

Questions and Answers Regarding CTSA RFA RM-07-002

Questions relating to application and review process

Q: What is the next deadline for CTSA submission after January 17, 2007?

A: The next CTSA receipt date after January 17, 2007, will be October 24, 2007 and the applications that are successful will be funded in FY2008.

Q: Is there any information available about how the review process will be conducted: will the applications be reviewed like an R01 with several reviewers assigned to review the whole grant submission or will they be reviewed like a PPG with specific sections assigned to different reviewers?

A: The CTSA's are reviewed both by assigning parts to individual reviewers, and also by assigning reviewers to assess the overall merit.

Q: How are the key functions and other units (e.g., training, design, etc.) of the CTSA grouped for review?

A: Actual assignments are not pre-determined since the applicant decides what is to be included in the application. The applications are assigned to cover all the review criteria listed in the RFA.

Q: How can more pediatricians be included as reviewers? Would patient advocates be acceptable as reviewers? Can community representatives of study or participant populations be included to review the merits of applications?

A: There are a variety of disciplines that need to be represented on the review panel; to accomplish this, it is not possible to have more than a few representatives from any given field or discipline. It is possible to consider patient advocates and community representatives as CTSA reviewers.

Q: What is the role/importance of tech transfer in the CTSA application?

A: CTSA's create new opportunities for translational research so it will be important to present a plan for dealing with intellectual property issues, and for reporting and sharing technical advances.

Q: Could funded CTSA's solicit patient advocates to suggest ideas for study? Possible areas relevant to community engagement could include:

- a. "Measures of 'undue influence'" to volunteer for a trial;
- b. Trial participant ideas about "ancillary care" or measurable benefits from participating in a trial;
- c. Overcoming barriers to participation in disadvantaged or marginalized groups;

d. Problems in recruiting for trials in populations for which payer or insurance barriers may act as barriers to access for proven therapies.

A: Yes, these are all possible areas of activity that are relevant to community participation research. Applicants may determine how best to engage patient communities in their own case.

Q: What if an institution is "nowhere near" where it would like to be with a particular CTSA component but could imagine a five-year plan that would get it there?

A: Institutions should not apply for a CTSA until they are confident that they meet the eligibility requirements. NCCR expects to publish an annual RFA for CTSA's for at least several years. Plans related to new approaches or activities need to be solid, complete, clear, and convincing. Innovative approaches are encouraged.

Q: What types of informatics should be included in the grant application? Should programs and methods in genomics, proteomics and/or computational mathematics be included in addition to medical record informatics?

A: The clinical research informatics component should be tailored to meet the current and anticipated needs of the users of the center/department or institute. Most applicants find that both types of informatics best serve the needs of their CTSA.

Q: We currently have a program in Radiation Sciences whereby residents in radiology get a PhD in radiation sciences. Can the T32 component of the CTSA support the stipends for these types of students?

A: If the residents already have an MD and have completed their basic training, they could be supported through the K12 component of a CTSA while they work for a PhD in a clinical or translational research field.

Q: Are the CTSA K12 or T32 programs submitted separately or as part of the U54 application?

A: The K and T components are submitted as part of the U54 application. A K12 component is required while the T32 is an optional component, but either a T32 or T32-like program may be needed to serve the research training needs of the CTSA.

Q: Are the K12 and the T32 separate grant applications or are the details of these two programs to be included in the 25 pages of the Education Key Function description?

A: The K and T components of a CTSA application should be integrated with the U component and described, with other "Research Education, Training and Career Development" activities, within the 25 page limit.

Q: What types of programs do you envision core facilities should provide in enabling training and new translational research?

A: It would be important to show that any proposed cores would be useful to multiple investigators, and that the resources supplied can be integrated into the whole. Where there are multiple partnering institutions, applicants should plan for the broad availability of the resource and avoid unjustified duplication.

Q: Were any psychosocial translational applications funded in the first RFA, and would they be discounted in the new initiative?

A: An application for a CTSA should meet the varied needs of investigators working on aspects of the multiple health conditions studied by a wide range of NIH Institutes and Centers. As appropriate for a proposed CTSA, psychosocial researchers may well contribute to and benefit from CTSA resources.

Q: We wondered whether the requirement for the combined doctoral degree with a Masters degree in clinical and translational research for the T32 component is limited to candidates for professional doctoral degrees, e.g., MD. Could we offer a Masters degree in clinical and translational research to PhD candidates in the basic sciences to enhance their involvement in clinical and translational research?

A: Eligibility for the CTSA T32 component is currently limited to trainees enrolled in Ph.D. programs in clinical research and research-related fields or combined degree programs that include a doctoral-level professional degree and a masters degree in clinical and translational research. Applicants who want to provide a clinical research experience for Ph.D. students in basic science could consider supporting curriculum development and short-term courses through the research education component of the U54 mechanism.

Q: Should the grant applications include specific metrics about how we will determine that we are achieving our goals in various areas, e.g., measure how protocols have improved with access to biostatistics training and consulting? Alternatively is it sufficient to just show the number of investigators who are attending classes or coming to consulting sessions?

A: A CTSA proposal should include milestones that will document the achievement of goals. The CTSA evaluation process should address outcomes (i.e., improvements) rather than just usage.

Q: Can we apply for a GCRC renewal and a CTSA award in the same year? Is this limited to calendar year? Please clarify.

A: NCCR aims to transition the GCRC program to CTSA's by September 30, 2010. This process allows for competing continuation GCRC applications to be submitted through June 1, 2007. GCRCs with a project period end date in 2008 may request a 1-year

extension of support for their M01 grant in lieu of a competing renewal application. Institutions submitting a CTSA application on 1/17/07 may not submit a GCRC renewal application on 2/1/07 or 6/1/07.

Q: For the first round of CTSA awards, there appear to be two funding mechanisms indicated: KL2 and TL1. It appears that all but one of the CTSA awards included both mechanisms. What are these two mechanisms?

A: The submitted application is for a U54 mechanism that includes both K and T components, which are linked to the U54 in the award process. The separation into UL1, KL2 and TL1 is done at NIH for administrative purposes only. It is not possible to apply directly for the L (linked) mechanisms.

Q: Do we have latitude in assignment of page limits, i.e., if we do not use all 15 pages for a key function, can we use the balance for another key function as long as we are within the overall maximum page limits?

A: The page limits given in the RFA should be observed.

Q: We are limited to 30 mentor biographical sketches in the application. Can additional biographical sketches for key personnel be included outside the 30 biographical sketch limit? If so, is there any overall limit to the number of biographical sketches to be included?

A: Biographical sketches should be limited to individuals who are named in the application. As regards mentors, 30 biographical sketches are sufficient to give reviewers an indication of the mentor pool.

Questions related to budgets

Q: Is the additional award amount of \$6 million TOTAL or DIRECT costs?

A: Applicants may request up to \$6M additional TOTAL costs.

Q: May we include a K30 award in our calculation of a base for the Jan. 17 submission?

A: Yes.

Q: The CTSA RFA, RM-07-002, at section 5.1.2 - Mentored Career Development Component - K12, states: "All costs of an existing RM K12, including infrastructure, will remain with the K12 component of the CTSA." Is this correct, or should all non-scholar costs be borne by the U component, with its higher F+A costs?

A: The CTSA K component budget should include only the costs of the scholars (e.g., salaries) and any related expenses (tuition, travel, research expenses, etc.). The non-scholar costs carry F&A costs at the full institutional rate associated with the U54 budget.

Q: When developing the budget for the K12 portion, the instructions state to use the amount awarded on the latest NGA prior to 10/1/06. Our latest NGA was just received and shows the funding for the last three years of this award. If our application is successful, it would not start until we are in the 4th (next) year of the RM K12 award. Should we use the Year 4 funding level as stated on the NGA instead of this year's level (Year 3) in the budget preparation?

A: You should use the latest NGA prior to 10/1/06 as instructed. If the budget of your K12 award escalated from year 3 to 4, you may use that escalation in the calculation of your budget in subsequent years.

Q: We have a Roadmap K12 that runs until 2010. The CTSA lasts 5 years. Can we budget the K12 to run 2 more years until 2012?

A: Existing Roadmap K12 and T32 awards are relinquished when a CTSA is awarded – and all the linked components of a CTSA run concurrently. You should therefore budget the K12 component of a CTSA for the full 5 years of an award.

Questions relating to amended applications for CTSA

Q: When an institution submits an amendment of a CTSA application that was not funded in 2006, should the application be structured as a re-submission? Should revised parts of the application be marked as such? Should a cover letter address the Summary Statement comments? If yes, how long should the letter be? Should there be a letter addressing Summary Statement comments at the beginning of each section of the application or only at the beginning of the entire CTSA application?

A: Amended applications will be accepted for the January 17, 2007 receipt date. An introduction to the application of up to 3 pages should indicate changes made in response to the previous summary statement and cite the relevant page numbers.

Q: We received an outstanding score for our first bioinformatics CTSA application submission. When we resubmit, will the informatics section be scored again or do we need to focus only on improving the sections where we desire a better score?

A: The entire application will be re-scored. Sections that received an outstanding score on first review could receive lower scores on second review. It is advisable to review and revise each section to insure that it is consistent with advances in the field.

Q: Is it possible to get access to successful applications via the Freedom of Information Act (FOIA) in a timely manner (e.g., several weeks)?

A: Responses to FOIA requests have to be redacted to ensure privacy. Many of the successful applicants have posted large parts of their proposals on the web (<https://www.ctnbestpractices.org/networks/nih-ctsa-awardees/>).

Q: A large number of CTSA grant applications were submitted the first round. Potentially an even larger number may be submitted on the second round. Only 7-8 are projected to be funded in this round. It is possible that some institutions might not be successful in three rounds. Will you consider allowing institutions to submit more than two amended applications for the CTSA mechanism?

A: Applications that are not successful after two amendments are likely to need extensive modifications. If the application takes a new approach and significantly changes the application, it could be submitted as a new application.