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Award Number: **W81XWH-10-2-0113**

TITLE: **Spouses/Family Members of Service Members at Risk for PTSD or Suicide**

PRINCIPAL INVESTIGATOR: **Keith D. Renshaw, Ph.D**

CONTRACTING ORGANIZATION: **George Mason University, Fairfax, VA 22030**

REPORT DATE: **October 2012**

TYPE OF REPORT: **Annual**

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

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Keith D. Renshaw, Ph.D.

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
The purpose of the study is to gain new knowledge about the experiences of family members of service members who are experiencing symptoms of PTSD or severe depression. The study is multi-method, with an initial qualitative phase, and a follow-up longitudinal, quantitative phase. During Year 2, the first several months continued to focus primarily on securing a site for the study. After a variety of efforts in collaboration with Walter Reed National Military Medical Center and NRMC Tele-health, a firm partnership was established with Ft. Belvoir Community Hospital (FBCH). A CRADA was established, and logistics and procedures were finalized. IRB documents were submitted and are currently under review. Recruitment materials were developed and are also under review. Although this places us behind with regard to the proposed statement of work, the study is still quite feasible to complete by budgeting for a no-cost extension.

15. SUBJECT TERMS
PTSD; Suicide; Marriage; Family

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Table of Contents

INTRODUCTION

This project focuses on marriages/romantic relationships and family relationships of service members with significant risk for PTSD and/or suicidality. Social support is one of the strongest buffers against PTSD (Brewin, Andrews, & Valentine, 2000; Ozer, Best, Lipsey, & Weiss, 2003), and relationship difficulties have been cited as the most common trigger of suicides in service members over the past several years (Keuhn, 2009). Thus, a healthy interpersonal environment is key for service members who may be struggling with behavioral health problems. Unfortunately, spouses of service members or veterans with symptoms of PTSD or depression have significantly elevated levels of psychological and interpersonal distress (Monson, Taft, & Fredman, 2009). It also appears quite likely that parents and other close relatives of service members with PTSD or depression experience significant distress, but there currently are almost no empirical data about relatives other than spouses or children. Based on the clear interaction between individual psychological problems in service members and their interpersonal environment, the ultimate objective is to gather data that will inform the future design of interventions for relatives of service members that will increase relatives' resilience and, consequently, their ability to provide support for service members. The purposes of this project are to: (1) identify the primary needs of relatives of high-risk (PTSD/depression) service members, and (2) identify potential distress and resilience mechanisms in these relatives. The research includes two phases. Phase 1 employs focus groups to (a) better understand the needs of romantic partners and (b) begin to identify needs of other types of family members (e.g., parents), who are rarely the focus of research. Phase 2 employs longitudinal assessment of service members and partners/relatives using interview and self-report measures to (a) validate information gathered in Phase 1 and (b) examine the longitudinal associations among service members' psychological functioning and the family environment. This information will, in turn, be used to identify primary targets for family intervention that can increase partners'/relatives' resilience and improve service members' psychological functioning.

BODY

Task 1a. The initiation of the project was hampered by a lack of recruitment site. Based on instructions in the application materials, no recruitment site was secured prior to applying for the award. However, at the "kick-off" meeting held on 20 Dec 2010 (1.6 months after the official start of the project), the PI was informed that CDMRP (or TATRC) was unlikely to provide such a site. Thus, activity in the first two years was focused primarily on securing a partner site. During year 2, this included multiple

meetings with individuals at Walter Reed National Military Medical Center (WRNMMC), National Intrepid Center of Excellence (NICOE), the Pentagon, Andrews Air Force Base (AAFB), Uniformed Services University of the Health Sciences (USUHS), Northern Regional Medical Command (NRMC) Tele-Health, and Fort Belvoir Community Hospital (FBCH).

These efforts primarily involved the PI and one Graduate Research Assistant (GRA). Initial activity was focused on being credentialed at WRNMMC, and exploring potential relationships with NICOE and AAFB. As logistical issues continued to impede these collaborative possibilities, efforts were shifted to a potential collaboration with NRMC Tele-Health. These efforts proved more promising, and steps were made to initiate a multi-site IRB protocol, to encompass multiple bases, including Ft. Drum, Ft. Bragg, Ft. Lee, and Ft. Knox. As work on this progressed, we also secured a collaborative agreement with FBCH. After beginning preparation of IRB materials, I received feedback that the multi-site approach might unnecessarily complicate the review process; thus, in late June 2012, the decision was made to partner solely with FBCH for this project.

Although the task of securing a site was not included in the original Statement of Work, this work has been essential to the project. We have now met with FBCH personnel and have a fully agreed upon set of procedures to execute Phase 1 of the study, with preliminary plans in place for Phase 2.

Task 1b. IRB documents are under administrative review at FBCH Department of Research Programs, after which they will be forwarded to WRNMMC IRB for review. Upon final approval, the protocol will be submitted to GMU IRB, and upon final approval from GMU, the documents will be forwarded for secondary review.

Task 1c. The focus group manual was completed in Y1.

Task 1d. The manual for managing suicidal ideation and behaviors is complete, pending any adjustments to meet FBCH requirements.

All remaining tasks were unable to be completed, due to the delays associated with securing a recruitment site.

KEY RESEARCH ACCOMPLISHMENTS

- Agreement for study execution at FBCH.
  - Site PI identified (LTC Jeffrey Yarvis)
  - Site AI identified (LTJG Mekeshia Bates)
  - CRADA between GMU and FBCH established.
- Procedures for recruitment and study execution at FBCH established.
- IRB documents submitted.

REPORTABLE OUTCOMES

- CRADA (see attached).
- IRB Review begun.

CONCLUSION

As we become able to recruit participants for the project, we look forward to being able to draw conclusions about the impact of PTSD and/or suicidality on service members' relatives. In addition, we look forward to using that information to inform efforts to assist these individuals in caring for affected service members.

REFERENCES

Brewin, C. R., Andrews, B., & Valentine, J. D. (2000). Meta-analysis of risk factors for posttraumatic stress disorder in trauma-exposed adults. *Journal of Consulting and Clinical Psychology, 68,* 748-766.

Keuhn, B. M. (2009). Soldier suicide rates continue to rise: Military, scientists work to stem the tide. *Journal of the American Medical Association, 301,* 1111-1113.

Monson, C. M., Taft, C. T., & Fredman, S. J. (2009). Military-related PTSD and intimate relationships: From description to theory-driven research and intervention development. *Clinical Psychology Review, 29,* 707-714.

Ozer, E. J., Best, S. R., Lipsey, T. L., & Weiss, D. S. (2003). Predictors of posttraumatic stress disorder and symptoms in adults: A meta-analysis. *Psychological Bulletin, 129,* 52-73.

A COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

Between
(Cooperator)
GEORGE MASON UNIVERSITY
and
FORT BELVOIR COMMUNITY HOSPITAL
(Laboratory)

Article 1. Background

1.00 This Agreement is entered into under the authority of the Federal Technology Transfer Act of 1986, 15 U.S.C. 3710a, et seq., between the Cooperator and the Laboratory, the parties to this Agreement.

1.01 Laboratory, on behalf of the U.S. Government, and Cooperator desire to cooperate in research and development on , "Spouses/Family Members of Service Members at Risk for PTSD or Suicide," Agreement Number: **Fort Belvoir Community Hospital, CRADA-1000-12** according to the attached Statement of Work (SOW) described in Appendix A. NOW, THEREFORE, the parties agree as follows:

Article 2. Definitions

2.00 The following terms are defined for this Agreement as follows:

2.01 "Agreement" means this cooperative research and development agreement.

2.02 "Invention" and "Made" have the meanings set forth in Title 15 U.S.C. Section 3703(9) and (10).

2.03 "Proprietary Information" means information marked with a proprietary legend which embodies trade secrets developed at private expense or which is confidential business or financial information, provided that such information:

(i) is not generally known, or which becomes generally known or available during the period of this Agreement from other sources without obligations concerning their confidentiality;

(ii) has not been made available by the owners to others without obligation concerning its confidentiality; and

(iii) is not already available to the receiving party without obligation concerning its confidentiality.

(iv) is not independently developed by or on behalf of the receiving party, without reliance on the information received hereunder.

2.04 "Subject Data" means all recorded information first produced in the performance of this Agreement.

2.05 "Subject Invention" means any Invention Made as a consequence of, or in relation to, the performance of work under this Agreement.

Article 3. Research Scope and Administration

3.00 Statement of Work. Research performed under this Agreement shall be performed in accordance with the SOW incorporated as a part of this Agreement at Appendix #1. It is agreed that any descriptions, statements, or specifications in the SOW shall be interpreted as goals and objectives of the services to be provided under this Agreement and not requirements or warranties. Laboratory and Cooperator will endeavor to achieve the goals and objectives of such services; however, each party acknowledges that such goals and objectives, or any anticipated schedule of performance, may not be achieved.

3.01 Review of Work. Periodic conferences shall be held between the parties for the purpose of reviewing the progress of work. It is understood that the nature of this research is such that completion within the period of performance specified, or within the limits of financial support allocated, cannot be guaranteed. Accordingly, all research will be performed in good faith.

3.02 Principal Investigator. Any work required by the Laboratory under the SOW will be performed under the supervision of Jeffrey S. Yarvis, Ph.D., MSW, M.Ed., LTC, MS Deputy Commander for Behavioral Health, Fort Belvoir Community Hospital, 9300 Belvoir Loop, Fort Belvoir, VA 22060, Phone: 703-732-7401, Fax: 571-231-1272, Jeffrey.yarvis@us.army.mil, who, as co-principal investigator has responsibility for the scientific and technical conduct of this project on behalf of the Laboratory. Any work required by the Cooperator under the SOW will be performed under the supervision of Keith D. Renshaw, Ph.D., Assistant Professor, Department of Psychology, George Mason University, 4400 University Dr. MSN 3F5, Fairfax, VA 22030-4444, Phone: 703-993-5128, Fax: 703-993-1359, krenshaw@gmu.edu, who, as co-principal investigator has responsibility for the scientific and technical conduct of this project on behalf of the Cooperator.

3.03 Collaboration Changes. If at any time the co-principal investigators determine that the research data dictates a substantial change in the direction of the work, the parties shall make a good faith effort to agree on any necessary change to the SOW and make the change by written notice to the addresses listed in section 13.04 Notices.

3.04 Final Report. The parties shall prepare a final report of the results of this project within six months after completing the SOW.

Article 4. Ownership and Use of Physical Property

4.01 Ownership of Materials or Equipment. All materials or equipment developed or acquired under this Agreement by the parties shall be the property of the party which developed or acquired the property, except that government equipment provided by Laboratory (1) which through mixed funding or mixed development must be integrated into a larger system, or (2) which through normal use at the termination of the Agreement has a salvage value that is less than the return shipping costs, shall become the property of Cooperator.

4.02 Use of Provided Materials. Both parties agree that any materials relating to them which were provided by one party to the other party will be used for research purposes only. The materials shall not be sold, offered for sale, used for commercial purposes, or be furnished to any other party without advance written approval from the Provider's official signing this Agreement or from another official to whom the authority has been delegated, and any use or furnishing of material shall be subject to the restrictions and obligations imposed by this Agreement.

Article 5. Financial Obligation Each party shall fund its own research tasks.

Article 6. Patent Rights

6.00 Reporting. The parties shall promptly report to each other all Subject Inventions reported to either party by its employees. All Subject Inventions Made during the performance of this Agreement shall be listed in the Final Report required by this Agreement.

6.01 Cooperator Employee Inventions. Laboratory waives any ownership rights the U.S. Government may have in Subject Inventions Made by Cooperator employees and agrees that Cooperator shall have the option to retain title in Subject Inventions Made by Cooperator employees. Cooperator shall notify Laboratory promptly upon making this election and agrees to timely file patent applications on Cooperator's Subject Invention at its own expense. Cooperator agrees to grant to the U.S. Government on Cooperator's Subject Inventions a nonexclusive, nontransferable, irrevocable, paid-up license in the patents covering a Subject Invention, to practice or have practiced, throughout the world by, or on behalf of the U.S. Government. The nonexclusive license shall be evidenced by a confirmatory license agreement prepared by Cooperator in a form satisfactory to Laboratory.

6.02 Laboratory Employee Inventions. Laboratory shall have the initial option to retain title to, and file patent application on, each Subject Invention Made by its employees. The Laboratory agrees to grant an exclusive license to any invention arising under this Agreement to which it has ownership to the Cooperator in accordance

with Title 15 U.S. Code Section 3710a, on terms negotiated in good faith. Any invention arising under this Agreement is subject to the retention by the U.S. Government of nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced, the invention throughout the world by or on behalf of the U.S. Government.

6.03 Joint Inventions. Any Subject Invention patentable under U.S. patent law which is Made jointly by Laboratory employees and Cooperator employees under the Scope of Work of this Agreement shall be jointly owned by the parties. The parties shall discuss together a filing strategy and filing expenses related to the filing of the patent covering the Subject Invention. If a party decides not to retain its ownership rights to a jointly owned Subject Invention, it shall offer to assign such rights to the other party, pursuant to Paragraph 6.05, below.

6.04 Government Contractor Inventions. In accordance with 37 Code of Federal Regulations 401.14, if one of Laboratory's Contractors conceives an invention while performing services at Laboratory to fulfill Laboratory's obligations under this Agreement, Laboratory may require the Contractor to negotiate a separate agreement with Cooperator regarding allocation of rights to any Subject Invention the Contractor makes, solely or jointly, under this Agreement. The separate agreement (i.e., between the Cooperator and the Contractor) shall be negotiated prior to the Contractor undertaking work under this Agreement or, with the Laboratory's permission, upon the identification of a Subject Invention. In the absence of such a separate agreement, the Contractor agrees to grant the Cooperator an option for a license in Contractor's inventions of the same scope and terms set forth in this Agreement for inventions made by Laboratory employees.

6.05 Filing of Patent Applications. The party having the right to retain title to, and file patent applications on, a specific Subject Invention may elect not to file patent applications, provided it so advises the other party within 90 days from the date it reports the Subject Invention to the other party. Thereafter, the other party may elect to file patent applications on the Subject Invention and the party initially reporting the Subject Invention agrees to assign its ownership interest in the Subject Invention to the other party.

6.06 Patent Expenses. The expenses attendant to the filing of patent applications shall be borne by the party filing the patent application. Each party shall provide the other party with copies of the patent applications it files on any Subject Invention, along with the power to inspect and make copies of all documents retained in the official patent application files by the applicable patent office. The parties agree to reasonably cooperate with each other in the preparation and filing of patent applications resulting from this Agreement.

Article 7. Exclusive License

7.00 Grant. The Laboratory agrees to grant to the Cooperator an exclusive license in each U.S. patent application, and patents issued thereon, covering a Subject

Invention, which is filed by the Laboratory subject to the reservation of a nonexclusive, nontransferable, irrevocable, paid-up license to practice and have practiced the Subject Invention on behalf of the United States.

7.01 Exclusive License Terms. The Cooperator shall elect or decline to exercise its right to acquire an exclusive license to any Subject Invention within six months of being informed by the Laboratory of the Subject Invention. The specific royalty rate and other terms of license shall be negotiated promptly in good faith and in conformance with the laws of the United States.

Article 8. Background Patent(s)

8.00 The parties grant to each other, to the extent that each has the authority to do so, expressed or implied, royalty-free, nonexclusive licenses to practice or have practiced on their behalf background Inventions necessary for the performance of work under this Agreement.

8.01 Laboratory Background Patent(s): Laboratory has filed patent application(s), or is the assignee of issued patent(s), listed below which contain(s) claims that are related to research contemplated under this Agreement. No license(s) to this/these patent applications or issue patents is/are granted under this Agreement, and this/these application(s) and any continuations to it/them are specifically excluded from the definitions of "Subject Invention" contained in this Agreement:

8.02 Cooperator Background Patent(s): Cooperator has filed patent application(s), or is the assignee of issued patent(s), listed below which contain(s) claims that are related to research contemplated under this Agreement. No license(s) to this/these patent applications or issue patents is/are granted under this Agreement, and this/these application(s) and any continuations to it/them are specifically excluded from the definitions of "Subject Invention" contained in this Agreement:

Article 9. Subject Data and Proprietary Information

9.00 Subject Data Ownership. Subject Data shall be jointly owned by the parties. Each party, upon request to the other party, shall have the right to review and to request delivery of all Subject Data, and delivery shall be made to the requesting party within two weeks of the request, except to the extent that such Subject Data are subject to a claim of confidentiality or privilege by a third party.

9.01 Proprietary Information/Confidential Information. Each party shall place a proprietary notice on all information it delivers to the other party under this Agreement that it asserts is proprietary. The parties agree that any Proprietary Information or Confidential Information furnished by one party to the other party under this Agreement, or in contemplation of this Agreement, shall be used, reproduced and disclosed by the receiving party only for the purpose of carrying out this Agreement, and shall not be

released by the receiving party to third parties unless consent to such release is obtained from the providing party.

9.02 Department of Defense (DoD) limited-access database. Notwithstanding anything to the contrary in this Article, the existence of established CRADAs specifying areas of research and their total dollar amounts may be documented on limited access, password-protected websites of the DoD, to provide the Command's leadership with a complete picture of military research efforts.

9.03 Laboratory Contractors. Cooperator acknowledges and agrees to allow Laboratory's disclosure of Cooperator's proprietary information to Laboratory's Contractors for the purposes of carrying out this Agreement. Laboratory agrees that it has or will ensure that its Contractors are under a written obligation not to disclose Cooperator's proprietary information, except as required by law or court order, before Contractor employees have access to Cooperator's proprietary information under this Agreement.

9.04 Release Restrictions. Laboratory shall have the right to use all Subject Data for any Governmental purpose, but shall not release Subject Data publicly except: (i) Laboratory in reporting on the results of research may publish Subject Data in technical articles and other documents to the extent it determines to be appropriate; and (ii) Laboratory may release Subject Data where release is required by law or court order. The parties agree to confer prior to the publication of Subject Data to assure that no Proprietary Information is released and that patent rights are not jeopardized. Prior to submitting a manuscript for review which contains the results of the research under this Agreement, or prior to publication if no such review is made, each party shall be offered an ample opportunity to review any proposed manuscript and to file patent applications in a timely manner.

9.05 FDA Documents. If this Agreement involves a product regulated by the U.S. Food and Drug Administration (FDA), then the Cooperator or the U.S. Army Medical Research and Materiel Command, as appropriate, may file any required documentation with the FDA. In addition, the parties authorize and consent to allow each other or their contractors or agents access to, or to cross-reference, any documents filed with the FDA related to the product.

Article 10. Termination

10.00 Termination by Mutual Consent. Cooperator and Laboratory may elect to terminate this Agreement, or portions thereof, at any time by mutual consent.

10.01 Termination by Unilateral Action. Either party may unilaterally terminate this entire Agreement at any time by giving the other party written notice, not less than 30 days prior to the desired termination date.

10.02 Termination Procedures. In the event of termination, the parties shall specify the disposition of all property, patents and other results of work accomplished or in progress, arising from or performed under this Agreement by written notice. Upon receipt of a written termination notice, the parties shall not make any new commitments and shall, to the extent feasible, cancel all outstanding commitments that relate to this Agreement. Notwithstanding any other provision of this Agreement, any exclusive license entered into by the parties relating to this Agreement shall be simultaneously terminated unless the parties agree to retain such exclusive license.

Article 11. Disputes

11.00 Settlement. Any dispute arising under this Agreement which is not disposed of by agreement of the principal investigators shall be submitted jointly to the signatories of this Agreement. A joint decision of the signatories or their designees shall be the disposition of such dispute. However, nothing in this section shall prevent any party from pursuing any and all administrative and/or judicial remedies which may be allowable.

Article 12. Liability

12.00 Property. Neither party shall be responsible for damages to any property provided to, or acquired by, the other party pursuant to this Agreement.

12.01 Cooperator's Employees. Cooperator agrees to be responsible for liability of any kind involving an employee of Cooperator arising in connection with this Agreement, and for all liabilities arising out of the use by Cooperator of Laboratory's research and technical developments, or out of any use, sale or other disposition by Cooperator of products made based on Laboratory's technical developments, except to the extent the liability is due to the negligence of Laboratory under the provisions of the Federal Tort Claims Act. This provision shall survive termination or expiration of this Agreement.

12.02 No Warranty. The parties make no express or implied warranty as to any matter whatsoever, including the conditions of the research or any Invention or product, whether tangible or intangible, Made, or developed under this agreement, or the ownership, merchantability, or fitness for a particular purpose of the research or any Invention or product.

Article 13. Miscellaneous

13.00 Governing Law. The construction, validity, performance, and effect of this Agreement shall be governed for all purposes by the laws applicable to the United States Government.

13.01 Export Control and Biological Select Agents and Toxins. The obligations of the parties to transfer technology to one or more other parties, provide technical

information and reports to one or more other parties, and otherwise perform under this Agreement are contingent upon compliance with applicable United States export control laws and regulations. The transfer of certain technical data and commodities may require a license from a cognizant agency of the United States Government or written assurances by the Parties that the Parties shall not export technical data, computer software, or certain commodities to specified foreign countries without prior approval of an appropriate agency of the United States Government. The Parties do not, alone or collectively, represent that a license shall not be required, nor that, if required, it shall be issued. In addition, where applicable, the parties agree to fully comply with all laws, regulations, and guidelines governing biological select agents and toxins.

13.02 Independent Contractors. The relationship of the parties to this Agreement is that of independent contractors and not as agents of each other or as joint venturers or partners.

13.03 Use of Name or Endorsements. (a) The parties shall not use the name of the other party on any product or service which is directly or indirectly related to either this Agreement or any patent license or assignment agreement which implements this Agreement without the prior approval of the other party. (b) By entering into this Agreement, Laboratory does not directly or indirectly endorse any product or service provided, or to be provided, by Cooperator, its successors, assignees, or licensees. Cooperator shall not in any way imply that this Agreement is an endorsement of any such product or service. Press releases or other public releases of information shall be coordinated between the parties prior to release, except that the Laboratory may release the name of the Cooperator and the title of the research without prior approval from the Cooperator.

13.04 Survival of Specified Provisions. The rights specified in provisions of this Agreement covering Patent Rights, Subject Data and Proprietary Information, and Liability shall survive the termination or expiration of this Agreement.

13.05 Notices. All notices pertaining to or required by this Agreement shall be in writing and shall be signed by an authorized representative addressed as follows:

If to Cooperator:

Eileen Gallagher
Associate Director, Contracts
Office of Sponsored Programs
George Mason University
4400 University Drive, MS 4C6
Fairfax, VA 22030
Phone: 703-993-2292
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Principal Investigator:
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Principal Investigator:

Jeffrey S. Yarvis, Ph.D., MSW, M.Ed., LTC, MS
Deputy Commander for Behavioral Health
Fort Belvoir Community Hospital
9300 Belvoir Loop
Fort Belvoir, VA 22060
Phone: 703-732-7401
Fax: 571-231-1272
Email: Jeffrey.yarvis@us.army.mil

Any party may change such address by notice given to the other in the manner set forth above.

Article 14. Duration of Agreement and Effective Date

14.01 Effective Date and Amendment. This Agreement shall enter into force as of the date it is signed by the last authorized representative of the parties. This Agreement may be amended at any time by mutual written consent of all Parties.

14.02 Signature Execution. This Agreement may be executed in one or more counterparts by the parties by signature of a person having authority to bind the party, which may be by facsimile signature, each of which when executed and delivered, by facsimile transmission, mail, or email delivery, will be an original and all of which will constitute but one and the same Agreement.

14.03 Expiration Date. This Agreement will automatically expire 3 years from effective date unless it is revised by written notice and mutual agreement.

Article 15.00 HIPAA Compliance PRIVACY OF PROTECTED HEALTH INFORMATION.

Introduction:
In accordance with DoD 6025.18-R "Department of Defense Health Information Privacy Regulation," January 24, 2003, the Collaborator meets the definition of Business Associate. Therefore, a Business Associate Agreement is required to comply with the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security regulations. This clause serves as that agreement whereby the Collaborator agrees to abide by all applicable HIPAA Privacy and Security requirements regarding health information as defined in this clause, and in DoD 6025.18-R and DoD 8580.02-R, as amended. Additional requirements will be addressed when implemented.

(a) **Definitions**. As used in this clause generally refer to the Code of Federal Regulations (CFR) definition unless a more specific provision exists in DoD 6025.18-R or DoD 8580.02-R.

Individual has the same meaning as the term "individual" in 45 CFR 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

Privacy Rule means the Standards for Privacy of Individually Identifiable Health Information at 45 CFR, Part 160 and Part 164, Subparts A and E.

Protected Health Information has the same meaning as the term "protected health information" in 45 CFR 160.103, limited to the information created or received by the Collaborator from or on behalf of the Government pursuant to the Agreement.

Electronic Protected Health Information has the same meaning as the term "electronic protected health information" in 45 CFR 160.103.

Required by Law has the same meaning as the term "required by law" in 45 CFR 164.103.

Secretary means the Secretary of the Department of Health and Human Services or his/her designee.

Security Rule means the Health Insurance Reform: Security Standards at 45 CFR, Part 160, 162 and Part 164, Subpart C.

Terms used, but not otherwise defined, in this clause shall have the same meaning as those terms in 45 CFR 160.103, 160.502, 164.103, 164.304, and 164.501.

(b) The Collaborator shall not use or further disclose Protected Health Information other than as permitted or required by the Agreement or as Required by Law.

(c) The Collaborator shall use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.

(d) The Collaborator agrees to use administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits in the execution of this Agreement.

(e) The Collaborator shall, at their own expense, take action to mitigate, to the extent practicable, any harmful effect that is known to the Collaborator of a use or disclosure of Protected Health Information by the Collaborator in violation of the requirements of this clause. These mitigation actions will include as a minimum those listed in the TMA Breach Notification Standard Operating Procedure (SOP), which is available at: http://www.tricare.mil/tmaprivacy/breach.cfm

(f) The Collaborator shall report to the Government any security incident involving protected health information of which it becomes aware.

(g) The Collaborator shall report to the Government any use or disclosure of the Protected Health Information not provided for by this Agreement of which the Collaborator becomes aware.

(h) The Collaborator shall ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by the Collaborator, on behalf of the Government, agrees to the same restrictions and conditions that apply through this Agreement to the Collaborator with respect to such information.

(i) The Collaborator shall ensure that any agent, including a subcontractor, to whom it provides electronic Protected Health Information, agrees to implement reasonable and appropriate safeguards to protect it.

(j) The Collaborator shall provide access, at the request of the Government, and in the time and manner reasonably designated by the Government to Protected Health Information in a Designated Record Set, to the Government or, as directed by the Government, to an Individual in order to meet the requirements under 45 CFR 164.524.

(k) The Collaborator shall make any amendment(s) to Protected Health Information in a Designated Record Set that the Government directs or agrees to pursuant to 45 CFR 164.526 at the request of the Government, and in the time and manner reasonably designated by the Government.

(l) The Collaborator shall make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by the Collaborator, on behalf of the Government, available to the Government, or at the request of the Government to the Secretary, in a time and manner reasonably designated by the Government or the Secretary, for purposes of the Secretary determining the Government's compliance with the Privacy Rule.

(m) The Collaborator shall document such disclosures of Protected Health Information and information related to such disclosures as would be required for the Government to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

(n) The Collaborator shall provide to the Government or an Individual, in time and manner reasonably designated by the Government, information collected in accordance with this clause of the Agreement, to permit the Government to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

General Use and Disclosure Provisions

Except as otherwise limited in this clause, the Collaborator may use or disclose Protected Health Information on behalf of, or to provide services to, the Government for treatment, payment, or healthcare operations purposes, in accordance with the specific use and disclosure provisions below, if such use or disclosure of Protected Health Information would not violate the HIPAA Privacy Rule, the HIPAA Security Rule, DoD 6025.18-R or DoD 8580.02-R if done by the Government.

Specific Use and Disclosure Provisions

(a) Except as otherwise limited in this clause, the Collaborator may use Protected Health Information for the proper management and administration of the Collaborator or to carry out the legal responsibilities of the Collaborator.

(b) Except as otherwise limited in this clause, the Collaborator may disclose Protected Health Information for the proper management and administration of the Collaborator, provided that disclosures are required by law, or the Collaborator obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Collaborator of any instances of which it is aware in which the confidentiality of the information has been breached.

(c) Except as otherwise limited in this clause, the Collaborator may use Protected Health Information to provide Data Aggregation services to the Government as permitted by 45 CFR 164. 504(e)(2)(i)(B).

(d) Collaborator may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j)(1).

Obligations of the Government

Provisions for the Government to Inform the Collaborator of Privacy Practices and Restrictions:

(a) The Government shall provide the Collaborator with the notice of privacy practices that the Government produces in accordance with 45 CFR 164.520.

(b) The Government shall provide the Collaborator with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect the Collaborator's permitted or required uses and disclosures.

(c) The Government shall notify the Collaborator of any restriction to the use or disclosure of Protected Health Information that the Government has agreed to in accordance with 45 CFR 164.522.

Permissible Requests by the Government

The Government shall not request the Collaborator to use or disclose Protected Health Information in any manner that would not be permissible under the HIPAA Privacy Rule, the HIPAA Security Rule, or any applicable Government regulations (including without limitation, DoD 6025.18-R and DoD 8580.02-R) if done by the Government, except for providing Data Aggregation services to the Government and for management and administrative activities of the Collaborator as otherwise permitted by this clause.

Termination

(a) Termination. A breach by the Collaborator of this clause, may subject the Collaborator to termination under any applicable default or termination provision of this Agreement.

(b) Effect of Termination.

(1) If this contract has records management requirements, the records subject to the clause should be handled in accordance with the records management requirements. If this Agreement does not have records management requirements, the records should be handled in accordance with paragraphs (2) and (3) below:

(2) If this Agreement does not have records management requirements, except as provided in paragraph (3) of this section, upon termination of this Agreement,

for any reason, the Collaborator shall return or destroy all Protected Health Information received from the Government, or created or received by the Collaborator on behalf of the Government. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of the Collaborator. The Collaborator shall retain no copies of the Protected Health Information.

(3) If this contract does not have records management provisions and the Collaborator determines that returning or destroying the Protected Health Information is infeasible, the Collaborator shall provide to the Government notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Government and the Collaborator that return or destruction of Protected Health Information is infeasible, the Collaborator shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as the Collaborator maintains such Protected Health Information.

Miscellaneous

(a) Regulatory References. A reference in this clause to a section in DoD 6025.18-R, DoD 8580.02-R, Privacy Rule or Security Rule means the section currently in effect or as amended, and for which compliance is required.

(b) Survival. The respective rights and obligations of Business Associate under the "Effect of Termination" provision of this clause shall survive the termination of this Agreement.

(c) Interpretation. Any ambiguity in this clause shall be resolved in favor of a meaning that permits the Government to comply with DoD 6025.18-R, DoD 8580.02-R, the HIPAA Privacy Rule or the HIPAA Security Rule.

Signature Page to Follow

IN WITNESS WHEREOF, the Parties have caused this agreement to be executed by their duly authorized representatives as follows:

For the Cooperator:

Michael Laskofski
Associate Vice President of Research Operations
Office of Sponsored Programs
George Mason University

DATE 8/17/12

For the U.S. Government Laboratory:

CHARLES CALLAHAN, COL, USA, MC
Commander
Fort Belvoir Community Hospital
9300 DeWitt Loop,
Fort Belvoir, Va., 22060

DATE 24 SEP 12

APPENDIX A

STATEMENT OF WORK

A. IDENTIFICATION

A.1. Subject Category: Medicine & Biology (Clinical Medicine), Code 57E, Title: "Spouses/Family Members of Service Members at Risk for PTSD or Suicide." Short Title: "Spouses/Family Members."

A.2. Fort Belvoir Community Hospital (FBCH), Department of Defense (DoD) (Federal Laboratory), and George Mason University (Cooperator) desire to collaborate in research and development and will cooperate in support of the research protocol at Walter Reed National Military Medical Center entitled, "Spouses/Family Members of Service Members at Risk for PTSD or Suicide," (the "Study") by LTC Jeffrey Yarvis (Principal Investigator), serving at Fort Belvoir Community Hospital, located at 9300 Belvoir Loop, Fort Belvoir, VA 22060, acting under the guidance of the Federal Laboratory.

A.3. This Statement of Work (SOW) is executed under authority of the Stevenson-Wydler Technology Innovation Act of 1980 as amended by the Federal Technology Transfer Act (15 U.S.C. §§3701 et seq.). Together, the CRADA and this SOW constitute the entire "Agreement" of the Parties. In the case of a conflict between the provisions of this SOW and the CRADA, the terms and provisions of the latter shall control.

B. PURPOSE

B.1. The Federal Laboratory and the Cooperator are entering into this Agreement for the mutual benefit of each Party. This joint research project will benefit the Cooperator by enabling recruitment for a USAMRAA-funded study intended to learn more about the experiences and needs of spouses/family members of at-risk service members with behavioral health problems. Funding has been provided to Dr. Keith D. Renshaw, an Assistant Professor at George Mason University. The project will benefit the Federal Laboratory by providing valuable research experience for the medical staff, residents, and fellows of the teaching program involved. In addition, patients at Federal Laboratory with PTSD and/or severe depression may benefit through generation of knowledge that can assist their family members in better helping them cope with their behavioral health difficulties.

C. MEDICAL OBJECTIVE

C.1. The primary objectives include:

C.1.1 Identify the primary needs of relatives of high-risk (PTSD/depression) service members.

C.1.2. Identify potential distress and resilience mechanisms in these relatives.

D. DESCRIPTION OF WORK

D.1. Service members will be recruited via fliers posted or distributed by clinicians in behavioral health clinics. Interested service members will contact the research team at George Mason University, where study information will be reviewed. Service members who agree to participate in Phase 1 and provide consent will provide contact information for a relative and complete screening questionnaires online. The George Mason University research team will contact relatives to determine interest in participating, and review study information for those who are interested. Relatives who agree to participate will be scheduled for focus groups. Focus groups will be conducted by the George Mason University research team. Service members who agree to participate in Phase 2 and provide consent will provide contact information for a relative, complete an in-person diagnostic interview, and complete questionnaires online. The George Mason University research team will contact relatives to determine interest in participating, and review study information for those who are interested. Relatives who agree to participate will also complete questionnaires online. Diagnostic interviews will be conducted and online questionnaires will be monitored by the George Mason University research team.

D.2. Tasks being provided by George Mason University

D.2.1. Primary communication with participants and interested potential participants, including full explanation of study and informed consent.

D.2.2. Provision of questionnaires to service member participants, and scoring of responses.

D.2.3. Scheduling and running focus groups for relatives.

D.2.4. Scheduling and conducting diagnostic interviews for service members.

D.2.5. Storage and protection of data.

D.2.6. Qualitative analysis of focus group data.

D.2.7 Quantitative analysis of diagnostic interview and questionnaire data.

D.2.8. Write-up and dissemination of results.

D.3. Tasks being provided by FBCH

D.3.1. Posting/distribution of recruitment fliers

D.3.2. Provision of room with space for up to 10 people for focus groups during weeknight or weekend hours.

D.3.3. Provision of space for diagnostic interviews.

D.4. All performance under this SOW will cease at either the completion of the study, exhaustion of funds, unilateral or mutual termination, or December 31, 2015, whichever occurs first.

E. RESOURCES PROVIDED BY COOPERATOR

E.1. The Cooperator will furnish the following research resources:

E.2. Equipment: secure online website for questionnaires; audio recorders for focus groups

E.3. Services of Personnel: Graduate Research Assistants to handle recruitment, consent; Focus Group facilitators.

E.4. The above are hereinafter referred to as "Resources." Information relating to them, including data generated under this Agreement, is hereinafter referred to as "Information." Federal Laboratory agrees that the Resources and Information will be used for research and clinical purposes only as provided in this Agreement. The Resources shall not be sold, offered for sale, used for commercial purposes, or furnished to any other Party without advance written approval from the Cooperator.

E.5. Financial Obligation. N/A

F. RESOURCES PROVIDED BY FEDERAL LABORATORY

F.1. FBCH will facilitate posting/distribution of study fliers in relevant clinics, as directed by the PI. For any focus groups or diagnostic interviews that are conducted on site at FBCH, FBCH will provide use of one room for the participants to engage in the research.

G. REPORTS

G.1. Federal Laboratory agrees to report in a timely manner the results of any research conducted with the Resources to the Cooperator. Federal Laboratory agrees to provide all data supporting research results to the Cooperator. All data will be handled by the Cooperator, as none of the research being conducted involves standard care.

H. PRINCIPAL INVESTIGATOR

H.1. All notices required by this Agreement to be sent to the Principal Investigator will be sent to the following address:

Jeffrey S. Yarvis, Ph.D., MSW, M.Ed., LTC, MS
Deputy Commander for Behavioral Health
Fort Belvoir Community Hospital
9300 Belvoir Loop
Fort Belvoir, VA 22060
Phone: 703-732-7401
Fax: 571-231-1272
Email: Jeffrey.yarvis@us.army.mil