



Date: January 24, 2014

TO: Office of Management and Budget (OMB)

Through: Keith Tucker, Report Clearance Officer, HHS
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FROM: Michael Montello, Cancer Therapy Evaluation Program (CTEP)
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SUBJECT: Change Request for NIH NCI Central Institutional Review Board (CIRB)
Initiative (NCI) (OMB No. 0925-0625, Expiration Date: 12/31/2016).

This is a request for OMB to approve the non-substantive change to forms of, "NIH NCI Central Institutional Review Board (CIRB) Initiative (NCI)" project. The National Cancer Institute (NCI) Central Institutional Review Board (CIRB) provides a centralized approach to human subject protection and provides a cost efficient approach avoiding duplication of effort at each institution. The CIRB provides services of a fully constituted IRB and provides a comprehensive and efficient mechanism to meet regulatory requirements pertaining to human subject protections including initial and continuing reviews, review of amendments, and adverse events.

This request does not change the originally requested number of burden hours. The changes to the forms include:

- 1) A revised Privacy Act Notification Statement (PANS) that was approved by the NCI Privacy Act Coordinator. Most forms included the revised PANS, except for Attachments 3A, 3F, 3G, 3H-I, 3K-M, 3J, 3N-Q, 5D, and 5F. These forms do not include the PANS because no personally identifiable information is being collected. Additionally, the PANS was removed from Attachment 5D.
- 2) Spelling corrections on:
 - Attachment 6A – Question #9
 - Attachment 6A – There were two Questions #10. Revised version has corrected number sequence: #9, #10, #11, #12.
 - Attachment 6B – Question #17
 - Attachment 6H – Question #12
 - Attachment 6L – Questions #3 and #11
- 3) The attachments without any changes from the previous submission are listed below and have not been included in this request:
 - Attachment 1A (Email invite) & 1B (Survey)
 - Attachments 3A, 3F, 3G, 3H-I, 3J, 3K-M, 3N-Q and
 - Attachment 5F

Thanks.