



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: September 12, 2018

To: Office of Management Policy and Compliance (OMPC)

Through: NCI PRA OMB Clearance Liaison, NIH

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 (NCI) approval. Based on a teleconference with OMB on 10/07/2010, a non-substantive change is sufficient for this request as it does not change the purpose or objectives of the program or change the overall burden to the public.

As outlined in Supporting Statements A of the OMB package submitted in 2018, a number of forms are used by CTEP and their contractors to ensure compliance with federal regulations and facilitate collection of information on participating institutions, investigators, and key clinical staff participating on NCI-sponsored clinical trials.

There are two versions of each file. The highlighted file Tracked Orig has strikethroughs to denote deletions, underlines to denote additions, and a highlighted text box with other changes. The second file shows the revised version with no highlights.

There are no substantial changes to any of the forms. In addition, there are no changes to the current levels of burden for completion or submission of these forms.

Summary of Changes:

Attachment A02

The requested nonmaterial/non-substantive change to the CTSU IRB Certification Form is editorial in nature and includes:

- Updated submission instructions
- Removed the statement in question #2, "Required for protocol amendments"
- Modified the instructional wording in 4
- Removed 6 and 6a - FWA number and expiration date¹

¹ The FWA number and expiration date is being removed because the CTSU Regulatory Office is no longer entering the FWA information and this information is not mandatory for processing the forms.

- Modified question numbering throughout document
- Modified 11 from “Commonly Used”
- Removed date formatting throughout document
- Updated submission and instruction information on Supplemental Page
- Removed columns 3 and 4 on Supplemental Page – FWA number and expiration date
- Removed “In Reference to Protocol #:” on Supplemental Page
- Updated for 508 compliance.

Attachment A03

The requested nonmaterial/non-substantive change to the Optional Form 1 – Withdrawal from Protocol Participation Form is editorial in nature and includes:

- Updated submission instructions
- Updated for 508 compliance

Attachment A04

The requested nonmaterial/non-substantive change to the Site Addition Form is editorial in nature and includes:

- Updated submission instructions
- Removed 3c and 4c - FWA number for Parent Institution and New Institution
- Updated for 508 compliance

Attachment A05

The requested nonmaterial/non-substantive change to the CTSU Roster Update Form is editorial in nature and includes:

- Updated instruction for registering in Registration and Credential Repository
- Updated instructions for assigning roles
- Relocated submission instructions with additional detail provided
- Removed internal processing instructions table
- Updated for 508 compliance

Attachment A06

The requested nonmaterial/non-substantive change to the CTSU Request for Clinical Brochure is editorial in nature and includes:

- Updated submission instructions
- Changed items listed in CTSU Internal Reminders box at bottom of form
- Updated for 508 compliance

Attachment A07

The requested nonmaterial/non-substantive change to the CTSU Supply Request Form is editorial in nature and includes:

- Updated submission instructions
- Format changed to improve readability and enhance functionality for responses
- Changed items listed in CTSU Internal Reminders box at bottom of form
- Updated for 508 compliance

Attachment A10

The requested nonmaterial/non-substantive change to the CTSU Data Transmittal Form is editorial in nature and includes:

- Updated for 508 compliance

Attachment A15

The requested nonmaterial/non-substantive change to the CTSU Patient Enrollment Transmittal Form is editorial in nature and includes:

- Updated and reversed order 2 and 3 in submission instructions box at top of form
- Changed 7 to indicate organization (rather than group affiliation)
- Removed 8 for date patient signed IRB consent form
- Removed 9 for date of HIPAA authorization
- Removed internal processing instructions box
- Updated for 508 compliance

Attachment A16

The requested nonmaterial/non-substantive change to the CTSU Patient Transfer Form is editorial in nature and includes:

- Relocated submission instructions and added information on notifications in a box at the top of page 2
- Removed Level of responsibility being transferred
- Removed the transfer between steps information
- Removed Data Share information
- Removed Office Use Only box at the bottom of the page 2
- Removed on Checklist regarding Transfer Effective Date and Level of responsibility rows
- Added Checklist to verify that The Study PI for the protocol must have an active status
- Updated for 508 compliance

Attachment A17

The requested nonmaterial/non-substantive change to the CTSU System Access Request Form (which is not used by clinical site staff) is editorial in nature and includes:

- Modified the definition of Admin-Staff in the CTSU Operations Roles table
- Replaced roles of CTEP Staff and CTEP/Tri Web Reporting with CM Review and CM Triage, respectively
- Added CM_Review, CM_Triage, Clinical Document Access, Contract Specialist, DTL Setup, NCI_Staff, RSS Authorizer, RSS User, Rave Primary URL Owner, Rave Secondary URL Owner to the CTSU Operations Roles table
- Added IROC, Wake and URCC to the List of Authorizers and change to the *as of* date