

**Date:** May 11, 2011

**To:** Office of Management and Budget (OMB)

**Through:** Mary Forbes, Report Clearance Officer, HHS

 Seleda Perryman, Program Officer, Project Clearance Branch, OPERA, NIH

**From:** Vivian Horovitch-Kelley, NCI OMB Project Clearance Liaison, OMAA

National Cancer Institute (NCI)/NIH

**Subject:** **Bundled Generic Sub-Studies for:**

**OMB Numbers: 0925-0046-14, -15, and -16**

This is a bundled generic sub-study submission of three projects. All three studies directly involve the Office of Communications and Education (OCE) at NCI. Two of the studies are a collaboration between OCE and the Division of Cancer Treatment and Diagnosis (DCTD). Sub-study #14 (WYNTK) uses in-depth interviews to assess whether a booklet is meeting the needs of its audience and how the content may be improved. Sub-studies #15 (Accrual CT) and #16 (CIRB Pilot) are both web-based surveys used to assess and improve the services offered by DCTD.

The topics are very different and the “Bundle Gen IC Form” for sub-studies #14, 15 and #16 highlight the abstract for each project.

The key to understanding the attachments and files in ICRAS/ROCIS is as listed below.

*Sub-study #14:*

Full title: **“In-Depth Interviews on NCI’s “What You Need To Know About Breast**

**Cancer” Booklet”**

Short Title: WYNTK

Files and attachments are labeled “#14” and include:

* Justification Memo and 14C (Review Guidelines) and 14D (Consent Form)
* Attachment 14A (Interview Guide) and 14B (Screener)

*Sub-study #15:*

Full title: **“Rapid Feedback Tool to Identify Accrual Problems with Active NCI Clinical**

**Trials”**

Short Title: Accrual CT

Attachments are labeled “#15” and include:

* Justification Memo
* Attachment 15A (Oncology Feedback) & 15B (Staff Feedback) Surveys

*Sub-study #16:*

Full title: **“A Pilot Study to Test a Proposed New Model for the NCI’s CIRB Participating Institution”**

Short Title: CIRB Pilot

Attachments are labeled “#16” and include:

* Justification Memo and Attachment 16A (Consent)
* Attachment 16B (Baseline, Midpoint, and Endpoint Surveys), 16C (Institution Worksheet), 16D (Principal Investigator Worksheet), 16E (Study-Specific Worksheet), and 16F (Study Transfer Worksheet).

Notes to OMB: The total requested responses and burden was calculated by taking the sum for the three sub-studies to account for the total in ICRAS. Types of respondents include both Individuals and Public Sector (Institutions), however because of the limitation of ICRAS, only Individuals will be entered.

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| Estimates of Hour Burden for Sub-Studies #14, 15 and #16 |
| Type of Respondents | Instruments | Number of Respondents | Frequency of Response | Average Response Time(minutes/hour) | Hour Burden |
| Breast Cancer Patients(Sub-study #14) | Screener(Attachment 14B) | 50 | 1 | 15/60 | 13 |
| Review Instructions(Attachment 14C) | 24 | 1 | 60/60 | 24 |
| Interview Guide(Attachment 14A) | 24 | 1 | 60/60 | 24 |
| Oncologists and Research Staff for NCI-Sponsored Trials(Sub-study #15) | Oncology Feedback Survey(Attachment 15A) | 912 | 1 | 5/60(0.08) | 76 |
|  Staff Feedback Survey (Attachment 15B) | 912 | 1 | 5/60(0.08) | 76 |
| Principal Investigators and Institutions (Sub-study #16) | Baseline Survey(Attachment 16B, pages 2-6) | 125 | 1 | 20/60(0.33) | 42 |  |
|  Midpoint Survey (Attachment 16B, pages 7-10) | 125 | 1 | 20/60(0.33) | 42 |
| Endpoint Survey(Attachment 16B, pages 11-14) | 125 | 1 | 20/60(0.33) | 42 |
| Institution Worksheet(Attachment 16C) | 25 | 1 | 30/60(.50) | 13 |
| Principal Investigator Worksheet(Attachment 16D) | 125 | 1 | 60/60(1 hour) | 125 |
| Study-Specific Worksheet(Attachment 16E) | 250 | 1 | 15/60(.25) | 63 |
| Study Transfer Worksheet(Attachment 16F) | 625 | 1 | 10/60(.166) | 104 |
| Total |  | 3322 |  |  | 644 |