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To: Office of Management and Budget (OMB)

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**Subject: Bundled Generic Sub-Study Packages for 0925-0046-07 and -08**

The “Combined Generic Sub-study (GS) Form” for sub-study #7 and #8 highlight the abstracts for each project and is included in this submission.

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

Sub-study #7:

Full title: **“Prostate-Specific Antigen (PSA) Decision-Making Focus Groups”**

Attachments are labeled “#7” and include:

- Justification Memo and Attachments 7C (Advertisements) and 7D (Consent)
- Attachments 7A ( Screener), 7B (Moderator Guide) and 7E (Questionnaire)

Sub-study #8:

Full title: **“Protocol and Information Office (PIO) External Customer Satisfaction Survey”**

Attachments are labeled “#8” and include:

- Justification Memo and Attachment 8B (Email Letter)
- Attachment 8A (PIO Survey)

Notes to OMB: The total requested responses and burden was calculated by taking the sum for the two sub-studies to account for the total in the electronic system.

Estimates of Hour Burden for Sub-studies #7 and #8					
Type of Respondents	Instruments	Number of Respondents	Frequency of Response	Average Response Time (minutes/hour)	Hour Burden
Males between the ages of 55-74 (Sub-study #7)	Screeener (Attach 7A)	80	1	5/60 (0.08)	7
	Focus Group (Attach 7B)	45	1	90/60 (1.5)	68
	Questionnaire (Attach 7E)	45	1	5/60 (0.08)	4
Project Investigators and Clinical Staff (Sub-study #8)	PIO Customer Satisfaction Survey (Attach 8A)	240	1	10/60 (0.167)	40
Total		410			119