revisions of this Document

November 2016: General updates
September 2017: General updates
January 2018: Update to Informatics DTF membership to include the CD2H PI on the Lead Team; clarification for creation of DTF WGs, general formatting updates

Glossary / Definitions

Abbreviation	Definition
ACWG	Advisory Council Working Group
CC	CTSA Program Coordinating Center
CO	Coordinator
CTSA	Clinical and Translational Science Awards
DCI	Division of Clinical Innovation
DTF	Domain Task Force
IOM	Institute of Medicine
NCATS	National Center for Advancing Translational Sciences
PM	Project Manager
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.

References

NCATS Council Working Group on the IOM Report: The CTSA Program at NIH
NCATS Advisory Council Working Group on the IOM Report: The CTSA Program at NIH – Draft Report, May 16, 2014
IOM Report: The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research

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Purpose of the CTSA Program Domain Task Forces

The CTSA Program Domain Task Forces (DTFs) align with CTSA Program strategic goals with the purpose of advancing 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

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
- Note about Informatics DTF Membership: For the Informatics DTF, there will be two co-chairs from the CTSA Program SC. One will be a PI of a UL1 and one will be a PI of the CTSA Program Data to Health Coordinating Center. The PI of the CTSA Program Data to Health Coordinating Center that is the SC member will serve to the end of the project period of the grant.

CTSA Program hub Representative:
- Each CTSA Program 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.

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 Program hub Representative:
- At the discretion of the CTSA Program hub PI.

Community Members:
- Each DTF may choose the length of term. However, a term of at least two years is preferable from an organizational/logistical standpoint.

Other Members:
- Determined by NCATS DCI processes.

Roles and Responsibilities

Lead Team:
- Vet and recommend workgroups to the SC for final approval, and ensure that WGs have appropriate sunset criteria.
- SC Lead Team Co-Chair:
  - Regularly update the CTSA Program 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 final approval of WGs
  - 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

DTF Working Groups

- Purpose: Perform distinct deliverables within timelines approved by the Lead Team, subject to the following guidance:
  - Up to five WGs can exist at any time under a single DTF.
  - 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.

- WGs propose and deliver well-defined projects that fill identified translational gaps and/or further the CTSA Program Objectives as laid out by the NCATS Advisory Council Working Group on the IOM Report: The CTSA Program at NIH, or other significant objectives/goals that would advance the goals of the CTSA Program. (See References)
- Projects may result in such outputs as workshops, consensus on harmonization across CTSA Program hubs, white papers, or new collaborations.
- Although no direct funding is provided, DTF and WG activities are supported by the CTSA Program Coordination Center (see section below: CTSA Program Coordinating Center Support).
- 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; However, if a project that originated in the WG does receive funding, requests for feedback from the DTF is encouraged to further the goals of the 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 must be approved by the Lead Team as large groups may be unwieldy in terms of meeting project goals.
- **Process for creation of a DTF WG:**
  - Governance: the WG will self-govern themselves, however, there must be at least 1 point of contact / lead for the WG identified.
  - Statement of Purpose: A succinct statement of purpose will be submitted to the Lead DTF for consideration. If approved by the Lead DTF, the WG lead(s) will present the WG idea to the Full DTF for feedback and approval. Information to be submitted to the DTF Lead Team:
    - Purpose of the Working Group
    - Deliverable(s)
    - Proposed Metrics (if applicable)
    - Workgroup Membership / Needed Expertise
    - Timeline / Milestones (including proposed start and end date)
    - Sunset criteria
    - Submitter's name(s), email address(es) and institution(s)
  - If the WG is approved by the Full DTF then the DTF SC Member will submit that this WG be presented to the SC for feedback and final approval.
  - WGs must summarize the outcomes of the WG in a succinct document and present outcomes to their respective DTF and the SC within a timely manner.

Elections

- Elections for the Lead Team will take place during November-December of every year. Elections must be completed by December 31st and appointments begin January 1st.
- Election processes are supported by the CTSA Program Coordination Center. [See Appendix B: Election Processes provided by CTSA Program Coordinating Center]
- Individuals are elected by a simple majority vote by DTF voting members. [See Appendix B: Election Processes provided by CTSA Program Coordinating Center]

- Elections may occur at an ad-hoc basis as needed to ensure continuity in the membership of the Lead Team:
  - 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.

CTSA Program Coordination Center Support

- Assign one coordinator to each DTF to provide support in such areas as teleconferencing, logistics, communication, membership roster management, and listserv maintenance. Assign one liaison to provide higher level strategic support, work with other DTF liaisons to identify cross-DTF synergies, and provide domain content support to coordinators. The coordinator and liaison are non-voting members 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. DTF meetings will be coordinated with the CTSA Program Meeting time and location, unless otherwise approved by the CLIC and NCATS. Level of support for off-site meetings is subject to available CTSA Program Coordinating Center resources.
- Provide survey support to include: access to the CTSA Program Coordinating Center REDCap survey platform for DTF use, REDCap technical support, survey design and analytic consultation as resources allow, and raw data transfer from REDCAP. Support may also include providing descriptive analytics of survey results, if using REDCap and a survey designed and implemented by the CTSA Program Coordinating Center. Survey support through the CTSA Program Coordinating Center will be provided for up to 3 surveys per DTF and all of its working groups per year (overall total of up to 15 surveys per year across all DTFs). Surveys administered by the Coordinating Center will follow the protocol identified in the NCATS CTSA Program Policy and Procedures for Surveys (see NCATS CTSA Program Policy and Procedures for Surveys).
- 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 and travel reimbursement 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 to one annual DTF face-to-face meeting (unless considered part of their employment).
- Community members will be required to make travel arrangements for F2F meetings through the CTSA Coordinating Center.
- Community members will receive honoraria for full DTF phone conferences (1 hour x up to 6 per year) at the rate of $100 per call (SREA REIMBURSEMENT RATES for mail in reviews 1-3 submitted per meeting).
- For community member participation in DTF special projects, community members will be reimbursed at the rate of $400 per project (SREA REIMBURSEMENT RATES for mail in reviews 4 or more submitted per meeting). To be eligible for reimbursement, project budgets will need to be submitted by the DTF committee prior to initiation. The community member will be reimbursed after project completion. The Coordinating Center will support a maximum of 5 person-projects per year.
- Total budget for all community member costs borne by the CTSA Coordinating Center will not exceed $20,000 annually. If advance requests for reimbursement exceed this amount, NCATS with assist the Coordinating Center in prioritizing these.
- Payments will be made by the CTSA Coordinating Center, 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)

Definitions and Abbreviations:

Abbreviation	Definition
CC	CTSA Program Coordinating Center
CTSA	Clinical and Translational Science Awards
DCI	Division of Clinical Innovation
DTF	Domain Task Force
NCATS	National Center for Advancing Translational Sciences
CO	Coordinator
SC	Steering Committee

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 DTFs.

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 DTFs.

The CC will collect nominations which, will include candidate name, statement of intent to lead the DTF, and a brief biosketch. The CC 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, the CC 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, the CC will introduce the new Lead Team members to the FULL DTF via an email to the group's listserv.

Procedure:

Step	Action	Timeframe
1	CC DTF CO sends email to FULL DTF listserv requesting nominations for the Lead Team positions. Email will: • 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	CC CO will compile candidate information into a REDCap survey for distribution and voting by the FULL DTF. 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. o DTF members will be given 10 calendar days to vote for their preferred candidates (or until quorum is achieved) o Each CTSA Program hub gets to vote once for their candidates o Members vote for as many candidates as there are vacancies (ex. 2 Lead Team vacancies so members vote for their favorite 2 candidates) o A quorum vote is 50% of the FULL DTF membership – CC 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 o DTF members will be given 5 calendar days to vote (or until quorum is achieved) o Each CTSA Program hub gets to vote once for their candidates o Members vote for one candidate	Early-December
3	Following elections, the CC CO 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