



Date: May 11, 2011

To: Office of Management and Budget (OMB)

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**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.

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)	Screeener (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
	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
Principal Investigators and Institutions (Sub-study #16)	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