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To: Office of Management and Budget (OMB)

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**Subject: Bundled Generic Sub-Studies for:
OMB Numbers: 0925-0046-20, 21, and 22**

This is a bundled generic sub-study submission of three projects. These studies represent collaboration between Office of Communications and Education (OCE) and other Divisions at NCI. All three sub-studies involve clinical trials; two of them look at testing new informed consents (#20 and #22) and the third is looking at clinical trial accrual.

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

Sub-study #20: Formative Evaluation of Concise Informed Consent Document (ICD)

Short Title: Concise ICD

Files and attachments are labeled “#20” and include:

- Justification Memo and Attachments 20A (Email Invitation) and 20D (Patient-Friendly Educational Materials)
- Attachment 20B (Screener)
- Attachment 20C (Survey Screenshots)

Sub-study #21: Revision of Rapid Feedback Tool to Identify Accrual Problems with Active NCI Clinical Trials

Short Title: Accrual CT

Attachments are labeled “#21” and include:

- Justification Memo and Attachment 21E (Email Invitation)
- Attachments 21A (Oncology Survey), 21B (Staff Survey), 21C (Concept Feedback Survey), and 21D (Prospective Template)

Sub-study #22: Formative Audience Research for Spanish Template Informed Consent Form

Short Title: Consent

Files and attachments are labeled “#22” and include:

- Justification Memo and Attachments 22F (Consent Form)
- Attachment 22A (Screener)
- Attachments 22B and 22C (Interview Guides in English and Spanish)

- Attachments 22D and 22E (Sample Consent Templates in Spanish and English)

Estimates of Hour Burden for Sub-Studies #20, #21 and #22					
Type of Respondents	Instruments	Number of Respondents	Frequency of Response	Average Response Time (minutes/hour)	Hour Burden
Patients with Colorectal Cancer (Sub-study #20)	Screeener (Attachment 20B)	190	1	10/60	32
	Survey (Attachment 20B)	150	1	60/60	150
Oncologists and Research Staff for NCI-Sponsored Trials (Sub-study #21)	Oncology Feedback Survey (Attachment 21A)	[456]	1	5/60	[38]
	Staff Feedback Survey (Attachment 21B)	[456]	1	5/60	[38]
	Concept Feedback Survey (Attachment 21C)	[456]	1	5/60	[38]
	Prospective Template (Attachment 21D)	[456]	1	5/60	[38]
General Public (Sub-study #22)	Screeener (Attachment 22A)	80	1	15/60	20
Latino adults eligible for prevention or treatment clinical trial (Sub-study #22)	In-depth Interview Guide (Attachment 22B and 22C)	30	1	1	30
Total					232

Notes to OMB:

- The respondents and hour burden for sub-study #21 are in square brackets [] because these burden hours were already requested and approved by OMB #0925-0046-15 on June 15, 2011. This sub-study has not begun information collection and is requesting to add two additional surveys. The total number of respondents and burden will not change from what was originally approved.
- The “Category of Respondents” is individuals for all three sub-studies.
- Total number of responses = 450