Award Number: W811XWH-08-2-0066

TITLE: “Addressing the Needs of Children of Combat Injured”

PRINCIPAL INVESTIGATOR: Stephen J. Cozza, M.D.

CONTRACTING ORGANIZATION:
The Henry M. Jackson Foundation
Rockville, MD 20852

REPORT DATE: April, 2010

TYPE OF REPORT: Annual

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

DISTRIBUTION STATEMENT:
  x 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.
Due to the length of time to obtain IRB approval, the data collection has not commenced. However, hiring personnel to conduct the study has been completed for the Walter Reed site and begun for the Brooke Army Medical site.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTRODUCTION</td>
<td>5</td>
</tr>
<tr>
<td>BODY</td>
<td>5</td>
</tr>
<tr>
<td>KEY RESEARCH ACCOMPLISHMENTS</td>
<td>6</td>
</tr>
<tr>
<td>REPORTABLE OUTCOMES</td>
<td>6</td>
</tr>
<tr>
<td>CONCLUSION</td>
<td>6</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>6</td>
</tr>
<tr>
<td>APPENDICES</td>
<td>6</td>
</tr>
</tbody>
</table>
INTRODUCTION:

This investigation focuses on measuring the impact of parental combat injury on military children and families. The study is a longitudinal design comparing families of combat-injured service members (CI group) and non-injured service members (NI group) across a 12-month time-frame. The CI group will be comprised of 200 injured service members and their spouses with at least one child between the ages of 3 and 18 years recruited from WRAMC and BAMC within the first 6 months of hospitalization. The NI group will be comprised of 200 active duty non-injured combat veterans (matched with CI participants for combat experience and relevant demographic factors) and their spouses with at least one child between the ages of 3 and 18 years recruited within 6 months of returning from deployment. Families will be assessed using self-report questionnaires and, for the CI Group, record review of a semi-structured interview currently used at clinical sites. Consenting parents and assenting children ages 6 to 18 years will complete questionnaires assessing the following domains: parental trauma exposure history, symptoms, and function; child traumatic exposure history, symptoms and function; parenting behaviors; and family functioning. Follow up assessments of parental symptoms and functioning, child symptoms and functioning, parenting behaviors, and family functioning will be completed 6 and 12 months after the initial assessment. For families who are not available to complete in-person assessment at 6 and/or 12 months, assessment will be conducted by telephone and measures will be administered verbally. Families will also be briefly contacted at 3 months and 9 months to check-in and inquire whether they are in need of additional resources.

BODY:

Below is a summary of the major activities undertaken by project team members during the last 12 months organized by the timeline in the Schedule of Work (SOW). Note, the project has not moved past month 6 of the SOW activities due to reported delays.

1. **Program personnel recruitment and hiring**: In process. Ms. Mona Mendelson, LCSW, has been hired for the position (“clinical research assistant”) at WRAMC and began work on March 1, 2010. BAMC has been consulted regarding any specific aspects unique to their setting and recruiting has begun for their parallel position. We are still working with Ft. Stewart to determine if there is a current staff member who can undertake this project on their behalf.

2. **Staff and clinician training**: Ms. Mendelson has begun CITI training, HJF orientation, and training related to other job “start up” requirements such as review of protocol and study measures.

3. **Organization and Preparation**: Maintained contacts with WRAMC and BAMC personnel. Met with a co-Investigator from BAMC in a face to face meeting to discuss hiring procedures and grant status in February, 2010 (Dr. Alan Maiers).

4. **Site Approval and Planning**: IRB approval has been obtained for USU, WRAMC and BAMC. The Fort Stewart collaborator has submitted the protocol to Eisenhower Medical Center IRB and review is underway.

5. **Finalize Plans**: Dr. Cozza and Ms. Mendelson met with local personnel at WRAMC to discuss the study and recruitment of subjects. Issues of space (work space for Ms. Mendelson and for conducting family assessments) and credentialing/privileging were also reviewed (03/11/10).
6. **Participant Enrollment and Data Collection:** Data collection will begin at WRAMC because we have received IRB approval and have just completed the hiring of relevant personnel. BAMC and Ft. Stewart will follow, upon finalization of personnel/remaining IRB issues.

7. **Problem Areas:** IRB approval has taken longer than expected. Due to delays in obtaining human subjects approval, we anticipate that data collection will not begin until April 2010.

**KEY RESEARCH ACCOMPLISHMENTS:**

Data have not yet been collected.

**REPORTABLE OUTCOMES:**

No reportable outcomes at this time.

**CONCLUSION:**

Study remains within the IRB approval phase, now moving to clinical and community subject site review.

**REFERENCES:**

No references were cited in this annual report.

**APPENDICES:**

None supplied.