DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: March 18, 2011

To: Office of Management and Budget (OMB)

Through: Seleda Perryman, DHHS Report Clearance Officer
Mikia Currie, Program Analyst, Project Clearance Branch, OPERA, NIH
Vivian Horovitch-Kelley, OMB Project Clearance Liaison, OMAA, NCI

From: Bu-Tian Ji, Staff Scientist
Occupational and Environmental Epidemiology Branch (OEEB),
Division of Cancer Epidemiology and Genetics (DCEG),
National Cancer Institute (NCI)/NIH

Subject: Bundled Generic Sub-study, "Nightshift Work and Sleep Pattern Questionnaire" under "Formative Research, Pretesting, and Customer Satisfaction of NCI's Office of Communication and Education,"
OMB No. 0925-0046-13; Expiration Date 02/28/2013

Background, Need and Use of Information

The Division of Cancer Epidemiology and Genetics (DCEG) is an intramural research program of the National Cancer Institute (NCI), National Institutes of Health (NIH) that conducts population and multidisciplinary research to discover the genetic and environmental determinants of cancer and new approaches to cancer prevention. The Division conducts broad-based research; maintains a national and international perspective, giving priority to emergent issues identified through clinical, laboratory, and epidemiologic observations, as well as to public health concerns identified by the Institute, Congress, regulatory agencies, and other appropriate bodies; and develops infrastructures, resources, and strategic partnerships in molecular epidemiology across NCI, NIH, and the extramural community. As a branch of the DCEG, the Occupational and Environmental Epidemiology Branch (OEEB) conducts research projects that are designed to identify occupational, environmental, and other factors affecting cancer risk; to characterize exposure response relationships; to elucidate biological mechanisms of action; to identify susceptible populations and gene environment interactions; and to improve research methods for occupational investigations.

Night-shift work involving disruption of circadian rhythms has been classified as a probable cause of human cancer by the International Agency for Research on Cancer (IARC), based on sufficient animal evidence and limited human evidence[1]. The epidemiologic evidence supporting this link has been inconsistent. A weakness of most existing studies is the inadequate assessment of the history of shift work, such as nightshift hours and frequency and rotation of shift, and non-occupational exposure to light at night. Since the IARC designation of night-shift work as probable human carcinogen has important

policy implications worldwide, including patient compensation among nightshift workers and workplace safety, we propose to initially conduct formative research and then possibly conduct the full-scare epidemiologic research to clarify this association. We have drafted a questionnaire that is designed to overcome the criticism on data collection in previous studies.[1, 2] This questionnaire is designed by NCI to capture shift work exposure for each job held over one year in participants' lifetime, as well as light exposure at night during different periods of life (**Attachment 13A**).

Participants and Collaborations

Occupational cancer risk is a major area of OEEB's research focus. We propose to conduct formative research to determine whether the draft questionnaire is effective in obtaining information as an initial step in further clarifying the association between nightshift work and cancer in the Shanghai Women's Health Study (SWHS). The SWHS is a prospective cohort study of 75,000 healthy women in Shanghai, China, recruited during 1997-2000. The participants are being re-contacted every two years to update their health status, including newly diagnosed cancer, and limited lifestyle and environmental exposures, such as dietary changes and employment status. The next biennial survey will begin in January, 2012. The response rates for the baseline in-person interview and the first, second, and third follow-up surveys were 93%, 99.8%, 98.7%, and 96.7%, respectively. Given the large size of the cohort and the limited resources, including interview time, NCI requires accurate, timely, and useful information about the relevance, usefulness, and appropriateness of the questionnaire. The formative research process is being used to pretest the questionnaire on a small part of the large target population, ensuring feasibility of the questionnaire message, user-friendliness, and the time use in an in-person interview. Given this proposal, it clearly fits under the active generic submission titled, "Formative Research, Pretesting and Customer Satisfaction of NCI's Communication and Education Resources," (OMB No. 0925-0046) which was revised and approved by OMB in 2010.

The SWHS is a collaborative project between NCI, Vanderbilt University and the Shanghai Cancer Institute. An NCI extramural grant to Vanderbilt University supported the baseline and follow-up in-person interviews of the SWHS participants, and collection of blood and urine from 20,000 of them at baseline (**Attachment 13D**). To expand the molecular component of this cohort, the OEEB/DCEG contributed intramural funds to support the collection of blood and urine samples from the remainder of the cohort. The biological samples from this cohort are also used in research jointly conducted by the Centers for Disease Control and Prevention and NCI, and other international research and academic institutions.

Given the existing collaboration, the rapport developed between the investigators and the cohort participants over the years, and the lifetime occupational history already collected from the participants, we propose to pretest the nightshift work and light exposure at night questionnaire on 300 of the cohort participants. This formative research/pretesting helps ensure that messages included have the potential to be received, understood, and accepted by the participants involved in the SWHS in China. If the pretest is successful, we plan to incorporate the shift-work questionnaire with the Vanderbilt survey questions to be collected at the next biennial update starting in January, 2012. We will seek separate OMB review and approval for the final questionnaire before we begin the main data collection.

A lifetime occupational history of all jobs held for one year or more outside the home was collected from each cohort participant at baseline, including job title, type of industry, and year started and ended each job. However, no information was collected on whether each job involved night shift, frequency of shift-work, hours of each shift, and pattern of shift, i.e., whether the shift work was rotating

or permanent. The proposed questionnaire will take advantage of the lifetime occupational history already collected, and append the questions regarding nightshift work for each job reported in the history.

The design of the proposed questionnaire was based on the IARC's extensive review of the literature and expert assessment on the information needed to adequately address the health effects of night shift work.[1,3]

Methodology and Research Instrument

An in-person interview will be conducted to complete the nightshift work and sleep pattern questionnaire. Based on experience from previous follow-up surveys, the responses from the participants were positive when we visited them at their homes. Therefore, for this proposed formative research, we plan to visit the participants at their homes and explain this survey to them. We will seek their consent (**Attachment 13B**) prior to the interview.

The questionnaire included questions concerning **(Attachment 13A)**:

- Type of shift work for jobs held for one year or longer reported as of the last follow-up (pre-printed the information of job history for use at the pretest)
- Duration and frequency of shift work during each job held
- Sleep pattern (e.g., usual bed time) during ages <=25, 25-55, and >55 years old
- Light exposure levels during bed time at night during ages <=25, 25-55, and >55 years old

The entire pretest of interviewing 300 subjects is expected to complete within two months. Each questionnaire will be pre-assigned with a participant study ID number. When the interview is completed, the responses will be coded and keyed into a computer data file at the Shanghai Cancer Institute. Statistical analysis will be conducted by NCI to review for completeness and consistency of the responses. Logic and range checks will be conducted to detect any problems in responding to the questions. Interviewers' comments will be reviewed to identify any difficulties that respondents might have with the understanding or responding to specific questions.

Other Considerations

The IRB for the SWHS has been approved by NCI SSIRB (Protocol ID: OH-98-C-N006) (See **Attachment 13C** for the IRB approval). All information provided by participants will be kept secure to the extent permitted by law. Additionally, the SWHS data kept under lock and key, and in password protected data files at the Shanghai Cancer Institute. NCI received only anonymous data for research purposes only. No personally identifiable information (PII) will be collected in the present questionnaire.

Burden

We aim to complete each interview within an average of 10 minutes. In a pilot test of the proposed questionnaire in 5 participants, the interviews varied around 10-15 minutes. Therefore we expect the total respondent burden for this proposed effort to be 50 hours. This effort will account for less than 1 percent of the total burden hours granted in the full generic OMB clearance package. To date, a total of 1758 burden hours have been used of the 7050 hours that were requested.

Types of Respondents	Number of Respondents	Frequency of Response	Average Response Time (Minutes/Hour)	Annual Hour Burden
Shanghai Women's Health Study Participants	300	1	10/60 (0.1667)	50
Totals	300			50

References:

1. International Agency for Research on Cancer. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume (8. Painting, Firefighting, and Shift-work. 2010. p, 562-763.
2. Pronk A, Ji BT, Shu XO, et al., Night-shift work and breast cancer risk in a cohort of Chinese women. Am J Epidemiol, 2010 (9): 953-959.
3. Stevens RG, Hansen J, Costa G, et al., Considerations of circadian impact for defining "shift work" in cancer studies: IARC Working Group Report. Occup Environ Med, 2011; 68: 154-162.

List of Attachments (attached in a separate file)

13A: Nightshift Work and Sleep Pattern Questionnaire

List of Attachments (attached below)

13B. Informed Consent Form
13C: IRB approval from SSIRB
13D: Notice of Grant Award to Vanderbilt University

Attachment 13B: Informed Consent From for the cohort study

Shanghai Women's Health Study

Follow-up Survey

CONSENT FORM

You have been invited to participate in the Shanghai Women's Health Study being conducted by the Shanghai Cancer Institute, Vanderbilt University, and the U.S. National Cancer Institute since 1997-2000. We are now conducting the 5th follow-up survey and hope you will continue to be a participant of this important health study.

If you agree to complete the survey, you will be asked to answer some questions regarding nightshift work and sleep patterns from a standardized questionnaire. The interview will take about 10 minutes. These are questions relating to the type, frequency, and duration of shift work for jobs you held as of the last follow-up 2 years ago; and sleep pattern (e.g., usual bed time) and light exposure levels during bed time.

All information we obtain from you will be used exclusively for scientific research only. Any personal information that can identify you as an individual will be kept secure to the extent permitted by law. Your name will never be used in any study reports. Your data will be put together with those from other participants to make totals, averages, and other descriptive statistics.

You may be contacted in the future to obtain missing or additional information, or to inquire about your interest in other studies; however, you have the right to refuse to participate in the study at any time without jeopardizing your relationships with the Shanghai Cancer Institute or Hospitals. If you have any questions about this study, you may contact Dr. Yu-Tang Gao at 64043057.

Your continuing participation in the study is completely voluntary. Your signature below indicates that you have read the information provided, and have agreed to participate. You will be offered a copy of this form to keep.

Date: _____

Participant's signature: _____

Attachment 13C: IRB approval from SSIRB

12/8

CLINICAL RESEARCH PROTOCOL **CONTINUING** REVIEW APPLICATION	PROTOCOL NO. OH98-C-N006	PRINCIPAL INVESTIGATOR (NIH Employee Name, Inst/Br, Address, Telephone and email): Dr. Wong-Ho Chow, NCI/DCEG/OEEB, EPS 8100, 301-435-4708

PROTOCOL TITLE:

A Prospective Cohort Study of Occupational Exposures and Cancer Risk among Women

PROTOCOL STATUS:
- ☐ Renew -Recruitment of participants has not yet begun.
- ☐ Renew -Participants are currently being recruited or enrolled.
- ☒ Renew -No longer recruiting or enrolling participants, subject follow-up only.
- ☐ Renew -Participants have completed study; study and data analyses ongoing.
- ☐ Renew -Clinical Hold/Recruitment or enrollment of participants suspended.
- ☐ Terminate -Study closed. Participants have completed study. Recruitment and data analysis complete.

SUMMARY OF PROTOCOL ENROLLMENT (Aggregate): Only when the NIH is the coordinating site, provide totals and enrollment table for other site.

NIH Site	Other Sites	Total	
	76,000	76,000	Accrual ceiling by IRB
	0	0	New subjects accrued since last CR
	75,366	75,366	Aggregate total accrued

Are you currently recruiting healthy volunteers? ☒ No ☐ Yes
Will the protocol involve adults unable to give informed consent? ☒ No ☐ Yes

Have analyses by sex, racial/ethnic subgroups been conducted for Phase 3 Clinical Trials as required? ☐ No ☐ Yes (answer a and b) ☒ N/A
a. Have analyses been reported? ☐ No (explain in narrative) ☐ Yes
b. Have significant differences been found? ☐ No ☐ Yes

Have any non-NIH Investigators or sites been added since the last review?
☒ No
☐ Yes (Identify the persons or sites and describe the collaboration in the summary report)

WITH THIS REVIEW, I AM REQUESTING A CHANGE TO THE FOLLOWING:
*Include Name, Inst/Branch, Telephone, Address, e-mail. Check box if an NIH Employee and initial line. Attach sheet if necessary.

PRINCIPAL INVESTIGATOR:
Delete: _____
Add*: ☐ _____

EXTRAMURAL ADJUNCT PRINCIPAL INVESTIGATOR:
Delete: _____
Add: _____

MEDICAL ADVISORY INVESTIGATOR:
Delete: _____
Add*: _____

LEAD ASSOCIATE INVESTIGATOR:
Delete: _____
Add*: ☐ _____

RESEARCH CONTACT:
Delete: _____
Add*: ☐ _____

ASSOCIATE INVESTIGATOR(S):
Delete: Mustafa Dosemeci, Ph.D.
Add*: ☐ _____

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET, etc.) check all that apply:
- ☒ None
- ☐ Medically indicated
- ☐ Research indicated. Since the last review,
  - ☐ Research usage HAS NOT changed.
  - ☐ Research usage HAS changed. (Explain in summary report)

INVESTIGATIONAL NEW DRUG/DEVICE: ☐ None ☐ IND ☐ IDE
*If reporting more than one IND/IDE, list on attached sheet.
FDA No. _____
Name: _____
Sponsor: _____
Who is the manufacturer of the above entity? _____

Does the protocol involve a Tech Transfer Agreement? ☒ No ☐ Yes

Does the protocol involve a drug/device/product that may lead to you or the NIH receiving payment and/or royalties?
☒ No
☐ Yes (Append a statement of disclosure)

Have there been any amendments since the last review?
☒ No
☐ Yes (Describe briefly in the attached narrative.)

Have there been any changes in the informed consent process or documentation since the last review?
☒ No
☐ Yes (Describe in Summary report)

Have there been any changes in the subject population, recruitment or selection criteria since the last review?
☒ No
☐ Yes (Explain changes in the attached narrative.)

Have any unexpected complications or side effects been noted since the last review?
☒ No
☐ Yes (Identify and explain in the attached narrative.)

Have any subjects withdrawn from this study since the last IRB approval?
☒ No
☐ Yes (Discuss in the attached narrative.)

Has any information appeared in the literature, or evolved from this or similar research, that might affect the IRB's evaluation of the risk/benefit analysis of human subjects involved in this protocol?
☒ No
☐ Yes (Discuss in the attached narrative.)

Has the NIH IRP COI Guide been distributed to new NIH investigators?
☐ No ☒ Yes ☐ N/A

Has the NIH IRP COI Guide been distributed to new Non-NIH investigators?
☐ No ☐ Yes ☒ N/A

CONFLICTS OF INTEREST REVIEW?
Date submitted to IC DEC: 9/17/10 Date cleared by IC DEC: 10/6/10

SIGNATURE	Wong-Ho Chow (Principal Investigator)	Wong-Ho Chow (Print/Type Name)	Date 9/21/10	Send to Accountable Investigator
RECOMMENDATION	Wong-Ho Chow (Accountable Investigator)	Wong-Ho Chow (Print/Type Name)	Date 9/21/10	Send to Branch Chief, or CC Dept. Head of Accountable Investigator
	D. Silverman (Br Chief/CC Dept. Head of Acct. Invest)	Debra Silverman (Print/Type Name)	Date 10/4/10	Send to Clinical Director
APPROVALS	(Clinical Director)	~~Kim Jarema~~ William Dod (Print/Type Name)	Date 11/12/10 11/10/2010	Send to Chair, Institutional Review Board
Expedited	(Chair, For Institutional Review Board)	Nancy Potischman (Print/Type Name)	Date ↓	Send to Office of Protocol Services, through IRB Protocol Coordinator
COMPLETION	(Protocol Specialist)	Date 11/23/10	Protocol & Consent Approved Effective	

Clinical Research Protocol Continuing Review Application
NIH-1195-1 (9-06)

Attachment 13D: Notice of Grant Award to Vanderbilt University

Notice of Award

METHOD TO EXTEND RESEARCH IN TIME AWARD **Issue Date:** 09/03/2009

Department of Health and Human Services
National Institutes of Health
NATIONAL CANCER INSTITUTE

Grant Number: 2R37CA070867-12 REVISED

Principal Investigator(s):
WEI ZHENG, MD

Project Title: Cancer Risk Reduction and Diet: A Cohort Study of Women

Stephens, Amie M
Administrative Officer
6014 Medical Center East
Nashville, TN 37203

Award e-mailed to: sponsored_research@list.vanderbilt.edu

Budget Period: 07/16/2009 – 06/30/2010
Project Period: 09/17/1996 – 05/31/2014

Dear Business Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to VANDERBILT UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release or other document that cites results from NIH grant-supported research must include an acknowledgment of NIH grant support and disclaimer such as "The project described was supported by Award Number R37CA070867 from the National Cancer Institute. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Cancer Institute or the National Institutes of Health."

Award recipients are required to comply with the NIH Public Access Policy. This includes submission to PubMed Central (PMC), upon acceptance for publication, an electronic version of a final peer-reviewed, manuscript resulting from research supported in whole or in part, with direct costs from National Institutes of Health. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. For additional information, please visit http://publicaccess.nih.gov/.

Award recipients must promote objectivity in research by establishing standards to ensure that the design, conduct and reporting of research funded under NIH-funded awards are not biased by a conflicting financial interest of an Investigator. Investigator is defined as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of NIH-funded research or proposed research, including the Investigator's spouse and dependent children. Awardees must have a written administrative process to identify and manage financial conflict of interest and must inform Investigators of the conflict of interest policy and of the Investigators' responsibilities. Prior to expenditure of these awarded funds, the Awardee must report to the NIH Awarding Component the existence of a conflicting interest and within 60 days of any new conflicting interests identified after the initial report. Awardees must comply with these and all other aspects of 42 CFR Part 50, Subpart F. These requirements also apply to subgrantees, contractors, or collaborators engaged by the Awardee under this award. The NIH website http://grants.nih.gov/grants/policy/coi/index.htm provides additional information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Jill Rogers
Grants Management Officer
NATIONAL CANCER INSTITUTE

Additional information follows

SECTION I – AWARD DATA – 2R37CA070867-12 REVISED

Award Calculation (U.S. Dollars)

Salaries and Wages	$257,018
Fringe Benefits	$58,133
Personnel Costs (Subtotal)	$315,151
Equipment	$14,056
Supplies	$656
Travel Costs	$10,617
Other Costs	$138,925
Consortium/Contractual Cost	$206,028
Federal Direct Costs	$685,433
Federal F&A Costs	$269,692
Approved Budget	$955,125
Federal Share	$955,125
TOTAL FEDERAL AWARD AMOUNT	$955,125

AMOUNT OF THIS ACTION (FEDERAL SHARE) $0

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
12	$955,125	$955,125
13	$975,199	$975,199
14	$1,013,011	$1,013,011
15	$1,045,914	$1,045,914
16	$1,081,184	$1,081,184

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Number:	93.393
EIN:	1620476822A2
Document Number:	RCA070867E
Fiscal Year:	2009

IC	*CAN*	*2009*	*2010*	*2011*	*2012*	*2013*
CA	8479565	$955,125	$975,199	$1,013,011	$1,045,914	$1,081,184

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: S5ER / **OC**: 414B / **Processed**: ROGERSJI 09/02/2009

SECTION II – PAYMENT/HOTLINE INFORMATION – 2R37CA070867-12 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 2R37CA070867-12 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.

e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at 'http://grants.nih.gov/grants/policy/awardconditions.htm' for certain references cited above.)

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase V Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).
In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Treatment of Program Income:
Additional Costs

SECTION IV – CA Special Terms and Conditions – 2R37CA070867-12 REVISED

INFORMATION: Congratulations! Your grant has been selected as a MERIT Award by the National Cancer Institute. The program announcement describing the special features of this program is in the NIH Guide for Grants and Contracts, Volume 15 #13, August 1, 1986.

INFORMATION: This MERIT award is eligible for a one to five year extension of the current project period. To apply for this extension, please submit an original PHS 398 application form and six copies to the Awards, Records and Control Center, OGA, and one copy to this award's program director. The MERIT extension application is due November 1, 2012. The MERIT extension application will be reviewed by NCI grants management and program staff and by the National Cancer Advisory Board at its January/February, 2013 meeting.

THE FOLLOWING TERMS FROM THE PREVIOUS NOTICE OF GRANT AWARD ISSUED ON 07/16/09 ALSO APPLY TO THIS AWARD:

INFORMATION: In accordance with the National Cancer Institute's (NCI's) Fiscal Year (FY) 2009 funding policies, this award has been issued at 93.7% of the adjusted requested level. Future year committed levels* have been adjusted accordingly.

* committed level: The level of support calculated by applying the NCI funding plan to the corrected recommended level for each budget category for all years of the project period.

Spreadsheets used to calculate this award are available upon request.

INFORMATION: Future year total cost commitments appearing on the award notice under "Recommended Future Year Total Cost Support" have been calculated by applying the negotiated facilities and administrative cost rate(s) in effect at the time of this FY 2009 award to the committed total direct cost level for each future year.

INFORMATION: This award includes funds awarded for consortium activity with Shanghai Cancer Center in the amount of $219,872 ($203,585 direct costs and $16,287associated facilities and administrative costs). Consortia are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH GPS is available at: http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm - _Toc54600251

INFORMATION: Although the budget period start date for this award is July 16, 2009, this award includes funds for 12 months of support. Future year budget periods will cycle on June 1st (see recycling term). Allowable preaward costs may be charged to this award, in accordance with the conditions outlined in the NIH Grants Policy Statement, (December 2003), and with institutional requirements for prior approval. The NIH GPS can be found on the internet at http://grants2.nih.gov/grants/policy/nihgps_2003/.

INFORMATION: See "Assurance Requirements and Institutional Review Boards" under Part II, Subpart A, Human Subjects, in the NIH Grants Policy Statement (NIHGPS)(rev. 12/03), for specific

requirements and grantee responsibilities related to the protection of human subjects, which are applicable to and are a term and condition of this award. The NIHGPS can found on the internet at http://grants2.nih.gov/grants/policy/nihgps_2003/. The referenced section of the NIHGPS is available at http://grants1.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Toc54600083.

INFORMATION: This award reflects the National Cancer Institute's acceptance of the certification that all key personnel have completed education on the protection of human subjects, in accordance with NIH policy, "Required Education in the Protection of Human Research Participants," as announced in the June 5, 2000 NIH Guide (revised August 25, 2000) (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html).

Any individual involved in the design and conduct of the study that is not included in the certification must satisfy this requirement prior to participating in the project. Failure to comply can result in the suspension and/or termination of this award, withholding of support of the continuation award, audit disallowances, and/or other appropriate action.

INFORMATION: This award, including the budget and the budget period, has been discussed between Jill Rogers of the National Cancer Institute and Carol Haas on July 14, 2009.

INFORMATION: In order to redistribute awards more evenly throughout the year, budget periods are being adjusted. In accordance with the notification from Jill Rogers of the National Cancer Institute to Carol Haas on July 14, 2009, this award is issued with an 11 month budget period and with 12 months of support. Continuation awards will cycle each year on June 1st.

INFORMATION: The recycling of this award has changed the receipt date for the next competing continuation (Type 2) application. Consult "Standard Due Dates for Competing Applications" at http://grants.nih.gov/grants/funding/submissionschedule.htm.

INFORMATION: None of the funds in this award shall be used to pay the salary of an individual at a rate in excess of the current salary cap. See current salary cap levels at the following URL:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-069.html

Therefore, this award and/or future years are adjusted accordingly, if applicable.

INFORMATION: In a continuing effort to provide exceptional customer service, the NCI Office of Grants Administration has set up a Feedback address on its web site (http://www.nci.nih.gov/admin/gab/index.htm). General concerns and issues related to NCI grants policies, procedures, and practices can be sent to the Customer Liaison using this feature. Specific questions or concerns related to this grant should be addressed to the Grants Management Specialist listed in the Terms of Award.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Jill Rogers
Email: rogersj@mail.nih.gov **Phone**: 301-496-8699

Program Official: Somdat Mahabir
Email: mahabir@mail.nih.gov **Phone**: 301-451-9414

SPREADSHEET SUMMARY
GRANT NUMBER: 2R37CA070867-12 REVISED

INSTITUTION: VANDERBILT UNIVERSITY

Budget	*Year 12*	*Year 13*	*Year 14*	*Year 15*	*Year 16*

Salaries and Wages	$257,018	$279,210	$299,325	$306,370	$329,776
Fringe Benefits	$58,133	$63,152	$67,703	$69,296	$74,590
Personnel Costs (Subtotal)	$315,151	$342,362	$367,028	$375,666	$404,366
Equipment	$14,056	$14,056	$14,056	$14,056	$14,056
Supplies	$656			$3,280	
Travel Costs	$10,617	$10,617	$10,617	$10,617	$10,617
Other Costs	$138,925	$134,192	$130,913	$139,815	$137,004
Consortium/Contractual Cost	$206,028	$206,028	$206,028	$206,028	$206,028
TOTAL FEDERAL DC	$685,433	$707,255	$728,642	$749,462	$772,071
TOTAL FEDERAL F&A	$269,692	$267,944	$284,369	$296,452	$309,113
TOTAL COST	$955,125	$975,199	$1,013,011	$1,045,914	$1,081,184

Facilities and Administrative Costs	***Year 12***	***Year 13***	***Year 14***	***Year 15***	***Year 16***
F&A Cost Rate 1	55%	55%	55%	56%	56%
F&A Cost Base 1	$490,349	$487,171	$42,380	$529,378	$551,987
F&A Costs 1	$269,692	$267,944	$23,309	$296,452	$309,113
F&A Cost Rate 2			56%		
F&A Cost Base 2			$466,178		
F&A Costs 2			$261,060		