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Introduction

This report highlights the progress and accomplishments of “Relationship Factors Contributing to the Progression of Combat Related PTSD and Suicidality Over Time” during our first year of funding from March 2, 2012 to March 1, 2013. Please note that the public title we have selected for use in IRB review, with our participants, and throughout this report is the “Relationships Among Military Personnel (RAMP) Project”. The RAMP project is designed to examine the key social context of intimate romantic relationships of active duty Army soldiers, and how interpersonal processes in this type of relationship can affect psychological functioning over time. The ultimate goal of this knowledge will be to enhance existing programs and therapies for military couples. This study will consist of confidential online surveys to be completed by active duty Army males recently returned from an OEF deployment, along with their significant romantic partner. A total of 5 surveys across a two year period will be administered to these couples. Survey 1 is planned to have a total of 600 participating couples; surveys 2-5 are planned to have a total of 270 participating couples. In this report period, the study team has developed the surveys, protocol, recruitment materials and website, all planned participant communications, and participant payment processes. The study has passed initial reviews by the University of Colorado Institutional Review Board (COMIRB), US Army Medical Research & Materiel Command (USAMRMC) Human Research Protection Office (HRPO), and NIMH Certificate of Confidentiality (COC) program, and is currently undergoing final reviews before proceeding to recruitment and data collection.

The specific aims for the RAMP project are:

- Aim 1:** To examine couple and partner responses to PTSD symptoms, and how these responses affect PTSD, relationship functioning, and psychological risk factors for suicide over time.
- Aim 2:** Examine additional PTSD and relationship predictors of psychological risk factors for suicide.
- Aim 3:** Assess mechanisms of the relationship between PTSD and relationship functioning over time.
- Aim 4:** Determine adaptive and maladaptive patterns of communication regarding combat.

Body

In our approved Statement of Work, we proposed eight general task categories to accomplish our specific aims:

1. Hiring and orientation of project staff, purchasing and installing equipment
2. Finalizing initial item pool
3. Creating IRB applications, obtaining initial IRB approval, and maintaining compliance
4. Finalizing surveys
5. Developing and maintaining study materials and infrastructure
6. Recruitment
7. Executing online surveys
8. Analysis and dissemination

A narrative of significant accomplishments, issues encountered, and synopsis of key milestones for each quarter related to these SOW task categories 1-6 are provided in Sections I – IV. Following these quarterly narratives, bulleted lists of key accomplishments are provided in the next section, *Key Accomplishments*, which are organized by task category and quarter.

I. First Quarter (March 2, 2012 – June 30, 2012)

To begin the startup process of the RAMP project, the principal investigator (PI) hired and oriented two graduate research assistants (GRAs). The PI and GRAs had regular consultations with our TATRC regulatory compliance specialist to develop a complete initial draft of the research protocol and consent form, data collection tools, and general recruitment materials. At the end of the quarter, the study team submitted these documents to the TATRC regulatory compliance specialist to undergo a pre-review process. Concurrent to this process, the PI worked with the University of Colorado Denver’s (UCD)

budget and the grants and contracts offices to assign and activate payment processes for subcontractors and consultants affiliated with the grant. These subcontractors and consultants were regularly involved, via phone meetings, email exchanges, and face-to-face meetings, in developing the unique items and measures required to achieve the aims of the project, as well as discussion of procedures and methods. Additional outreach has been made to other scholars on a collegial basis to discuss measures that they have been developing for their own studies on related topics. This high quality engagement with scholars has been focused particularly around the identification, development, expansion, and/or adaptation of measures assessing key constructs of interest in the current study. In this quarter, GRAs also began developing the content of the study website, including an extensive resources page for various military support services available nationally and locally.

Key milestones this quarter:

- **FY11, Yr1 Q1, 03-02-2012:** Hired and gave orientations to 2 graduate research assistants (GRA).
- **FY11, Yr1 Q1, 03-07-2012:** Grant kickoff meeting and conference call with funding agency.
- **FY11, Yr1 Q1, 04-02-2012:** Computers and phone lines set up for project.
- **FY11, Yr1 Q1, 06-22-2012:** Created and submitted a pre-review packet to our TATRC regulatory compliance specialist, Brigit Ciccarello.
- **FY11, Yr1 Q1, 06-30-2012:** All subcontracts and consultant billing procedures finalized.

II. Second Quarter (July 1, 2012 – September 30, 2012)

In the second quarter, we hired a replacement GRA (20 hours/week), and brought on an undergraduate research assistant (10 hours/week) to help with the project. The new GRA and undergraduate were oriented to the project, and completed both human subjects research and HIPAA trainings. Our TATRC regulatory compliance specialist provided feedback on our pre-review submission; she found our protocol to be excellent and well detailed, and provided helpful suggestions/comments. We responded to her suggestions to her satisfaction, including adding a new step to the eligibility process to verify military service. After we made all suggested revisions, we sent the revised protocol to the rest of the study team (including collaborating researchers and consultants) to get additional feedback. After compiling feedback from this iterative process, we submitted the revised documents to our local review board, the Colorado Multiple Institution Board (COMIRB), for review. This included an electronic application, detailed protocol, eligibility screening and consent form, draft of all measures, website text, local and national resource list, and sample recruitment material text.

We continued in the development of novel measures and selection among existing measures to adequately operationalize all aims and hypotheses of the project. One of our collaborating researchers (Dr. Keith Renshaw) received IRB approval to conduct a preliminary test of a measure we developed and plan to use for our study focusing on lay knowledge of and assumptions about PTSD. We acquired a website hosting and development tool, an official domain name for our website (www.RAMPproject.net), and an online survey development and data collection tool (Qualtrics). Within Qualtrics, we began to build survey logic and participant payment processes.

Key milestones this quarter:

- **FY12, Yr1 Q2, 07-13-2012:** Received and responded to pre-review feedback from our TATRC regulatory compliance specialist; circulated the revised research protocol for feedback to all investigators and made additional changes according to their feedback.
- **FY12, Yr1 Q2, 08-01-2012:** Trained research assistant (RA) in Mendeley to manage our research library and curate hundreds of relevant articles in our RAMP Mendeley account.
- **FY12, Yr1 Q2, 08-05-2012:** Dr. Keith Renshaw, a collaborating researcher on the project, received IRB approval from George Mason University to test a measure for the study entitled “Psychological Experience and Impressions of Behavior”.
- **FY12, Yr1 Q2, 08-30-2012:** Purchased Qualtrics, an online survey builder and data collection tool. RAs have been learning Qualtrics and entering our measures into this interface.
- **FY12, Yr1 Q2, 09-10-2012:** As part of developing the project website, we purchased a website domain name (RAMPproject.net), and a web hosting/development tool.

- **FY12, Yr1 Q2, 09-24-2012:** Submitted protocol and necessary attachments to COMIRB for approval. This includes full protocol, consent form, draft recruitment ads, website content, and draft measures.

III. Third Quarter (October 1, 2012 – December 31, 2012)

During the third quarter we received initial COMIRB approval and then submitted the study to HRPO review. We hired a part-time Professional Research Assistant (PRA), and a consultant/subcontractor based in Colorado Springs to advise on military recruitment. We held a Key Informant meeting at Colorado College with anthropological scholars studying the military. Dr. Renshaw implemented his pilot study and collected data on 150 subjects. (In the fourth quarter, from this data, we extracted a set of psychometrically sound items to discriminate levels of knowledge about PTSD, and a set of items to assess assumptions about the course of PTSD over time.) We continued to refine the full item pool for all five surveys, including distribution into the five surveys. This is an exacting process, as each of the five planned surveys is different and requires close attention regarding which measure will be assessed at which time point and under which contingency (e.g., if the couple breaks up) so that we (1) fulfill all study aims and (2) do not overburden participants. We finished the text and images for the project website. We also made progress on many important administrative tasks necessary for the project, such as applying for budget office approval for our system of gift card payments for participants and procurement card access to accomplish this for our project manager.

We proposed in our initial scope of work timeline that we would begin administering surveys in January 2013; however, various stages of the study development have taken longer than anticipated. This included significant measure consideration and development with input from the literature, research team, key informants, and actual pilot research this quarter at George Mason University. Whereas this delayed the finalization of the item pool, we believe that the final item pool is much stronger and reflects cutting edge conceptualizations of the aims. We were also slightly delayed by COMIRB processing; it required 3 months to approve the project, despite only minor revisions requested. A more realistic survey rollout date is late April 2013.

Key milestones this quarter:

- **FY12, Yr1Q3, 11-09-2012:** Held a Key Informant meeting in Colorado Springs, CO.
- **FY12, Yr1Q3, 11-14-2012:** Hiring plan and scope of work documents for Colorado Springs consultant/subcontractor approved by UCD Human Resources and the Procurement Services Center. Consultant hired.
- **FY12, Yr1 Q3, 12-01-2012:** Hiring plan for our part-time Professional Research Assistant (PRA) position approved by UCD human resources. PRA hired.
- **FY12, Yr1Q3, 12-14-2012:** Obtained COMIRB approval for the study (11/1/12 submitted a detailed response and revisions, 11/7/13 PI attended COMIRB full board review meeting, 12/4/12 resubmitted COMIRB request for minor modifications).
- **FY12, Yr1 Q3, 12-20-2012:** Submitted protocol and necessary attachments to HRPO for approval (i.e., full protocol, consent form, recruitment ads, website content, and full item pool).

IV. Fourth Quarter (January 1, 2013 – March 2, 2013)

Meetings between the PI and our consultant familiar with local military populations led the PI to expand recruitment to a national level in order to fulfill our proposed recruitment goal. We applied for a Certificate of Confidentiality (COC) through NIH/NIMH, which is currently under review. We received feedback from USAMRMC's HRPO on 2/26/13, where the reviewer determined that we were in compliance with all applicable federal, DOD, and USAMRMC human subjects protection regulations. As updates had been made to measures, consent form, etc., we submitted all of our revised documents to COMIRB to review and approve these updates (this happened 3/8/12 just after the end of this quarter; approval obtained 4/1/13; now resubmitting to HRPO for final approval). Once HRPO and COC approval are finalized, we will have full approval to begin our recruitment. Measures have been finalized, and we continue to build and test the infrastructure for our survey launch (e.g., surveys being built and tested in Qualtrics, templates for all participant communications being built and automated, tracking databases

built). Additional undergraduate RA volunteers have been proofing and testing the recruitment and screening system and the surveys. The PI has held phone and email meetings with Amber Shryer (Grants/Contracts Officer's Representative) and Robert Doan (USAMRAA Grants Specialist) to maintain active communication with grant officer representatives.

Key milestones this quarter:

- **FY13, Yr1 Q4, 01-26-2013:** Undergraduate RAs completed the CITI Human Subjects research training, as well as the Social and Behavioral research courses online.
- **FY13, Yr1 Q4, 02-07-2013:** Completed the Certificate of Confidentiality application and received feedback from the COC coordinator; minor revisions were requested and necessary revisions were made; currently under review.
- **FY13, Yr1 Q4, 02-11-2013: FY13, Yr1 Q4, 02-26-2013:** Received confirmation that HRPO determined that the project complied with all applicable federal, DOD, and USAMRMC human subjects protection regulations. Preparations have been made to submit all of our revised documents to our local IRB to review and approve. Upon IRB approval, we will route the stamped documents back to HRPO for final review.
- **FY13, Yr1 Q4, 02-27-2013:** Project manager and PI completed all fiscal compliance training and authorization with the University to enable participant payments.

Key Research Accomplishments

Below are our key accomplishments, organized by task category and then quarter. Task categories 7 (executing online surveys) and 8 (analysis and dissemination) are not listed since they are contingent on data collection, which has not yet begun. Upon receiving all of the necessary approvals from COMIRB, HRPO, and COC, we anticipate that our recruitment and survey launch date will occur late April 2013.

Table 1. Hiring and orientation of project staff, purchasing and installing equipment.

First Quarter	• Two graduate research assistants (GRAs) formally contracted, completed CITI Human Subjects and Social/Behavioral Research trainings. • Computer access and phone lines set up.
Second Quarter	• Replacement GRA completed CITI Human Subjects and Social/Behavioral Research trainings.
Third Quarter	• Hiring plan approved and hirings completed for Professional Research Assistant (PRA) and consultant. • PRA completed CITI Human Subjects and Social/Behavioral Research trainings.
Fourth Quarter	• Two volunteer, undergraduate research assistants (RAs) brought onto the project; RAs completed CITI Human Subjects and Social/Behavioral Research trainings. • Project fully staffed.

Table 2. Finalizing the initial item pool.

First Quarter	• Measure identification and development begun with work from PI, GRAs, co-investigators, and scholar colleagues.
Second Quarter	• Ongoing measure identification and development. • Full draft of the survey measure item pool completed and submitted to IRB. (This item pool to be refined and the finalized set of measures submitted to IRB as an addendum.)
Third Quarter	• Ongoing measure identification, refinement, and development. Additional insights into novel items and constructs to consider measuring occurred after Key Informant meeting (held in Colorado Springs, CO). • Level of review from co-investigators has included (a) optimal measures to achieve aims while keeping respondent burden manageable, (b) close review of measures per

	- time point and partner to achieve planned analyses such as HLM with dyads, (c) final development of novel measures needed to fill gaps. - Revised item pool submitted to COMIRB and approved 12/14/12.
Fourth Quarter	- In consultation with all study investigators, survey measures approved and allocated for each time point, gender, and contingency (e.g., leaving army, break-up, etc.). - Item pool finalized for surveys 1 and 2. Very close to finalized for surveys 3, 4, and 5, pending some development for unique contingencies which could occur later in time for the sample such as re-deployment. These will be submitted as amendments when developed.

Table 3. Creating IRB applications, obtaining initial IRB approval, and maintaining compliance.

First Quarter	- Documented the PI and GRA's completed human subjects training. - PI and GRAs developed initial IRB applications (i.e., protocol, consent form, etc.) using subcomponents of the proposal and guidelines provided by COMIRB, TATRC. - Compiled pre-review packet for TATRC regulatory compliance specialist to review. - PI in regular contact with GRAs and TATRC regulatory compliance specialist to monitor progress of the applications and perform revisions as needed.
Second Quarter	- Received pre-review feedback from TATRC regulatory compliance specialist; study team attended to all comments and received additional consultation on military verification methods. - Collaborating researcher, Dr. Renshaw, received IRB approval at George Mason University to test a measure that our study plans to use. - Finalized application documents submitted to COMIRB.
Third Quarter	- Documented the PRA's completed human subjects training. - PI met with IRB to discuss protocol and address any questions. - Received initial response of minor modifications; study team attended to all comments and suggestions provided by COMIRB, and re-submitted the protocol for full board review in December. - COMIRB approval obtained 12/14/12. - Submission for USAMRMC HRPO review sent 12/20/12.
Fourth Quarter	- Documented the RAs' completed human subjects training. - Application for Certificate of Confidentiality (COC) completed. - PI maintained active communication via email and phone with HRPO reviewer. - HRPO found project compliant with all applicable federal, DOD, and USAMRMC human subjects protection regulations. - COC and HRPO review suggested minor changes. Moreover, materials and measures had continued to be refined. Preparations made to submit all of our revised documents to our local IRB to review and approve (<i>submission occurred just after quarter on 3/8/2013</i>). Upon IRB approval (<i>occurred after quarter on 4/1/2013, no changes requested</i>), we will route the documents back to HRPO for final review and approval.

Table 4. Finalizing surveys for Phase 1 and Phase 2.

First Quarter	See tasks completed in category 2 (finalizing initial item pool)
Second Quarter	Starting process of entering skip logic, prompts, and questions into Qualtrics (online survey provider).
Third Quarter	- Study team continues to build survey in Qualtrics, including planning for complex logic patterns. - PI, collaborating researchers, and consultants working to distribute items across

	surveys based on time point and gender; careful attention being paid to the fulfillment of aims, abilities to conduct model testing, and respondent burden.
Fourth Quarter	• Study team continues to plan and build surveys in Qualtrics. Surveys built with complete variable names, variable labels, and variable values to allow for instant download into complete SPSS database. • Eligibility survey completed and piloted with RAs to ensure proper working condition. Errors identified and fixed. • PI, collaborating researchers, and consultants finishing the survey measures revisions and allocation for each time point, gender, and contingency (e.g., leaving army, children vs. no children, break-up, etc.). • PI and statistical consultant ensure measures appear at appropriate time points and presentations conducive to hypothesis model testing.

Table 5. Developing and maintaining study materials and infrastructure.

First Quarter	• Planning database systems to track participants • GRA developing and compiling text to include on the study website.
Second Quarter	• Online resource and citation library created and made accessible to all project team members using Mendeley. • Purchased Qualtrics survey provider and completed trainings to begin survey measure entry • Purchased website domain name and website development tools. • Project manager building and updating website. • PI and project manager are working within UCD rules and regulations to develop specific participant payment procedures. • Military verification procedures being developed by GRA. • Developing email drafts that will be sent to participants for range of study contingencies (e.g., invites, reminders, non-eligible for study).
Third Quarter	• Continuing to update our online resource and citation library via Mendeley. • Purchased all images to be used on our website and recruitment materials. • Project manager finalized content and graphics for website. • PI and project manager continue to create participant payment procedures and apply for relevant fiscal roles and approvals within the university. • GRA, PRA, and consultant developing the specific military verification procedures.
Fourth Quarter	• PI and project manager complete all applications, trainings, and authorizations for fiscal roles within the University. • Full draft of all participant communications (e.g., invites, reminders, non-eligible for study) completed and ready for review. • PRA, GRA, and RAs have been extensively proofing the eligibility survey and entering the survey measures into our survey host. • Excel databases developed for participant tracking and payment tracking,

Table 6. Recruitment.

First Quarter	• Recruitment materials, such as sample text for advertisements, newspapers, banner ads, and flyers, created for our pre-review. • Started drafts of standardized emails associated with recruitment.
Second Quarter	• Recruitment materials received pre-review approval from TATRC. • Compiling necessary paperwork to hire a consultant familiar with military culture to support recruitment efforts.
Third Quarter	• Recruitment images selected and purchased. • Recruitment materials received and approved by COMIRB. • Hired a consultant/subcontractor from Colorado Springs who is familiar with local

	military to advise recruitment efforts.
Fourth Quarter	• PRA expanding recruitment efforts to a national level to ensure adequate recruitment. Protocol revised to accommodate this and increased internet advertising and media pieces; revision prepared to submit to COMIRB. • Plans for a piece on SpouseBuzz regarding the study discussed with site manager.

Reportable Outcomes

Due to the early stage of the study, reportables such as manuscripts, abstracts, and presentations are not yet present. Of reportable outcomes, the main one is employment or research opportunities received based on experience/training supported by this grant.

- We have provided training and experience to three compensated Graduate Students and one Professional Research Assistant (currently an undergraduate at the University of Colorado Denver).
- We have provided training and experience to three volunteer undergraduate Research Assistants.
- We have subcontracts with four co-investigators and three consultants.

Conclusions

This report highlights the progress and accomplishments during the first year of funding (March 2, 2012 to March 1, 2013) for the study: “Relationship Factors Contributing to the Progression of Combat Related PTSD and Suicidality Over Time” (publically known as the Relationships Among Military Personnel [RAMP] Project). In the past year we have been able to utilize our time and resources effectively, as we have hired an entire core study team (principal investigator, project manager, graduate research assistants, professional research assistant) and put into place formal contracts for collaborating researchers and consultants to contribute to the project. The study team has created and revised protocol documents throughout the year as it has progressed through various levels of review, including a pre-review with a TATRC regulatory compliance specialist, an initial COMIRB review, a review of materials to obtain a Certificate of Confidentiality, and a review by HRPO. The study team has worked diligently to attend to details on the project, including the careful input and internal pilot testing of survey item flow and logic, setting up mechanisms to track participant surveys and compensation, and designing a functional, user-friendly website in preparation for the official survey launch. As this is a longitudinal study, the study team has also been mindful of the way survey measures are allocated across time points and contingencies (e.g., gender, leaving the army, children vs. no children, break-ups) to maximize the PI’s ability to utilize appropriate statistical modeling to test hypotheses. By taking the time to carefully plan for cutting edge assessment across all five surveys, we have built the foundation to extract the maximum yield from this study design.

We look forward to Year 2 on this project. COMIRB approval of all amendments was received 4/1/2013, and we will submit the revised approved materials to HRPO within a few days for final review. After we attend to any necessary feedback and receive approval from HRPO and COC, we plan to officially launch the study. Advertising will begin, directing all interested parties to our website. Our study website will be live, and will educate interested parties about the study and direct them to a screening survey. The screening survey will have an informed consent procedure and automatically screen out nonconsenting and most ineligible persons. The remaining pool will be further screened by our study team for military verification and dyadic enrollment (both members of the couple screened and consented). Couples will then be invited to complete the initial survey until we reach a total of approximately 600 couples. Of these, approximately 270 couples will then be invited to complete 4 additional surveys spaced six months apart. We feel prepared going into Year 2 to execute this study, and look forward to providing our funders with updates on the project.

References N/A

Appendices N/A