



**Date:** March 25, 2011

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

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**Subject: Bundled Generic Sub-Study Packages for:  
OMB No. 0925-0046-011, -12, and -13**

This is a bundled generic sub-study submission of three projects. All three come from different divisions at NCI. The project from DCCPS is submitting an application and competency assessment to measure the feasibility of a mentorship program (#11). CCR is proposing a formative study to examine the patterns of practice in medical oncologists (#12). And DCEG is conducting questionnaire development/testing in the area of nightshift work and cancer on a small sample of women in China (#13).

The topics are very different and the “Bundle Gen IC Form” for sub-studies #11, 12 and #13 highlight the abstract for each project.

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

Sub-study #11:

Full title: **“Research to Reality (R2R) Mentorship Program Application”**

Short Title: R2R

Files and attachments are labeled “#11” and include:

- Justification Memo and Attachments 11A (Email), 11B (Flyer), and 11D (Agreement)
- Attachment 11C (Application and Competency Assessment)

Sub-study #12:

Full title: **“Examining the Management of Muscle Invasive Bladder Cancer (MISC) by Medical Oncologists”**

Short Title: MISC

Attachments are labeled “#12” and include:

- Justification Memo and Attachments 12A (Invitation Email)
- Attachment 12B (Web-based Survey)

Sub-study #13:

Full title: **“Nightshift Work and Sleep Pattern Questionnaire”**

Short Title: Nightshift

Attachments are labeled “#13” and include:

- Justification Memo and Attachments 13B (Consent), 13C (IRB) and 13D (Grant Award)
- Attachment 13A (Nightshift Work and Sleep Pattern Questionnaire)

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 the electronic system.

Estimates of Hour Burden for Sub-Studies #11, 12 and #13					
Type of Respondents	Instruments	Number of Respondents	Frequency of Response	Average Response Time (minutes/hour)	Hour Burden
Public Health Practitioners/Cancer Control Planners Applicants for Mentor Program (Sub-study #11)	Attachment 11C	50	1	60/60 (1)	50
Post-Program Competency Assessment of Mentees (Sub-study #11)	Competency Assessment Only in Attachment 11C	6	1	10/60 (0.167)	1
Medical Oncologist from BCAN Bladder Cancer Think Tank Meeting 2010 and US Oncology (Sub-study #12)	Attachment 12B	100	1	10/60 (0.1667)	17
Shanghai Women’s Health Study Participants (Sub-study #13)	Attachment 13A	300	1	10/60 (0.1667)	50
Total		456			118