GENERIC SUB-STUDY SUBMISSION – 0925-0046-19

DATE OF REQUEST: December 19, 2011

SUB AGENCY (I/C): OCE and DCTD

TITLE OF SUB-STUDY: Addendum to Pilot Study Proposed New Model for the CIRB Participating Institution

GENERIC CLEARANCE UNDER OMB #0925-0046-19 ***EXP. DATE: 02/28/2013***

TOTAL BURDEN APPROVED:	7050 hours
BURDEN APPROVED TO DATE:	2676 hours
BURDEN THIS REQUEST:	29 hours

ABSTRACT:

This submission is an addendum to the previous generic sub-study, "A Pilot Study to Test a Proposed New Model for the NCI's CIRB Participating Institution" which was approved by OMB on June 15, 2011 (OMB No. 0925-0046-16). The program staff seek approval of two additional forms which are part of the previously approved pilot study, but were not finalized in time for the OMB review (in May-June, 2011). The purpose of the additional worksheets is to collect necessary information required to implement and evaluate the processes necessary for the new pilot model to be in compliance with regulations and guidelines.

The process to obtain IRB approval for new clinical trials has historically contributed to a delay in trial activation. As a result, NCI's Central Institutional Review Board (CIRB) program is considering changing its model of operation and adopting a new model to use with its 300+ enrollees. NCI is first planning to pilot test the new model with 25 sites. As part of this pilot, NCI is planning to survey 3-5 IRB staff members at each site before, during and after the pilot study to identify areas of the new model that worked well or not. The findings from this project are integral to CIRB in developing its program and all relevant, related communication materials should the new program be perceived as more satisfactory over the original program. The feedback from the survey (approved by OMB on June 15, 2011; OMB No.: 0925-0046-16) and forms will be critical to determine if NCI should roll out the new model nationwide and invest the resources.

IS RACE AND ETHNICITY DATA COLLECTED AS REQUIRED?
_____YES __X___NO_____N/A

OBLIGATION TO RESPOND:
___X__ VOLUNTARY
_____ REQUIRED TO OBTAIN OR RETAIN BENEFITS
_____ MANDATORY

HOW WILL THIS SURVEY BE OFFERED?
__X___ WEB SITE
_____ TELEPHONE INTERVIEW
_____ MAIL RESPONSE
_____ IN PERSON INTERVIEW
_____ OTHER: _____

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