September 28, 2012

Christopher P. Austin, M.D
Director, National Center for Advancing Translational Sciences (NCATS)
National Institutes of Health
Bethesda, MD 20892-4874

Dear Dr. Austin:

Congratulations on your appointment as Director of NCATS. As CTSA academic and community partners and as members of Community-Campus Partnerships for Health,¹ we believe in the potential of CTSA to improve health and eliminate health disparities. Community engagement is essential to achieving that potential. We are writing to share our concerns about the future of community engagement in NCATS and the CTSA program.

We have organized our comments below around four recommendations:

1. Maintain the Broad Clinical and Translational Goals of the CTSA Program
2. Support Community Engagement as Central to the Missions of NCATS and the CTSA Program
3. Invest in Critical Infrastructure for Community Engagement and Community-Engaged Research
4. Ensure Community Participation in Priority-Setting and Decision-Making

Thank you for your consideration. We are eager work with you to ensure that the CTSA fully realize their potential to improve the health of communities. We look forward to your response and request an opportunity to speak with you by phone or meet with you in person. You may contact us through CCPH's Executive Director Sarena D. Seifer, M.D. at sarena.seifer@gmail.com

1. Maintain the Broad Clinical and Translational Goals of the CTSA Program

While delivering new, more effective drugs, diagnostics and medical devices is a worthwhile goal, we strongly urge that NCATS not position the CTSA to narrow their broad clinical and translational goals or prioritize this goal over others. Prior to establishing NCATS, the NIH Director established a trans-NIH working group to recommend a strategy for ensuring that the CTSA program most effectively facilitates the translation of science into improved human health. The working group recommended that the CTSA program should continue to provide infrastructure to support the full spectrum of translational research. We wholeheartedly agree. The reality is that improving the behavioral and social determinants of health through changes in policies, practices and systems has the greatest potential for improving human health. To improve health, research on the most effective approaches to behavioral and social determinants is critical.

¹ Founded in 1997, CCPH is a national membership organization that promotes health equity and social justice through partnerships between communities and academic institutions. A CCPH-CTSA member interest group was established in 2010 to provide a space for CCPH members involved in CTSA (from community and academic settings) to meet regularly. The group is comprised of 73 people from 29 CTSA and 2 CTSA applicants. In 2011, with support from the National Institute of Minority Health and Health Disparities, CCPH and the Center for Community Health Education Research and Service in Boston sponsored a National Community Partner Forum on Community-Engaged Research that drew nearly 100 community leaders, 30% of whom are involved in CTSA. Input from both groups has been incorporated into this letter.
The Senate Appropriations Committee emphasized this point in the report that accompanied the NCATS budget in the Consolidated Appropriations Act of 2012, indicating:

"As the CTSA program transitions to NCATS, the Committee urges the NIH Director to ensure that the current focus on the full spectrum of translational research is maintained. The inclusion of patient-centered outcomes research, community engagement, training, dissemination science, and behavioral research is extremely important to the translation and application of basic science discoveries and success of the CTSAs.”

In testimony before the House Appropriations Subcommittee on March 20, 2012, however, NCATS Acting Director Thomas Insel noted “In 2013 we will be launching CTSA 2.0… to accelerate research on rare diseases and new therapeutics.” We are concerned that if CTSAs are positioned to become aligned with an NCATS mission that privileges the development of drugs, diagnostics and medical devices over other goals, funding will flow in that direction and CTSAs will increasingly focus on those areas at the expense of the other components of the translational research continuum. To have a meaningful and measurable impact on health, the CTSAs need to be most concerned with the translational barriers that lie beyond the clinic and in the community.

2. Support Community Engagement as Central to the Missions of NCATS and the CTSA Program

Community engagement is essential to delivering new, more effective drugs, diagnostics and medical devices – and adequate resources are needed to support it. If we continue to recruit clinical trial participants who are predominantly white and develop new drugs, diagnostics and medical devices that are in many instances costly and challenging to deliver, we will at best not achieve the health outcomes envisioned by the NIH roadmap when it recommended creating CTSAs and at worst exacerbate racial, ethnic and socioeconomic health disparities, thus surpressing the overall health status of the country. Further, the vast medication adherence literature underscores that we do not yet understand how best to assure that people will take effective drugs, use effective medical devices, or accept diagnostics without improved behavioral and social science research to understand the gap between clinical trials and real life.

Clinical trial research is a major concern in minority, immigrant and low-income communities and support for community engagement can play a critical role in earning their trust. Egregious practices in the conduct and reporting of clinical trials contribute to distrust in and fear of research and medical practice that work against any efforts to address the health disparities that impact our most vulnerable communities. Fully supported and acknowledged partnerships between research institutions and trusted community members and organizations can rebuild public confidence in the medical research system, increase participation in clinical trials, facilitate mutual learning and help ensure that translational science yields findings that will have utility and support outside of the acute care hospital setting. The AHRQ and NCI-funded report, Communities as Partners in Cancer Clinical Trials: Changing Research Practice and Policy makes 60 specific recommendations for how communities can and must be involved as partners in every phase of clinical research (http://communitiesaspartners.org).

Community engagement is essential to the CTSAs being able to bring better health to our communities and must be a supported and expected component of the program. A 2008 report co-authored by the CTSA Consortium’s Community Engagement Key Function Committee and Community Engagement Workshop Planning Committee noted that, “Successful translation of science into improved population health requires community support and involvement at every level – from volunteers who participate in clinical trials, to physicians and other health providers and community leaders who assist their neighbors in behavior change, to community-based organizations and engaged citizenry who instigate political and policy change.” (http://bit.ly/I1L4IE) Indeed, the vision of the NIH roadmap that led to the CTSA program and other significant NIH investments in translational research included participatory community involvement as a core component of the paradigm shift required to translate research findings into improved health care and health outcomes.
There is genuine cause for concern about NCATS’ support for community engagement. During a Feb 27, 2012 webinar to describe, as the title indicated, “what NCATS is and isn't,” Acting Director Dr. Thomas Insel indicated that “we've been asking ourselves a lot of questions about how can NCATS and especially the CTSAs, make sure that clinical research is cheaper, faster and better, and how do we make that happen? Will we be at a point in 5 years when the other 26 NIH institutes will be able to say that because of NCATS they can run twice as many trials at half the price in half the time with even better quality - those are the kinds of things that I think we have to really be focused on in the next few months, laying the foundation for that and then over 5 years saying that's what we want in terms of success.” Yet there was no indication during the webinar that community engagement, community-engaged research, implementation research or alternative study designs to clinical trials in the CTSA program would be essential for doing so. We are deeply concerned that the emphasis on “cheaper, faster and better” clinical trials will undermine the trust and participation in research that has been built in communities by many CTSAs through their investments in community engagement and community-engaged research. Many community-based organizations joined CTSA community advisory bodies and became involved in CTSA activities with the hope of shaping research that would lead to improved health outcomes. To pull back from that investment now would be a significant setback and indeed could seriously undermine the participation of diverse communities in research and the benefits these communities derive from research. In addition, having “cheaper, faster and better” clinical trials will not solve the problem of applying the results of those trials into clinical practice, community programs and public policy.

No requirement for a community engagement key function in the current CTSA funding announcement sends the message that community engagement is not an essential CTSA component. Further, in his opening remarks at the CTSA Community Engagement Conference on August 23, 2012, Dr. Insel appeared to suggest that not all CTSAs would be expected to pursue community engagement as an essential component of their operations, indicating that those with strengths in community engagement could respond to a forthcoming funding announcement to support it while implying that some CTSAs could consider it optional.

There are troubling signs that CTSAs are already responding to a perceived lack of NCATS support for community engagement. Researchers and community partners at some CTSA institutions are experiencing a withdrawal of resources for community engagement because institutional leaders view it as a low NCATS priority. Other CTSA institutions appear to be paralyzed by the uncertainty around whether NCATS will value community engagement and are putting initiatives on hold. In some cases, CTSAs were already underfunding their community engagement cores before NCATS had been established. There are community partners – deeply invested in the success of CTSAs and involved in the program for many years – who feel betrayed by being invited into research collaborations designed to address community-identified needs, building community trust in research and developing research knowledge and skills in communities, only to discover that the genuine intentions of a few are being undermined by shifting institutional priorities tied to the perceived priorities of NCATS and the next round of CTSA funding.

We urge NCATS to make a strong and unequivocal statement of its support for community engagement as essential to its mission and to conducting and applying the results of clinical and translational research – and allocate the resources needed to back it up. While we are pleased to see that the first approved NCATS concept proposal is for strengthening community-engaged research in the CTSA program, its narrow focus on testing strategies to overcome barriers to effective community-engaged clinical research is insufficient. The concept proposal emphasizes discreet research projects rather than the infrastructure needed for sustained, impactful community engagement. We urge NCATS to maintain the program’s broad clinical and translational focus, require CTSAs to have community engagement cores, articulate expectations for what authentic community engagement is and is not, and implement a merit review process that includes community-based as well as academic peer reviewers. (Note: We will be submitting specific comments about the concept proposal shortly as per the instructions on the NCATS website).
3. Invest in Critical Infrastructure for Community Engagement and Community-Engaged Research

**Invest in developing and sustaining community-academic research partnerships:** Just as having funding for lab space and supplies is crucial to successful basic science research, the same is necessary to support the relationship-building and partnership infrastructure that is essential to successful community engagement and community-engaged research. This includes, for example, support for partnership governing boards, community-academic liaison positions, community health workers, memoranda of understanding, data sharing agreements, etc.

**Invest in research capacity and infrastructure in communities:** As more community organizations enter into research partnerships with CTSA and other NIH-funded institutions as well as initiate and conduct research, it is clear that they need direct support for research capacity building and research infrastructure. In 2009, NIH released RFA-OD-09-010 for Building Sustainable Community-Linked Infrastructure to Enable Health Science Research to support the infrastructure needed to facilitate collaboration between academic health centers and community organizations for health science research. Regrettably, community-based organizations involved in health research from across the country that had hoped to apply were prevented from doing so as eligibility was restricted from the usual wide range of organizations to only accredited academic institutions that regularly and widely engage in health research. Funding mechanisms are needed that directly support research infrastructure in communities, just as the CTSA program has built research infrastructure in academic institutions.

**Invest in training, mentoring and research funding support for community-engaged investigators:** We must invest in researchers who are ready and able to pursue community-engaged clinical and translational research. Many faculty who are passionate about community-engaged research are reluctant to significantly pursue it because it isn’t valued by their institution and could undermine their career advancement. Funds are needed both for training and mentoring that equips them with the competencies they need to succeed in both “doing” community-engaged research and “documenting” results for publication, promotion and tenure, as well as for developing and sustaining the community partnerships that are the foundation of productive community-engaged research. NCATS should develop a Career Development Award (K-series) for collaborative community-engaged translational research rather than relying on the disease- and technology-oriented Centers and Institutes for Career Development Awards. Having developed this cadre of community-engaged investigators, NCATS and CTSA funding mechanisms and peer review processes must explicitly value community engagement and community-engaged research.

**Support community engagement collaborations among CTSAs and other research institutions located in the same city/region:** It simply does not make sense from the standpoints of cost and impact to have multiple CTSAs in the same city or region independently engaging with communities, conducting community assessments, recruiting study participants, training community partners in research ethics and research methods, etc. We urge NCATS to invest in community engagement collaborations among CTSAs and other research institutions located in the same city/region. The Chicago Consortium for Community Engagement is one example (http://www.c3ctsa.org/)

**Include community partners in CTSA governance, decision-making and professional development at local and national levels.** Although CTSAs should be able to determine their own governance and decision-making structures and processes, we believe they should be required to demonstrate meaningful roles for community partners and other stakeholders based outside of the CTSA institution and specific supports for their participation, including compensation for their time and expertise. The CTSA Consortium Community Engagement Key Function Committee’s Community Partner Integration Workgroup and Value of Communities Subgroup recently conducted an inventory of community representatives’ involvement in CTSA activities and found they had limited representation and leadership roles outside of the community engagement cores, minimal influence on the overall direction of the CTSA and little feedback on whether the recommendations they provide is reviewed or acted upon. The inventory also found that compensation for community representatives was relatively low and 21% of CTSAs did not provide them with any monetary compensation.
CTSA community partners must also have a voice in the CTSA consortium. We applaud the leadership structure of the CTSA Community Engagement Key Function Committee that now requires a CTSA community partner serve as one of the co-chairs. We would like to see community partners meaningfully serving as leaders and members across the CTSA consortium committees. The National Community Committee of the CDC Prevention Research Centers program, and its representation on the PRC steering committee could serve as a working model (http://www.cdc.gov/prc/community-voice/index.htm).

CTSA community partner participation in the annual CTSA community engagement conference should be a priority. Very few community partners have participated in these conferences. We recommend that CTSA community partners serve as planning committee members, speakers and participants; funds be provided for at least one community partner from each CTSA to attend the conference; and an opportunity be provided for community partners at the conference to meet, on their own, as a group.

*Invest in assessing the impact of community engagement:* The NIH CTSA/NCATS Integration Working Group found that “community outreach…is one of the most highly variable aspects of the CTSA’s.” We believe it is critically important to evaluate CTSA community engagement efforts and widely disseminate findings and promising practices. The substantial public investment in the CTSA program demands this level of accountability, not to mention the important role the findings will have in informing “the field” and future practice and policy. We recommend a participatory evaluation be undertaken in which CTSA leadership, faculty, students, community partners, funders and other key stakeholders collaboratively define the indicators, metrics and methods used. There are a number of existing assessment frameworks and tools that could be built upon for this purpose, including, for example, those developed by the CDC Prevention Research Centers (http://www.cdc.gov/prc/program-material/report_winter2010.htm), NIEHS Partnerships for Environmental Public Health Program (http://www.niehs.nih.gov/research/supported/programs/peph/metrics/index.cfm) and the NIH/IHS funded Research for Improved Health: A National Study of Community-Academic Partnerships (http://narch.ncaiprc.org/index.cfm).

**4. Ensure Community Participation in Priority-Setting and Decision-Making**

*Invest in equitable governance and transparent decision-making:* Even for NIH funded investigators, NIH can be difficult to navigate and understand. An aggressive and robust engagement and technical assistance strategy is needed to ensure that community organizations are able to provide input on NCATS and CTSA policy and strategic directions, access funding, serve as peer reviewers and serve on the NCATS advisory council. The advisory council currently has no members who are community-based partners in research, a situation we believe should be rectified as soon as possible with the appointment of at least two individuals.

*Ensure fair and equitable peer review:* All NIH extramural funds, whether awarded through program announcements, requests for applications or “administrative” or other supplement mechanisms must undergo a merit peer review process. Community partners in research need to be included in the peer review process. The few NIH review panels that include community-based reviewers are still dominated by academics and a culture that may prevent community members from speaking freely. We believe that any NCATS funding announcement that includes a community engagement component (e.g., the CTSA program) must have reviewers with relevant experience, including community-based peer reviewers, who are properly prepared for their roles. We recommend a standing study section to review CTSA applications comprised of an equal number of academics and community members with community-engaged research experience and facilitated by community and academic co-chairs. Review criteria should also align with inclusion of community engagement. Standard NIH review criteria must not overlook key aspects of community engagement in research. Reviewers are asked to assess “scientific and technical merit,” but in community-engaged research, for example, these must include the nature and extent of community participation and the authenticity of the partnership, including the budget and how funds are distributed. We suggest that NCATS review the guidelines developed in 2008 by the NIH Council of Public Representatives as a starting point (http://copr.nih.gov/reports1/). The California Breast Cancer Research Program’s peer review process could serve as a working model (http://cbrp.org/apply/call/#overview).
Thank you again for your consideration and we look forward to hearing from you soon.

Sincerely,

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