



Date: January 15, 2016

To: Office of Management and Budget (OMB)

Through: Darius Taylor, Report Clearance Officer, HHS
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From: Dr. Mike J. Montello, Pharm. D., CTEP (National Cancer Institute)

Subject: Nonmaterial/Non-substantive change request for Cancer Trials Support Unit (CTSU) IRB/Regulatory Approval Transmittal Form
OMB #0925-0624, Expiration Date: 1/31/2017

This is a request for OMB to approve a nonmaterial/non-substantive change to the Cancer Trials Support Unit Program (CTSU). Based on a teleconference with OMB on 10/7/2010, a nonmaterial/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.

The Cancer Trials Support Unit (CTSU) is a contractor operated service offered by the National Cancer Institute - Cancer Therapy Evaluation Program (CTEP) - to enhance and facilitate access to cancer clinical trials in the United States and Canada. The CTSU maintains a broad menu of trials developed by the NCI-funded sponsoring networks and works with these organizations to offer patient enrollment, data collection, data management, and regulatory support services to clinical sites entering patients in these trials.

As outlined in Supporting Statements A and B of the OMB package submitted in 2013 for the CTSU, a number of project specific forms are being used to facilitate data collection and processing. Forms are submitted by participating clinical sites to the CTSU as needed. The use of CTSU IRB Approval/Regulatory Data Transmittal Form improves processing of regulatory documentation submitted by the sites participating on CTEP-sponsored oncology trials.

The requested nonmaterial/non-substantive change is to add a barcode to the existing IRB Approval/Regulatory Data Transmittal form to facilitate internal processing. This change

does not change the current level of burden to the clinical sites for completion or submission of this optional form.

Summary of Changes:

Attachment 1a – CTSU IRB/Regulatory Approval Transmittal Form

- Addition of barcode to the top center of the form; and
- Total Pages Sent field was moved to below the Date Sent field to allow for the barcode.