

AD _____

Award Number: DAMD17-01-1-0675

TITLE: Vietnam Head Injury Study Phase III: A 30 Year Post-Injury Follow-Up Study

PRINCIPAL INVESTIGATOR: Jordan H. Grafman, Ph.D.

CONTRACTING ORGANIZATION: The Henry M. Jackson Foundation for the
Advancement of Military Medicine
Rockville, MD 20850

REPORT DATE: October 2005

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.

20060315 059

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.

1. REPORT DATE 01-10-2005			2. REPORT TYPE Annual		3. DATES COVERED 24 Sep 2004 -23 Sep 2005	
4. TITLE AND SUBTITLE Vietnam Head Injury Study Phase III: A 30 Year Post-Injury Follow-Up Study					5a. CONTRACT NUMBER	
					5b. GRANT NUMBER DAMD17-01-1-0675	
					5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Jordan H. Grafman, Ph.D.					5d. PROJECT NUMBER	
					5e. TASK NUMBER	
					5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) The Henry M. Jackson Foundation for the Advancement of Military Medicine Rockville, MD 20850					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. SPONSOR/MONITOR'S ACRONYM(S)	
					11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited						
13. SUPPLEMENTARY NOTES						
14. ABSTRACT During this reporting period, 108 subjects have attended for testing: 95 head-injured subjects and 13 controls. To date, there have been a total of 144 participants. All subjects have had blood samples taken for genetic analysis and all head-injured subjects have undergone a CT brain scan and EEG (if their individual physical condition allowed it). We have identified two cases of probable undetected epilepsy and two further cases with likely meningiomas. In May 2005 we submitted a description of the methodology of the Vietnam Head Injury Study for publication in Military Medicine. We are continuing to test subjects on our five day battery, at weekly intervals.						
15. SUBJECT TERMS Head injury; military; Vietnam veterans; disease management system						
16. SECURITY CLASSIFICATION OF:				17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U	19b. TELEPHONE NUMBER (include area code)			
				UU	5	

Table of Contents

Cover.....	1
SF 298	2
Table of Contents.....	3
Introduction.....	4
Narrative	4
Key Research Accomplishments	4
Reportable Outcomes.....	5

Introduction

This report summarizes events for the period September 24, 2004 to September 23, 2005 in the implementation of the Vietnam Head Injury Study - Phase III: A 30-Year Post-Injury Follow-up Study, funded by the US Army Medical Research and Materiel Command, under grant no. DAMD17-01-1-0675.

Narrative

In October 2004 we hired our Physician's Assistant, Gerry Tasick. We also received NNMC approval of modified consent forms and HIPAA documents due to a change in the NNMC Principal Investigator to Dr John Hughes. In November 2004 Kathy Reding was hired as a data entry clerk/research assistant, which completed our current team of staff. In January 2005, adverse events reports were submitted successfully. In February 2005 we submitted our NNMC Annual review. Unfortunately at this time, one of the Principal Investigators, Dr Andres Salazar failed to renew his medical license, and hence the study was suspended, but was shortly afterwards reinstated. In February Drs Grafman, Salazar and Raymont met with new NNMC Admiral for command support. In March 2005 we submitted a successful audit, and there was a NNMC approved modification of the protocol. In this month one adverse event report was submitted. Further similar reports were submitted in June, July and August 2005. All adverse events reported this year were minor and were not a result of the research study. In September 2005 we ran an advertisement in the Disabled American Veterans publication for further control recruitment, with some success.

We are continuing to test three subjects every 5 days, with the battery now taking 5 full days for each subject to complete. Data is being entered into the VHIS – Phase III computer database on a continual basis.

During this reporting period, 108 subjects have attended for testing: 95 head-injured subjects and 13 controls. To date, there have been a total of 144 participants. All subjects have had blood samples taken for genetic analysis and all head-injured subjects have undergone a CT brain scan and EEG (if their individual physical condition allowed it). We have identified two cases of probable undetected epilepsy and two further cases with likely meningiomas. In May 2005 we submitted a description of the methodology of the Vietnam Head Injury Study for publication in Military Medicine.

Key Research Accomplishments

- Refinement of the test battery, test software, forms, and task administrative procedures, including adjustment of testing roles of study staff.
- Training of all new study staff in their required duties within the test battery.
- Gathering of data and maintenance of the VHIS – Phase III computer database.

Reportable Outcomes

CT scans performed: 95

EEGs performed: 95

Blood Samples collected: 92 (1 = we weren't able to get the blood; 2 = refused to donate)

Total participants seen:

Subjects: 95

Controls: New: 6

Returning: 7

Total Adverse Events reported: 8 – none related to study.