We are writing as CTSA academic and community partners and members of Community-Campus Partnerships for Health (CCPH) in response to NOT-TR-13-001 Request for Information: Enhancing Community-Engaged Research through the Clinical and Translational Science Awards (CTSA) Program. As requested in the RFI, we have organized our comments around critical issues and recommended approaches.

Thank you for the opportunity to share our perspectives. We look forward to working with you to ensure that the CTSAs fully realize their potential to improve the health of communities. If we can be helpful in any way, please contact us through CCPH's Executive Director Sarena D. Seifer at sarena.seifer@gmail.com

Critical Issue: Community engagement is essential to the ability of CTSAs to conduct clinical and translational research that brings better health to our communities, yet it is no longer a required component of the program. The RFI incorrectly assumes that several years of requiring community engagement activities and research in the CTSA program have established the institutional culture and infrastructure needed for sustained community engagement and community-engaged research and thus requiring them and funding them is no longer needed.

Recommended Approach: Require CTSAs to have, support and sustain community engagement cores. Invest in the critical infrastructure needed for community engagement and community-engaged research in the CTSA program. Work collaboratively with CTSAs and their community partners to articulate expectations for authentic community engagement and meaningful, measurable indicators of success. Hold CTSAs accountable for these expectations and outcomes.

Community engagement is essential to the CTSAs’ ability to bring better health to our communities and must be a supported and expected component of the program. 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 in community as well as clinical environments. Prior to establishing NCATS, the NIH Director established a trans-NIH working group to recommend a strategy for ensuring that CTSAs could effectively facilitate the translation of science into improved human health on an ongoing basis. The working group recommended that the CTSA program continue to provide infrastructure to support the full spectrum of translational research, including through community engagement. 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.”

(Other links to articles and reports should be included here.)

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 CTSAs (from community and academic settings) to meet regularly. The group is comprised of 80 people from 32 CTSAs 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 CTSAs. Input from both groups has been incorporated into this letter. For more information about CCPH, visit http://ccph.info
The Senate Appropriations Committee emphasized the critical role of community engagement 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.”

Community engagement is essential to delivering new, more effective drugs, diagnostics and medical devices – and adequate resources are needed to support it. Community engagement is required to ensure that health care innovations reach underserved and marginalized communities. Without community engagement, CTSAs will continue to recruit clinical trial participants who are predominantly white and middle class, and develop new drugs, diagnostics and medical devices that are in many instances costly and challenging to deliver. Failure to diversify participation in clinical research will prevent achievement of the health outcomes envisioned by the NIH roadmap when it recommended creating CTSAs, and is likely to exacerbate racial, ethnic and socioeconomic health disparities, thus reducing and undermining 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 accept and adhere to use of 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. Nor can we be sure why and under what circumstances drugs and devices believed to be effective for all, are less effective for some.

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). The forms of involvement recommended take time to develop and require ongoing maintenance to be effective. The Patient Centered Outcomes Research Institute is also advancing greater patient engagement in the governance, design, implementation and dissemination of clinical research (http://pcori.org).

There is genuine cause for concern about whether and to what degree NCATS supports 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 that same webinar that community engagement, community-engaged research, implementation research or study designs alternative to clinical trials in the CTSA program would be considered essential for producing these quality results. We are deeply concerned that the emphasis on “cheaper, faster and better” clinical trials will undermine the trust and participation in research that many CTSAs have already built in communities 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 withdraw from or reduce 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. Further, “cheaper, faster and
better” clinical trials will not address the problem of how to apply the results of those trials in clinical practice, community programs and public policy.

The elimination of the community engagement key function in the current CTSA funding announcement sends the message that community engagement is not essential to achieving the CTSA mission. Further, in his opening remarks at the CTSA Community Engagement Conference on August 23, 2012, Dr. Insel suggested 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 might choose to respond to a forthcoming funding announcement to support it. His comments, along with the concept proposal posted on the NCATS website (http://www.ncats.nih.gov/files/FOA-Concept-CTSA-Engagement.pdf) and NOT-TR-13-001, send a clear message that NCATS regards community engagement as optional in the CTSA program.

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 facing the withdrawal of resources for community engagement because institutional leaders view it as a low NCATS priority. Other CTSA institutions appear to be uncertain about whether NCATS will value community engagement and are putting initiatives on hold. Some community partners and faculty who have been deeply invested in the success of CTSAs and involved in the program for many years feel betrayed at having forged research collaborations designed to address community-identified needs, build trust in research and develop community research knowledge and skills which are now being undermined by shifting institutional priorities tied to the perceived priorities of NCATS and the next round of CTSA funding. The newer CTSA have barely had time to engage with their communities at all.

There are a number of critical infrastructure investments that are essential to strengthening and sustaining community engagement and community-engaged research in the CTSA program:

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 is building research infrastructure in academic institutions. Investments in training, mentoring and research funding support for community organizations are essential.

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.

**Invest in 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/)

**Invest in mobilizing the considerable knowledge and experience that exists in community engagement and community-engaged research.** There is a wealth of knowledge and experience in community-engaged research, both within and outside of CTSAs, that is challenging to access and utilize. There will probably never be a “one stop” website, service or organization that will house all of the tools and resources available to support community engagement and community-engaged research. The CTSA program has already invested in a number of online clearinghouses and toolkits to support community-engaged research (e.g., http://communityresearchpartners.net, http://researchtoolkit.org, http://ctsacorus.org), not to mention those developed outside of the CTSA program (e.g., http://ecph.info, http://cbprcurriculum.info, http://CES4Health.info), and these must be better coordinated, publicized and evaluated.

**Invest in assessing the impact of community engagement:** We would not frame the evaluation of the community engagement in the CTSA program in terms of “value added” but rather in terms of assessing and documenting its impact. The NIH CTSA/NCATS Integration Working Group found that “community outreach…is one of the most highly variable aspects of the CTSAs.” 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 develop the indicators, metrics and methods to be 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).

**Critical issue:** Academic, government and industry perspectives are privileged in the priority-setting and decision-making processes at NCATS and the CTSA program

**Recommended Approach:** Involve the full range of stakeholders in shaping the future of the CTSA program, invest in equitable governance and transparent decision-making, and ensure fair and equitable peer review
stakeholders are not only consulted but also actively engaged over time through multiple mechanisms to contribute to a research and action agenda.

We would like to suggest a friendly amendment to the categories of key stakeholders the RFI explicitly sought comments from. The RFI states: “Key stakeholders include all researchers involved in bringing basic science through the translational pipeline to improve health in the community; those public and private partners who fund such research and services; and members of the public who are advocates, clinicians, patients, and community leaders seeking better diagnostics, treatments, preventions, and cures.” From our perspective, there are two important groups missing from this list. First, there are researchers who are improving health in the community through research that does not involve bringing basic science through the translational pipeline (as defined by NCATS). In other words, researchers who conduct community-engaged research that may have no basic science component, no focus on drug or device development, etc. Also missing from the list are the community leaders and community partners who are engaged in clinical and translational research alongside the academic researchers, who serve as PIs, co-PIs, research team members, community-academic liaisons, research advisory board members, etc. We realize there is of course overlap between this group and the members of the public referred to in the RFI, but they should be included as a distinct group because of the critical role they can and do play in the design, conduct and application of research.

**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. Establishing priorities must be accomplished through a transparent, inclusive and open public process.

**Include community partners in CTSA governance, decision-making and professional development at local and national levels.** 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](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.
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 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://cbcrp.org/apply/call/#overview).

Critical Issue: Community-engaged research raises ethical considerations that go beyond individual-level protections to include those at the community level.

Recommended Approach: Invest in research that seeks to understand and address the ethical issues that arise in community-engaged research. Support institution-based IRBs to effectively review community-engaged research and support the development of community-based IRBs and community-based research review boards.

Community-engaged research creates challenges for Institutional Review Boards (IRBs), which are designed to protect the rights and welfare of individual study participants and not the rights and welfare of communities involved in research. The Belmont principles and federal regulations that guide IRBs do not preclude them from reviewing community-level ethical issues, specifying, “risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society).” However, the Belmont principles do not explicitly address the scope of ethical considerations that arise in community-engaged research and thus IRB application of these principles may not provide a thorough ethical analysis. In a review of 30 university-IRB application forms, for example, Flicker et al. found that community considerations were often missing (http://www.ncbi.nlm.nih.gov/pubmed/17436114).

In order to effectively review community-engaged research, including assessing community-level risks, IRBs would need to undertake a number of steps, including: increase their understanding of community-engaged research, strengthen their community composition and explicitly include community-level ethical considerations in their policies, processes and application forms. Establishing IRBs specifically dedicated to reviewing community-engaged research or community research review boards that collaboratively work with investigators to strengthen their research designs and ethical protections are also viable models. Individual CTSA and the CTSA consortium could help to address these issues by developing and evaluating new models, undertaking multi-site interventions and sharing promising practices. Several such initiatives are already underway through CTSA community engagement supplement and NIH ARRA funding mechanisms and more should be supported.

An important aspect of protecting research participants is assuring that IRB members, chairs, researchers and research teams have an understanding of research ethics, the assessment of research risks and benefits, and strategies for minimizing research risks that is appropriate to their role. Although education does not necessarily translate into behavior change, we believe that supporting an institutional culture of ongoing professional development and continuous improvement will enhance the ability of IRBs, researchers and research teams to protect human research participants in an effective and efficient manner. Any educational requirement,
however, must give flexibility as to how that education is to be delivered and by whom. Several CTSA institutions that conduct significant amounts of community-engaged research, for example, are developing innovative research ethics training programs for community partners that aligns with their educational background, literacy level and research roles rather than requiring them to take the online CITI course. *These should be evaluated, disseminated and able to ‘count’ towards the federal requirement for research ethics training.*

*We are concerned about the expectation that CTSA institutions identify one IRB of record for all multi-site studies because it may undermine the ability of communities involved in the research being reviewed to contribute to the ethical analysis of the proposed research.* For example: In situations in which the selected IRB of record is not local to the study population, the IRB may not have adequate knowledge of relevant local context that a local IRB possibly could. In situations in which an institution-based researcher is collaborating with community partners that either operate or have access to a community IRB, mandating a single IRB of record would likely privilege the institution-based IRB. In the case of a multi-site study involving a site operated by a tribal community, mandating a single central IRB might undermine the tribal government’s right to self-determination by not permitting tribal IRB review.

To ensure the ethics and integrity of the research in which they and their communities are engaged, a growing number of community groups have developed their own research ethic review processes that operate independently or in conjunction with institution-based Institutional Review Board (IRBs). The first systematic study of these processes identified 109 community groups across the U.S. with such processes in place, described their challenges and benefits, and documented the ethical issues they consider that institution-based IRBs normally do not (http://www.ncbi.nlm.nih.gov/pubmed/21164086). Community IRBs and community-based research review boards could potentially play a more significant role in ensuring the ethics and integrity of community-engaged research conducted through CTSAs. *Research is needed to better understand these models and their impact, and support provided to communities seeking to establish them.*

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