**NCATS CTSA Program Policy and Procedures for Surveys**

The CTSA Program supports high quality translational and clinical research locally, regionally and nationally and fosters innovation in research methods, training, and career development. The intellectual capital and resources within the CTSA Program are rich sources of information. Surveys are one way to capture a snapshot of this information. The purpose of a survey may be to uncover answers, evoke discussion, discover resources, base decisions on objective information and/or to compare results.

There is a need for a controlled process for survey deployment and archival within the CTSA Program. A Federal agency cannot collect ***or sponsor a collection of information*** from 10 or more public respondents without obtaining approval from the Office of Management and Budget (the Paperwork Reduction Act, PRA[[1]](#footnote-1)). This tends to be a lengthy approval process, often taking several months for processing and approval.

However, due to the 21st Century Cures Act, a bipartisan effort “to accelerate the discovery, development, and delivery of 21st Century Cures”, NIH research activities are exempt from PRA approval.

*“SEC. 2035. Exemption for the National Institutes of Health from the Paperwork Reduction Act requirements. Subchapter I of chapter 35 of title 44, United States Code, shall not apply to the voluntary collection of information during the conduct of research.’’*

**Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge** (*46 CFR 46.102 and the Common Rule .102(l))*

When making determinations to assess whether the project, in question, is subject to PRA clearance, NIH needs an answer to the following questions:

1. Will the program analyze the project outcomes in a systematic way?
2. Will the program publicize the results of your systematic analyses?

If the answer to both questions is yes, then the program is conducting NIH research and will be considered exempt from the PRA approval requirements as outlined by the 21st Century Cures Act.

**Implementation of Surveys within the CTSA Program:**

* NCATS, through the CTSA Program Coordinating Center, will identify/confirm that the activity is research by requesting the above mentioned questions are answered by people requesting to deploy a survey. If unsure if the activity is research, NCATS staff will obtain a determination through the NIH Office of Policy for Extramural Research Administration.
* NCATS, through the CTSA Program Coordinating Center, will ensure documentation of exemption from PRA.
* If the activity is not research, but NCATS determines that the survey is of value to proceed, NCATS staff, working with the requestors, will develop the appropriate materials and submit the request to the NIH Office of Policy for Extramural Research Administration for processing of PRA approval.

An example of an item that is exempt from PRA approval includes the following:

* Customer Satisfaction / Feedback Surveys if outcomes are analyzed in a systematic way and the results are publicized.

For additional guidance from the CTSA Program Coordinating Center please contact: <https://clic-ctsa.org/contact> or [help@clic-ctsa.org](mailto:help@clic-ctsa.org)

1. 44 U.S.C. Chapter 35, the Paperwork Reduction Act of 1995 (PRA), see https://policymanual.nih.gov/1825#52E077E2 [↑](#footnote-ref-1)