November 14, 2012

Christopher P. Austin, M.D.
Director
National Center for Advancing Translational Sciences
6701 Democracy Blvd, Room 9113, MSC 4874
Bethesda, MD 20892-4874

Re: Request for Information: Enhancing Community-Engaged Research through the Clinical and Translational Science Awards Program

Dear Dr. Austin:

The Association of American Medical Colleges (AAMC) is pleased to have this opportunity to provide comments on the development of a community-engaged research agenda utilizing the infrastructure developed through the Clinical and Translational Science Awards (CTSA) Program.

The AAMC is a not-for-profit organization representing all 141 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs Medical Centers; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 75,000 medical students, and 110,000 resident physicians. These institutions and individuals invariably have strong commitments to communities, either in the adjacent regions they serve or among more disparate populations linked by common heritage, purpose, or affliction. Our members, which include most all CTSA institutions, have pioneered programs to engage these communities as partners in research. The AAMC, therefore, commends the National Center for Advancing Translational Sciences (NCATS) for acknowledging the crucial role of community engagement in fostering research collaborations, enhancing public trust, and catalyzing the development of methods and technologies that will improve the public’s health. Our comments are delineated below:

Community-engaged research is an essential pillar of translational research. The AAMC applauds the operating principle of the NIH that the CTSA should have flexibility in developing community engagement programs in the context of their institutional priorities and strengths and community needs in order to most effectively enhance translational research benefits to the communities. However, just as improving health through enhancing translational research is a foundational core of the CTSA, and just as the CTSA have a strong expectation to support the integration of basic discovery and the acceleration of clinical efficacy and effectiveness research, so too should they have an expectation and infrastructure to support community-engaged research.

Strategic investment in and assessment of the infrastructure to support community-engaged research is crucial. Like all research programs, the success of a community-engaged research program will depend on an adequately funded and institutionalized infrastructure with clear indication from all stakeholders – the CTSA, the institution, and the NIH – of their collective commitment to sustaining a strong community engagement foundation demonstrated by, for example, aligned and consistent budget allocations. The infrastructure should not only support public education and recruitment to ensure that
clinical trials engage historically underserved and/or at risk populations who deserve to benefit from research innovations enjoyed by majority groups, but also equally support the building of long-lasting community relationships that continue well beyond a two- or three-year clinical trial. The infrastructure for community-engaged research should extend to implementation or dissemination research to ensure that rigorous scientific methods are used to help guarantee not just the involvement of the community in participating in and defining research questions and protocols, but also in the implementation and dissemination of the results back to their communities.

**Community-engaged research should be integrated with NIH Institutes’ and Centers’ efforts.** A number of community-engaged research initiatives focus on specific diseases, which opens up the possibility of the CTSA engagement community joining forces with other NIH Institutes and Centers to share practices, resources, targeted training, and to maximize the outreach to those communities in need.

**Community-engaged research collaboratives could enhance the CTSA mission.** The techniques, databases, tools, use of telemedicine and social media, etc., will vary across the CTSAs. However, the successful creation of an evidence base to improve health across communities could be accelerated by community-engaged research collaboratives that either join CTSAs to each other, or to other networks such as practice based networks, area health education centers, or private insurers. For example, CTSA consortia might focus on engagement with communities that share common environments, health or health care needs, or socio-demographic characteristics. These consortia could develop joint recruitments; foster data and resource sharing; engage in distance learning, mentoring, and other training opportunities; and facilitate the exchange of best practices, successful methods, and various other activities to improve efficiencies and outreach. A commitment to research collaboratives across communities could be reflected in the CTSA budget, evaluation criteria, and commitment of the institution(s) and communities.

**Community-engaged research should help create a balanced and synergistic portfolio of research questions.** Building on growing evidence that diverse perspectives create better answers to challenging questions, community-engaged research should provide the foundation and infrastructure to develop and refine research questions informed by community-perceived needs. Not to supplant innovations derived from basic research, but to create a balanced and synergistic portfolio of research questions.

**The CTSAs should embed community-engaged research in their research training and workforce development initiatives.** The CTSAs have a central commitment to research training and workforce development. The distinct characteristics of community-engaged research offer opportunities for innovative training models that are targeted to team-based training for community leaders, researchers, educators, residents, students, and others. This could also provide an opportunity for the CTSAs to partner with local communities to jointly invest through shared funding from community stakeholders, where possible.

**Rigorous metrics developed by the CTSA, community, and outside evaluators are essential to improve and advance community-engaged research outcomes.** Evaluations of the community engagement enterprise must be rigorous, developed in partnership with communities, and subjected to scrutiny by external evaluation. Some metrics should be specifically aimed at minimizing or eliminating health inequities within the local community. The evaluations should necessarily include metrics that speak to study enrollment and attrition, with specific attention to historically underserved populations.
For the communities with which CTSA institutions engage, capacity building and sustainability of relationships are often key, and outcomes in these areas should also be included. There should also be an ongoing evaluation of not only the inputs that support the community-engaged research infrastructure but also its outputs; the extent to which the infrastructure enhances community-engaged research and benefits the community.

We also support broad evaluation of the community engagement endeavor across all CTSAs to quantify through a variety of complementary methods and with input from all stakeholders, the institutional, community, and social impacts of the research. Building an evidence base that demonstrates the tangible benefits of community engagement on drug/device development and in addressing the health needs of CTSA communities will advance the science of engagement and disseminate promising practices more widely.

**Regulatory and community engagement stakeholders should partner to address some of the inherent regulatory challenges with community-engaged research.** Institutional Review Boards (IRBs) often face challenges when reviewing community-engaged or -partnered research. Many IRBs are unfamiliar with the process of engaging communities and many IRB policies are not interpreted to allow this review body to approve research developed through an iterative process. In addition, most IRBs are familiar with consideration of the protections of and risk analysis for individual human subjects, not the potential risks and benefits facing communities who are engaged in research. The AAMC has been working with member institutions to identify best practices for IRB review of research involving communities, and is developing a set of case studies addressing these issues.

Again, the AAMC congratulates NCATS and the CTSAs for addressing how to enhance community-engaged research. The AAMC stands ready to work with CTSA institutions to strengthen capacity to conduct community-engaged and -partnered research. Successfully engaging local communities in all aspects of the translational research enterprise including dissemination and implementation is vital to not only developing drugs and devices, but also to reducing and eventually eliminating health disparities and inequity.

Sincerely,

Ann Bonham, Ph.D.
Chief Scientific Officer