



National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: December 3, 2009
To: Office of Management and Budget (OMB)
Through: Seleda Perryman, DHHS Report Clearance Officer
Marilyn Tuttleman, NIH Project Clearance Officer, OPERA
From: Vivian Horovitch-Kelley, NCI OMB Project Clearance Liaison, OMAA
National Cancer Institute/NIH
Subject: **Key to Bundled Generic Sub-Study Packages for 0925-0046
(Expiry Date: 1/31/2010)**

This bundled generic sub-study package includes two requests. The key to understanding the attachments and files in ICRAS/ROCIS is as listed below.

- 1) Full title: "Evaluation and Needs Assessment of the HINTS Program"

Abbreviated Title: HINTS

Numbered: #17

Attachments Include:

GC Summary

Justification Memo

Attach A: Current Data User Guide

Attach B: Potential Data User Guide

Attach C: Current Results User Guide

Attach D: Potential Results User Guide

Attach E: Student Guide

Attach F: Invitations - E-mail and Telephone

Attach G: HINTS Screener Questions

Attach H: Reminders - E-mail and Telephone

Attach I: Informed Consents for interviews with and without Federal employees, focus groups with and without Federal employees, and triad interviews

- 2) Full title: “Online Needs Assessment Survey to Inform the Development of Tools and Materials to Further NCI-designated Cancer Centers’ Clinical Trial Accrual Practices”

Abbreviated Title: CT

Numbered: #18

Attachments Include:

GC Summary

Justification Memo

Attach A: Accrual Needs Assessment Instrument

Attach B: Informed Consent Form

It should also be noted that in bundling these two sub-studies, there was more than one “Affected Public.” HINTS comprised of Individuals, Private Non-Profits, and Federal government employees. The Clinical Trials (CT) comprised solely of Private Non-Profits. Since the majority of the affected public was Private Non-Profit for the combined studies (92%) it was entered into ICRAS/ROCIS as the majority. We were unable to select other affected public, however Individuals comprised of 4% of the combined studies total and the Federal government employees comprised of an additional 4%.