



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

National Institutes of Health  
National Cancer Institute  
Bethesda, Maryland 20892

Date: July 12, 2023

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:  
CTSU OPEN Rave Request Form (National Cancer Institute)  
(OMB #0925-0753, Expiration Date: 05/31/2024)

This is a request for OMB to approve non-substantive changes to the attached CTSU OPEN Rave Request Form. The updates to the CTSU OPEN Rave Request Form are updates to Section II a new question 2.8 ("Will this protocol use IROC credentialing? If yes, indicate each type of credentialing that will be collected in OPEN (i.e. IMRT, 3D)."), Section IV question 4.3 ("If yes, will this trial use the standard Phase 2/3 Form Timeliness Windows?" There is also a notation defining the Phase 2/3 Form Timeliness Windows.), and Section IV a new question 4.5 ("What method will be used to assign reviewable data points in Rave?"). These additional questions are needed as part of the initial protocol set up in our regulatory application to support new functionality that was added in OPEN and Rave. The addition of the three questions will not increase the burden to complete the form.

Attached to this request is the revised form (clean and tracked versions). All the changes can be seen in **bold red** (additions and strikes) in the "Revised Marks" file.