AD_____

Award Number: DAMD17-99-1-9248

TITLE: Physiological Stress Reactivity and Breast Cancer

PRINCIPAL INVESTIGATOR: Pathik Wadhwa, M.D., Ph.D.

CONTRACTING ORGANIZATION: University of California at Irvine
Irvine, California 92697

REPORT DATE: October 2001

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	October 2001	Annual (1 Oct 00 - 30 Sep 01)

4. TITLE AND SUBTITLE
Physiological Stress Reactivity and Breast Cancer

5. FUNDING NUMBERS
DAMD17-99-1-9248

6. AUTHOR(S)
Pathik Wadhwa, M.D., Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
University of California at Irvine
Irvine, California 92697

E-Mail: pwadhwa@uci.edu

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 Words)*

The objective of the present program of research is to study physiological processes that may mediate the links between psychological states and cancer. Specifically, the present study is designed to conduct an investigation of the cross-sectional associations between indices of stress reactivity and psychological coping styles in women with breast cancer and matched healthy controls. The aims of the project are: (1) To quantify parameters of biological reactivity to a behavioral stress paradigm in women with and without breast cancer; (2) To examine effects of menopause and familial risk on biological stress reactivity and emotional expression; and (3) To develop the methodology and obtain preliminary data which could justify subsequent, prospective research with high-risk populations. This report outlines the steps that have been taken to resume this research study at University of California-Irvine ever since the author left the previous site, University of Kentucky. These steps include setting up a behavioral medicine research laboratory, obtaining IRB approval for the project from UCI, obtaining approval from the University's General Clinical Research Center to conduct the study, setting up a collaboration with an oncologist and biochemist, and recruit other necessary staff.

14. SUBJECT TERMS
breast cancer risk, stress, coping, behavior

15. NUMBER OF PAGES
5

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

Table of Contents

NOTE:

The project's Principal Investigator, Pathik D. Wadhwa, M.D., Ph.D., has taken the many steps necessary, as elaborated below, in transferring the grant from the University of Kentucky College of Medicine (applicant organization) to the current institution where he is employed, University of California, Irvine. The PI is currently waiting for the Department of Defense to process the request for the grant transfer before data collection begins. During the period that the present report covers, no new data collection has been performed. The PI was not aware that a progress report is needed since there has not been data collection, and apologizes for the delay in submitting this progress report.

INTRODUCTION:

The broad objective of the present program of research is to study physiological process that may mediate the links between psychological states and cancer. Specifically, the present study is designed to conduct and investigation of the cross-sectional associations between indices of stress reactivity and psychological coping styles in women with breast cancer and matched healthy controls. The aims of the project are: (1) To quantify parameters of biological reactivity to a behavioral stress paradigm in women with and without breast cancer; (2) To examine (a) group differences between women with and without breast cancer in biological stress reactivity, and (b) the effects of menopause and familial risk on biological stress reactivity and emotional expression; and (3) To develop the methodology and obtain preliminary data which could justify subsequent, prospective research with high-risk populations.

BODY:

The research plan is unchanged from the original application. However, the statement of work has been revised as follows:

A. Recruitment and assessment: Subjects will be recruited and assessed at the rate of approximately 5-6/month (2-3 from BC group; 2-3 from HC group) for all months of year 02 and the first nine months of year 03 of funding. Thus, approximately 60 subjects will be assessed in year 02 and 50 subjects in year 03 of funding, to complete recruitment of the entire study sample.
B. Database: The database will comprise of these categories of data: clinical, sociodemographic, psychosocial, and physiological. With the exception of hormonal data, all data will be entered continuously into a relational database. Reliability checks to assure accuracy in transcription and data entry will be performed every 3 months.
C. Hormonal assays: Hormone bioassays on plasma samples will be run in four batches
D. Data analyses and final reports: Preliminary data analyses will be conducted at approximately the half-way point of the study (months 17-19 of funding), and final data analyses will be completed by month 33 of funding

Since moving to the University of California, Irvine, the PI has now completed all the steps required to resume this research study. These steps include:

1. Setting up a behavioral medicine research laboratory
2. Obtaining IRB approval for the project from the University of California, Irvine

3. Obtaining approval from the University's General Clinical Research Center (GCRC) to conduct the study at the GCRC.
4. Obtaining the necessary documentation for the UCI Certificate of Environmental Compliance (Appendix 4), IRB approval (Appendix 5), and Safety Program Plan (Appendix 7).
5. Obtaining approval from the University's Oncology Practice to screen and recruit research subjects for the study.
6. Setting up a collaboration with an oncologist (Dr. Rita Mehta) and biochemist (Dr. Aleksandra Chicz-DeMet) for conducting the clinical and physiological components of the study.
7. Recruiting the necessary staff (graduate research assistant, laboratory assistant) to conduct the study.
8. Applying for the grant to be transferred, so that data collection can begin as soon as possible

KEY RESEARCH ACCOMPLISHMENTS:

Steps have been taken to resume research study as indicated above. Data collection at the new site will begin as soon as the transfer of grant is approved.

REPORTABLE OUTCOMES:

There are no reportable outcomes at this stage of the project.

CONCLUSIONS:

As soon as the request to transfer has been processed and approved, data collection will begin at the new institution.