DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information (RFI): Soliciting Input for the National Center for Advancing Translational Sciences (NCATS) Strategic Planning Process

SUMMARY: The National Center for Advancing Translational Sciences (NCATS) seeks input on the development of a five-year strategic plan. We invite input from any and all interested parties.

DATES: To ensure consideration, responses must be submitted by Jan. 8, 2016, 11:59:59 p.m. EST.

ADDRESSES: Comments must be submitted electronically using the web-based form available at *http://grants.nih.gov/grants/rfi/rfi.cfm?ID=50.*

FOR FURTHER INFORMATION CONTACT: Specific questions about this notice should be sent via email to: *NCATSstrategicplan@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

Several thousand diseases affect humans of which only about 500 have any treatment. Thanks to our growing understanding of human biology, along with the increased availability of innovative technologies, there is an unprecedented opportunity to translate scientific discoveries more efficiently into new, more effective and safer health interventions. Currently, a novel intervention can take about 14 years and $2 billion to develop, with a failure rate exceeding 95 percent.

To address the challenges, NCATS strives to develop innovations to reduce, remove or bypass costly and time-consuming bottlenecks in the translational science process in an effort to speed the delivery of interventions (*e.g.* drugs, diagnostics and medical devices) to patients. Rather than targeting a particular disease or fundamental science, NCATS focuses on what is common across diseases and the translational process. The Center emphasizes innovation and deliverables, relying on the power of data and new technologies to develop, demonstrate and disseminate improvements in translational science that bring about tangible improvements in human health. NCATS' current programs focus on pre-clinical innovation to drive advances in early stages of the translational process, from target validation to first-in-human studies; clinical innovation to support clinical and translational research, creating and sharing expertise, tools and training needed to develop and deploy effective treatments in people; and reengineering translational science through cross-cutting programs that address common scientific and organizational barriers to enable faster and more effective interventions that tangibly improve human health.

For more information about NCATS, visit *https://ncats.nih.gov.*

Translation and Translational Science

NCATS defines translation as the process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public—from diagnostics and therapeutics to medical procedures and behavioral changes. Translational science is defined as the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

The translational science process can be envisioned as a spectrum (*https://ncats.nih.gov/translation/spectrum*) encompassing each stage of research along the path from the biological basis of health and disease to interventions that improve the health of individuals and the public. The spectrum is not linear or unidirectional; rather, each of the five stages (Basic Research, Pre-Clinical Research, Clinical Research, Clinical Implementation, and Public Health) builds upon and informs the others. Patient Involvement plays a central role in the entire process.

Basic Research, while not typically conducted at NCATS, reveals fundamental mechanisms of biology, disease or behavior that inform and can be informed by each of the other stages. *Pre-clinical Research* connects those basic discoveries made in the laboratory or clinic to a new medical intervention. *Clinical Research* tests the safety and effectiveness of those interventions in human subjects, and also can include behavioral and observational studies, outcomes and health services research, and the testing and refinement of new technologies. Research on the adoption of medical interventions into routine clinical care for the general population, the evaluation of clinical trial results, and the identification of new clinical questions and gaps in care occur in the *Clinical Implementation* stage. The *Public Health* stage of translation includes studies on health outcomes at the population level to determine the effects of diseases and efforts to prevent, diagnose and treat them. Central to the translational science spectrum is *Patient Involvement* in which NCATS researchers collaborate and engage with patients and community members to better identify and understand public health needs and develop useful medical interventions. For more information, including a graphical depiction of the translational science spectrum, visit *https://ncats.nih.gov/translation/spectrum.*

At all stages of the spectrum, NCATS develops new approaches, demonstrates their usefulness, disseminates the findings, and engages with patients and community members to better identify and understand public health needs.

Strategic Planning Process

NCATS is in the process of developing its first strategic plan to set the goals and priorities of the Center over the next five years. We anticipate that the strategic plan will outline and provide a roadmap of translational research priorities and the most pressing scientific and operational opportunities and challenges in translation; emerging research needs; barriers to progress; and the resources, infrastructure, or tools needed to catalyze major scientific advances in translation.

NCATS is soliciting stakeholder input through this Request for Information and through a series of webinars (details at *https://ncats.nih.gov/strategicplan*) to ensure that members of the community and our partners have a voice in framing the Center's future scientific direction.

Information Requested

NCATS seeks input on the scientific and operational opportunities, challenges and research needs in translational science to help set the Center's strategic priorities and inform the development of a five-year strategic plan.

Some examples of particular issues of interest that apply across the translational science spectrum include:

- Breaking down professional, cultural and scientific silos across the translational science spectrum
- Focusing on inter-operability of data systems (such as integrating patient data and electronic health records into pre-clinical research)
- Expanding research efforts at NCATS into new therapeutic modalities
- Focusing on patient-driven research and patient/community engagement
- Forming innovative partnerships with a wide variety of stakeholders
- Identifying skillsets and competencies needed for training the next generation of translational scientists
- Utilizing modern communication and dissemination tools to expand awareness of translational science to a wide variety of stakeholders

NCATS encourages stakeholders from all sectors to provide input on these and

any other relevant issues. Stakeholders include, but are not limited to: Patients and members of the health advocacy community; basic, translational and clinical scientists at universities and research institutions; health care providers; biotechnology, venture capital and pharmaceutical industry members; colleagues at other NIH institutes, centers and offices; partners at other government agencies (*e.g.* the Food and Drug Administration, other agencies of the Department of Health and Human Services, the Environmental Protection Agency, and the Department of Defense); policy makers and funders; as well as the general public. Organizations are encouraged to submit a single response that reflects the views of their organization and membership as a whole.

To respond to this RFI, please go to *http://grants.nih.gov/grants/rfi/rfi.cfm?ID=50.* To ensure consideration, responses must be submitted by Jan. 8, 2016, 11:59:59 p.m. EST.

General Information

Responses to this RFI are voluntary. Do not include any proprietary, classified, confidential, trade secret or sensitive information in your response. Respondents are advised that the U.S. Government is under no obligation to acknowledge receipt of the information provided and will not provide feedback to respondents. The Government will use the information submitted in response to this RFI at its discretion. The Government reserves the right to use any submitted information on public NIH Web sites, in reports, in summaries of the state of the science, in any possible resultant solicitation(s), grant(s), or cooperative agreement(s), or in the development of future funding opportunity announcements.

This RFI is for information and planning purposes only and shall not be construed as a solicitation, grant, or cooperative agreement, or as an obligation on the part of the Federal Government, the NIH, or individual NIH Institutes and Centers. The Government will not pay for the preparation of any information submitted or for the Government's use of such information. No basis for claims against the Government shall arise as a result of a response to this request for information or from the Government's use of such information.

NCATS looks forward to your input and encourages you to share this RFI document and the information about the upcoming webinars with your colleagues.

Dated: September 25, 2015.

Christopher P. Austin,

Director, National Center for Advancing Translational Sciences (NCATS).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Violence Intervention to Enrich Lives (VITEL) Supplement—NEW

This data collection is to study the intersection of intimate partner violence (IPV) and trauma for women with HIV, at risk for HIV, and at risk for substance use disorders (SUDs). VITEL provides supplemental funding to existing SAMHSA Targeted Capacity Expansion: Substance Abuse Treatment for Racial/Ethnic Minority Women at High Risk for HIV/AIDS (TCE–HIV: Minority Women) grantees. The goals of the VITEL program are (1) reduce IPV through screening and referrals, (2) reduce risky behaviors that lead to new HIV infections and SUDs, (3) increase access to care and improve health outcomes for people living with HIV and AIDS, (4) reduce HIV-related health disparities resultant from IPV screening tool implementation, and (5) determine the feasibility of integrating IPV screening in behavioral health settings. A multi-stage approach has been used to develop the appropriate theoretical framework, conceptual model, evaluation design and protocols, and data collection instrumentation. Process and outcome measures have been developed to fully capture community and contextual conditions, the scope of the VITEL program implementation and activities, and client outcomes. A mixed-method approach (*e.g.,* surveys, semi-structured interviews, focus groups) will be used, for example, to examine collaborative community linkages established between grantees and other service providers (*e.g.,* primary health care, SUD recovery), determine which program models and what type and amount of client exposure to services contribute to significant changes in IPV, SUD, and HIV risk behaviors of the targeted populations, and determine the impact of VITEL services on providers, clients, and communities.

The data collection for this program will be conducted quarterly (during this one year supplemental period) and the client outcome data collection will be ongoing throughout the program and will be collected at baseline, discharge and 6-months post baseline for all treatment clients. The respondents are clinic-based social workers and counselors, clinic-based administrators and clinic-based clients. The estimated annualized burden is summarized below:

Instrument/activity	Number of respondents	Responses per respondent	Total response numbers	Total response numbers	Hours per response	Total burden hours
Baseline data collection (Clients)	500	1	500	500	.42	210
Discharge data collection (Clients)	500	1	500	500	.42	210
6-month post Baseline data collection (Clients)	500	1	500	500	.42	210