



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: August 9, 2019

To: Office of Management and Budget (OMB)

Through: Reports Clearance Officer, DHHS
Project Clearance Chief, NIH
Project Clearance Liaison, NCI

From: Michael Montello, Pharm. D., CTEP (National Cancer Institute)

Subject: Nonmaterial/Non-substantive change request for:
CTEP Branch and Support Contracts Forms and Surveys (National Cancer Institute)
(OMB #0925-0753, Expiration Date: 07/31/2021)

This is a request for OMB to approve a non-substantive change to the CTEP Branch and Support Contracts Forms and Surveys (National Cancer Institute) approved on 7/31/2018.

This non-substantive change request does not change the purpose or objectives of the website or change the overall burden to the public. The CTSU contract uses the OPEN-Rave request form to support setup of the study in the CTSU Regulatory Support System and the Oncology Patient Enrollment Network (OPEN) systems.

The changes to the OPEN-Rave form include:

- Corrected estimated completion time in burden statement per the SSA and corrected editorial errors;
- Removing question 2.1, "Specify the RandoNode URL" as it is no longer relevant;
- Removal of the Count Accrual Step column in question 2.2 as it is no longer relevant;
- Rewording of question 4.4 to support renaming of the Central Monitoring Portal to Source Document Portal;
- Addition of configuration information to question 4.4 (Step Number, patient parameters) to support Central Monitoring setup and configuration;
- Removal of question 4.7, "Will this protocol use the CTSU Imaging Portal?", as it is no longer relevant; and
- Renumbering of questions with the removal of questions 2.1 and 4.7.

Three files are provided – the original form, a clean copy of the revised form, and a Revised Marks file. All the changes can be seen in **bold red** (additions and strike throughs) in the "Revised Marks" file.

Summary of Changes:

- Corrected Burden Statement
- Removing question 2.1
- Removing the Count Accrual Step column in section 2.2.
- Rewording of question 4.4
- Adding configuration sub-section to question 4.4
- Removing question 4.7
- Renumbering of questions