The CTSA program, individually and as a consortium, have tremendous potential to improve health and eliminate health disparities. As we elaborate in our comments below, community engagement is essential to the success of the CTSA program and must be a supported and expected outcome. A CCPH-CTSA member interest group was established in 2010 to provide a space for CCPH members involved in CTSAs (from both community and academic settings) to meet regularly. The group is comprised of seventy-three people from 29 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, as well as the CCPH board of directors and members-at-large, has been incorporated into these comments.

Positioning the CTSA program to overcome one or more of the barriers in moving insights from research into and along the translational pipeline to inform clinical care

As clearly articulated on the NCATS homepage, the mission of NCATS is “to catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions” and “the translational pipeline” refers to the pipeline that delivers new drugs, diagnostics and medical devices to patients.

While delivering new, more effective drugs, diagnostics and medical devices is a worthwhile goal, we strongly urge that NCATS not position the CTSA program to narrow their broad clinical and translational goals or prioritize this goal over others. As noted in the NCATS RFI, 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 social determinants of health through changes in policies, practices and systems have the greatest potential for improving human health.

The Senate Appropriations Committee emphasized this point in the report that accompanied the 2012 NCATS budget, 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 that “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.

We also believe it is important for NCATS to recognize that community engagement is essential to delivering new, more effective drugs, diagnostics and medical devices – and to provide adequate resources 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. Our report, Communities as Partners in Cancer Clinical Trials: Changing Research Practice and Policy, developed with the Education Network to Advance Cancer Clinical Trials and funded by AHRQ and NCI developed 60 specific recommendations for how communities must be involved as partners in every phase of cancer clinical research (http://communitiesaspartners.org). 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.

Fostering the role of the CTSAs in bringing better health to our communities through implementation and delivery research (e.g., innovative new approaches include mobile tools for outcome assessment, social media for community outreach, analytic approaches to assess health practices, and working with public and private sponsors for community outreach)

Community engagement is essential to the CTSAs being able to bring better health to our communities and must be a supported and expected outcome 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. Our Communities as Partners in Cancer Clinical Trials report also makes recommendations based on this principle.

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. Further, having “cheaper, faster and better” clinical trials will not solve the problem of applying the results of those trials into clinical practice and public policy.

There are troubling signs that CTSAs are already responding to perceived NCATS priorities. 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 even been proposed. 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 then allocate the resources to back it up. The next CTSA funding announcement is a timely opportunity to demonstrate that support by maintaining the program’s broad clinical and translational focus, requiring CTSAs to have community engagement cores, providing expectations for what authentic community engagement is and is not, and implementing a merit review process that includes community-based as well as academic peer reviewers.

We also respectfully request that the term “community outreach” in NCATS communications be replaced by community engagement and community participation. Past CTSA funding announcements refer to the “community engagement and research core” and while it may seem like a minor word substitution, community outreach implies that institutions and researchers “reach out” into communities to deliver or solicit information. It is not a term that conveys the building of mutually beneficial partnerships that are essential to the CTSAs being able to bring better health to our communities.

Identifying critical infrastructure investments that are essential to strengthening translational research (e.g., types of consultative services or clinical research facilities, possible sharing across sites)
There are a number of critical infrastructure investments that are essential to strengthening the full spectrum of translational research. Below we highlight those in particular we believe are needed:

**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. Indeed, the funding mechanisms and peer review processes at NIH are designed to support academic institutions, even if technically community organizations are listed among the eligible applicants. Not all community organizations are in a position to lead NIH grant-funded research, of course, but some have demonstrated their capacity to do so and others could be positioned to do so through funding mechanisms that support training, coaching and technical assistance from seasoned peers and academic partners.

**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 CTSA 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 CTSA 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 CTSA and other research institutions located in the same city/region, such the Chicago Consortium for Community Engagement (http://bit.ly/eBBONH)
Ensure fair and equitable peer review

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 recommend that NCATS review the guidelines developed in 2008 by the NIH Council of Public Representatives as a starting point: http://copr.nih.gov/reports1/

Invest in equitable governance and participation

Although CTSAAs 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(s).

CTSA community partners need to have a voice in the CTSA consortium. We applaud the recent change to 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.

CTSA community partner participation in the annual CTSA community engagement conference should be a priority. Very few community partners have participated in past 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.

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 policy and strategic directions, access NCATS funding and serve as peer reviewers. The NCATS advisory council membership should be posted on the NCATS website, with an open application process for new members. The comments you receive in response to this RFI should be posted publicly along with a clear statement of how the comments informed decisions about the CTSA program and what those decisions are.

Improving the protection of human subjects in ways that simultaneously will improve oversight and minimize burden and delays (e.g., central or reciprocal IRB reviews, model consent processes)

Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators,” published in the July 26, 2011 Federal Register. Below we highlight points made in those comments that are particularly relevant here and suggest ways that CTSAs could help to address them.

**Ethical oversight of community-engaged research:** Community-engaged research raises ethical considerations that go beyond individual-level protections to include those at the community level. This creates challenges for 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 CTSAs 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.

**The informed consent process:** With regard to informed consent, we urge the CTSAs to focus on improving the process of seeking and obtaining informed consent, with particular emphasis on the ongoing and iterative nature of the consent process; the responsibilities that researchers bear for ensuring that truly informed consent is obtained and the importance of educating researchers about their role; and methods for assessing comprehension and determining whether and to what extent an authentic consent process actually takes place. While the researcher is responsible for assuring that informed consent is obtained and documented, we believe it is acceptable for properly prepared representatives of the researcher such as patient educators, patient navigators and community health workers to carry out the informed consent procedures.

The lengthy and jargon-laden forms approved by many IRBs to document a participant’s informed consent must be vastly improved, and also consider linguistic and cultural literacy. There is already a provision in the federal regulations for use of the “short form” and a robust process or discussion, although seldom approved by IRBs. Written forms used to document consent should summarize the information provided to prospective participants rather than include all of the elements of informed consent required in the federal regulations. Further, the documentation of informed consent should be permitted in ways other than signed, written forms such as audio recording over the phone or video recording in person. Again, individual CTSAs and the CTSA consortium could help to address these issues by developing and evaluating new models, undertaking multi-site interventions and sharing
promising practices.

Aligning extent of research ethics review with the risk to participants: The extent of oversight of research should vary depending on the potential risk of the research. One reason the current system is overly burdensome is that studies often receive the same level of review, regardless of the potential risk to participants. In some cases, low-risk studies are over-scrutinized; in others, high-risk studies do not receive enough attention. *IRBs at CTSA institutions should take full advantage of existing flexibility in regulations, such as making exempt determinations or using the expedited procedure for review of research.*

Central or reciprocal IRB reviews: We do not support OHRP’s proposal in the ANPRM to mandate that there be one IRB of record for all multi-site studies. First, there is nothing in federal regulations currently prohibiting the institutions and organizations involved in single or multi-site studies to voluntarily enter into some sort of central or reciprocal review process. Second, in a worst-case scenario, this proposed change, without further clarification, could lead to “IRB shopping” in which a researcher selects an IRB he or she feels will be most lenient or favorable.

We are primarily concerned about this proposed requirement, however, 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.

Assuring IRB members, researchers and research teams are prepared for their roles in protecting research participants: 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.

People are participants in research, not “subjects.” We respectfully request that NCATS consistently use the term “research participants” when referring to people who are enrolled in research studies and eliminate the term “research subjects” from its lexicon. This seemingly simple change in terminology has profound implications for how researchers view the people enrolled in their studies and for how those people view their roles, rights and responsibilities in research.
Establishing priorities for shared, consortial activities across the CTSA sites as well as methods to encourage and support the high priority activities

We wholeheartedly agree with the importance of establishing priorities for shared, consortia activities across the CTSA sites and establishing methods to encourage and support those activities. Establishing priorities must be accomplished through a transparent, inclusive and open public process involving community partners and other key stakeholders outside of CTSA institutions. All extramural funds, whether awarded through program announcements, requests for applications or “administrative” or other supplement mechanisms must undergo a merit peer review process.

Encouraging shared investments with public and private funders, both non-profit and for-profit (e.g., shared goal setting and metrics of success, redistribution or timing of risks and benefits)

We believe there are tremendous opportunities for public and private funders to collaboratively invest in clinical and translational research. Since 2007, CCPH has been facilitating the Community-Based Participatory Research Funders Interest Group, currently comprised of about 50 public and private funders in the US and Canada, many of whom do not refer to themselves as research funders per se but view community-engaged clinical and translational research as a strategy for building healthier communities. Certainly, individual CTSAs have engaged public and private funders as investors and partners. The CTSA consortium, having identified priorities through the process referred to above, should aggressively pursue mutually beneficial partnerships with public and private funders.

With respect to partnerships with for-profit entities, we strongly urge that policies be established that ensure publicly funded research data and findings are publicly accessible and profits generated are shared.

Measuring the value added of the CTSA program for science, the translational mission, and the improvement of the Nation’s health

We would not frame the evaluation of 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 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 program (http://www.cdc.gov/prc/program-material/report_winter2010.htm) and the NIEHS Partnerships for Environmental Public Health Program (http://www.niehs.nih.gov/research/supported/programs/peph/metrics/index.cfm)

Involving the full range of key stakeholders in shaping the future of the CTSA program

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 we advocate they be included as a distinct group because of the critical role they can and do play in the design, conduct and application of research.

**Thank you for the opportunity to share our views**

We look forward to working with you to ensure that the CTSA's fully realize their potential to improve the health of communities. We are eager to apply our expertise and experience in community engagement, community-engaged research and community-academic partnerships in any way that may be helpful. You may contact us through CCPH's executive director Sarena Seifer at sarena.seifer@gmail.com

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MORE ABOUT COMMUNITY-CAMPUS PARTNERSHIPS FOR HEALTH

CCPH is a national non-profit organization that promotes health equity and social justice through partnerships between communities and higher educational institutions. We view health broadly as physical, mental, emotional, social and spiritual well-being and emphasize partnership approaches to health that focus on changing the conditions and environments in which people live, work and play. Our strategic goals are to:

- Leverage the knowledge, wisdom and experience in communities and in academic institutions to solve pressing health, social, environmental and economic challenges
- Ensure that community-driven social change is central to the work of community-academic partnerships
- Build the capacity of communities and academic institutions to engage each other in partnerships that balance power, share resources, and work towards systems change

CCPH members – a diverse group of over 2,000 individuals affiliated with community organizations, colleges and universities, health care delivery systems, student service organizations, foundations and government – are advancing these goals in their work on a daily basis.

We view research as an essential tool for improving health and eliminating health disparities. Since its inception in 1997, CCPH has played a leadership role in advancing a community-based participatory research paradigm in which community members and researchers collaborate to conduct research that builds capacity, leads to knowledge that directly benefits communities and influences policies that affect health. We seek to ensure that communities benefit from health research through their meaningful involvement in decisions about what research is conducted, how it is conducted and used, and by whom.