Development of the
Deployment Risk and Resilience Inventory (DRRI)
VA Form 10-21087
OMB 2900-XXXX

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify legal or administrative requirements that necessitate the collection of information.

A recent Program Announcement for the Department of Defense (DoD) Post-Traumatic Stress Disorder (PTSD) Investigator-Initiated Research Award, noted a critical need for the development, improvement, and/or validation of measures for screening, detection, and diagnosis related to PTSD. This project is directly responsive to this research gap by creating and implementing scales that can be used to assess deployment-related factors with documented implications for PTSD and other mental health problems. Specifically, the primary objectives of the proposed program of study are to create Deployment Risk and Resilience Inventory (DRRI) scales, VA form 10-21087, in a sample of Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) veterans and to develop abbreviated scales for use in both research and clinical endeavors. The long-term goal of this project is to provide a suite of scales that will be optimally useful to researchers and clinicians interested in studying factors that increase or reduce risk for PTSD and other health problems. Given the breadth of the warfare experiences of the most contemporary cohort of OEF/OIF veterans, as well as the diverse nature of military personnel who have participated in this conflict (e.g., many more women and National Guard/Reservist personnel), this sample provides an ideal context within which to conduct development and implementation of the DRRI.

This project is also responsive to the recent Health Services Research and Development (HSR&D) Service Deployment Health solicitation for studies that can test the reliability and validity of previously developed instruments and measures within the newest deployment cohort, as well as the broader recognition of the importance of accurate assessment of deployment experiences as a precursor to the treatment of returning veterans of the Iraq and Afghanistan War, as reflected in the Iraq War Clinician Guide (Litz & Orsillo, 2004). Furthermore, consistent with the HSR&D Deployment Health Solicitation's call for attention to "how female and male deployment health concerns differ" and "how family separation, social support, and coping issues vary across National Guard, Reserve, and Active Duty forces," a secondary objective of this project is to evaluate differences in deployment risk and resilience factors and health outcomes for men and women and for veterans deployed from Regular Active Duty versus National Guard/Reservist units.

Legal authority for this data collection is found under 38 USC, Part I, Chapter 5, Section 527 that authorizes the collection of data that will allow measurement and evaluation of the Department of Veterans Affairs Programs, the goal of which is improved health care for veterans.

2. Indicate how, by whom, and for what purposes the information is to be used; indicate actual use the agency has made of the information received from current collection.

This project is responsive to identified research priorities within VA and DoD. This work will build on a recently funded project (by VA HSR&D) to create DRRI scales using information derived from focus groups with OEF/OIF veterans who are VA patients. The upcoming study (and focus of the current request) represents a natural extension of this work by administering DRRI scales to a national sample of OEF/OIF veterans. This will allow delivery of a more refined, validated, and broadly applicable product for potential use by other researchers and policy-makers. Objectives for this study are to: (a) administer

DRRI scales to a national sample of OEF/OIF veterans; (b) analyze resultant data; (c) finalize the survey instrument; and (d) prepare materials for presentation and publication.

The project will provide information to assist military leaders to better prepare personnel for future deployments and DOD and VHA health-care policy-makers and practitioners to plan and implement more effective prevention and treatment programs. The major product, a risk and resilience assessment device, will be a standard tool for use by other researchers (psychosocial, biomedical, or otherwise) and a prototype measure of psychosocial features of future deployments.

The information will also be used to publish articles that will increase the knowledge base about the physical and mental health status and needs of OEF/OIF service members. The researchers will disseminate the findings to organizations with interest in active duty service members and in mental health among veterans. These organizations will include the Department of Defense, the Office of Seamless Transition, Veterans Health Administration (VHA) Quality Enhancement Research Initiative programs, the National Center for Post-Traumatic Stress Disorder, and the VHA Mental Illness, Research, Education and Clinical Care Centers.

The information will be provided through reports, presentations at national conferences, and publications in scientific peer-reviewed journals. It will also be provided to VHA clinical mental health service managers, clinical program leaders, and administrators and policy makers. Several VHA medical centers are interested in developing appropriate programs to address the mental health needs of the post-deployed population. This data collection will assist those efforts.

No use has yet been made of this information because there is no current collection of these data.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g. permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

This project involves a survey which will be administered in a mailed paper-and-pencil format. No information will be collected through automated, electronic, mechanical, or other technological means. Conducting the survey electronically would mean that military personnel without access to computers or the Internet would be excluded from the study and preclude the ability to randomly sample a representative population of veterans.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

The information that will be collected is not readily available and cannot be obtained in any way other than by self-report. Given that the Principal Investigator (PI) on this project is an author of the DRRI, there is confidence that these scales have not been validated in other work.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

No small businesses or other small entities are impacted by this information collection.

6. Describe the consequences to Federal program or policy activities if the collection is not conducted or is conducted less frequently as well as any technical or legal obstacles to reducing burden.

This data collection activity will occur one time only (and will involve administering two versions of the data collection instrument to two separate samples of participants). Data will be collected on OEF/OIF service members to obtain information about risk, resilience, and physical and mental health. This activity will allow the VHA to be responsive to a very important population of veterans and to develop interventions that will meet their needs. VHA would not be able to be as responsive to the needs of this population of patients if the data collection is not conducted.

7. Explain any special circumstances that would cause an information collection to be conducted more often than quarterly or require respondents to prepare written responses to a collection of information in fewer than 30 days after receipt of it; submit more than an original and two copies of any document; retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years; in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study and require the use of a statistical data classification that has not been reviewed and approved by OMB.

There are no such special circumstances.

8. a. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the sponsor's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the sponsor in responses to these comments. Specifically address comments received on cost and hour burden.

The notice of Proposed Information Collection Activity was published in the Federal Register on May 14, 2008 (Volume 73, Number 94, Page 27896-27897). No comments have been received in response to this notice.

b. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, clarity of instructions and recordkeeping, disclosure or reporting format, and on the data elements to be recorded, disclosed or reported. Explain any circumstances which preclude consultation every three years with representatives of those from whom information is to be obtained.

To determine the data elements to be developed and collected, the investigators consulted with researchers within the VHA and the DoD. In addition to conducting a thorough review of all documents, both those distributed by the Federal Government and those published in the scientific literature, the Principal Investigator and research team have engaged in lengthy discussions with other researchers and experts on what data elements are needed regarding psychosocial risk and resiliency factors and how these data elements should be queried. Although DoD does some screening of post-deployed service members, they are not using the comprehensive standardized measures proposed for use in this research study. Consequently, these data are not available from any other source. Outside consultation will be conducted with the public through the 60- and 30-day Federal Register notices.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

All potential study participants will receive a small token of appreciation in the amount of $30 in the first mailing of the survey. The decision to include this token is a response to the finding that response rates are better when incentives are used. High response rates are important to ensure the generalizability of study results.

10. Describe any assurance of **confidentiality provided to respondents and the basis for the assurance in statue, regulation, or agency policy.**

Participants will be assured that all data will be kept confidential and that no identifying information will be used in any dissemination activities. Study participants will review an information sheet that contains all the elements of an informed consent form. Participants are not required to complete any portion of the consent page. Completion of the survey implies consent. All data collection procedures will be approved by the Institutional Review Board (IRB) at the VA Boston Healthcare System.

11. Provide additional justification for any questions of a sensitive nature (Information that, with a reasonable degree of medical certainty, is likely to have a serious adverse effect on an individual's mental or physical health if revealed to him or her), such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private; include specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

The data collection instrument does not include questions that would be likely to have a serious adverse effect on an individual's mental or physical health. There are some questions that may be sensitive or elicit emotional responses for particular individuals. This includes items from the DRRI scales: Sexual and General Harassment; Combat Experiences; and Aftermath of Battle. Additionally, some items on the Post-traumatic Stress Disorder questionnaire administered to participants in the second wave of data collection(Deployment Experiences – Part II) collection, may be sensitive for certain individuals. Although there will be some sensitive questions, individuals are aware of these issues if they apply to them and will be electing to reveal the information. In addition, in order to understand risk and resilience factors for post-deployment veterans, these data are crucial. As described previously, a number of safeguards have been put in place to protect the privacy and confidentiality of participants. In addition to these strategies, respondents are provided the opportunity to meet with the clinical contact, Dr. Jeff Knight (a licensed and trained Clinical Psychologist who specializes in the treatment of trauma) if they should become distressed. Finally, information will not be obtained from anyone other than the survey respondent.

12. Estimate of the hour burden of the collection of information:

Before data collection begins, pre-notification letters will be sent to all randomly selected potential participants to inform them about the study, with an “opt-out” postcard included if they choose not to participate. The survey will be conducted only with those service members who do not opt out; individuals who choose to return the “opt-out” postcard will have no further contact from us.

In addition, data collection has been split into two waves to minimize the number of items each participant is asked to complete. Only half of the sample (n = 750), that which is required to ensure adequate power for hypothesis testing, will be asked to complete a subset of DRRI items and all health measures. The other half of the sample (n = 750) will not complete the health scales, with the exception of a brief measure of Posttraumatic Stress Disorder, but will be asked to complete both all DRRI items to allow for an examination of incremental validity . Although some DRRI items may appear similar, it is important to administer all of them to establish the consequences of changes to the DRRI. Given an

estimate that participants can complete 7-10 items per minute, the total time to complete the first survey section, Deployment Experiences (Part I) (all DRRI items, PTSD, and demographics only) is estimated at 50 minutes; the total time to complete the second survey, Deployment Experiences (Part II) (subset of DRRI items, all health outcome measures, and demographics) is estimated at approximately 1 hour; For non-participants who complete the opt-out postcard, the estimated time to complete the postcard is estimated at less than 1 minute. The estimated time to complete cognitive testing for the 29 individuals who will participate in this activity is 60 minutes.

The estimated total burden hours is 1412.

750 respondents x 50 min. per respondent / 60 = 625 annual respondent hours
750 respondents x 60 min. per respondent / 60 = 750 annual respondent hours
29 respondents x 60 min. per respondent / 60 = 29 annual respondent hours
Up to 500 respondents x 1 min. per respondent / 60 = 8 annual respondent hours

b. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB 83-I.

This request covers only one form.

c. Provide estimates of annual cost to respondents for the hour burdens for collections of information. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14 of the OMB 83-I.

Because respondents are reimbursed for their time, there will be no cost to them. The research project manager will keep records of completed questionnaires and payments to participants.

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).

There will be no costs to respondents or record keepers.

14. Provide estimates of annual cost to the Federal Government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operation expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

The estimated total budget for the two years of this study, including all staff time, equipment, and other expenses, is $569,600. This averages $284,800 in each of the two years. However, this includes the cost of the entire national survey including collection and analysis of survey data, reporting of results, dissemination of results, etc.

15. Explain the reason for any burden hour changes since the last submission.

This is a new collection and all burden hours are considered a program increase.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule

for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

This study will involve the administration of DRRI scales, as well as measures to assess PTSD and other health problems and potential confounders. Additional measures are included for the purpose of examining discriminant and criterion-related validity, as well as conducting secondary analyses to address substantive questions about relationships between deployment risk and resilience factors and measures of physical and mental health. With respect to criterion-related validity analyses, the primary hypothesis asserts that multiple dimensions of risk and resilience will be associated with PTSD and other health measures, such that OEF/OIF veterans who report greater exposure to risk factors (e.g., combat exposure) and less access to resilience factors (e.g., post-deployment social support) will endorse more symptoms of PTSD and other mental and physical health problems. Secondary analyses will involve examining evidence for validity separately for men and women and for Active Duty and National Guard/Reservists to explore the extent to which scales perform similarly for these key military subgroups.

Both Classical Test Theory (CTT) and Item Response Theory (IRT) analyses will be conducted to inform the psychometric evaluation of DRRI scales and the development of abbreviated item scales. CTT analyses will employ the Statistical Package for the Social Sciences (SPSS); IRT analyses will be conducted using the BILOG-MG or MULTILOG statistical software, as appropriate. Based on Gulf War I samples and Co-I Dr. Jennifer Vasterling's more recent research with OEF/OIF veterans, it is not expected that missing data will result in the loss of more than 5% of the sample in the current study. If missing data does exceed 5%, a single imputation will be computed using the Expectation-Maximization (EM) algorithm to generate a complete dataset for subsequent CTT and IRT analyses, as recommended by Graham, Cumsille, and Elek-Fisk (2003). As these authors note, multiple imputation procedures are unnecessary for the calculation of item characteristics.

The frequencies of distribution and probabilities of endorsement for each DRRI item will be examined to confirm the quality of selected items, and internal consistency reliability estimates for each finalized scale will be computed. The next examination will be associations between scores on DRRI- II scales and measures of social desirability and negative affectivity to examine discriminant validity. It is not anticipated that associations will be significant. However, if associations are significant, social desirability and negative affectivity will be controlled for in subsequent analyses.

To evaluate Hypothesis 1 (which posits main effects of risk and resilience factors on PTSD and other health measures), and to provide critical evidence for the criterion-related validity of DRRI scales, bivariate correlations will be calculated between each of the DRRI scales and scores on PTSD and associated health problems. To account for any multicollinearity among deployment risk and resilience factors within deployment timeframes, this set of analyses will be followed by simultaneous regression analyses in which each of the health measures is regressed on each sets of pre-deployment, deployment, and post-deployment risk and resilience factors, in turn. Consistent with prior work (Vogt et al., 2005), deployment factors will be split into two separate sets of mission-related and interpersonal stressors, and analyses will be conducted separately for these two sets of variables. For example, one analysis will involve regressing the measure of PTSD, the PCL, on the set of mission-related factors. If necessary to control for possible self-report bias, negative affectivity and social desirability will be entered into each regression equation prior to the entry of risk and resilience factors. Significant partial regression coefficients (serving as estimates of effect size) will provide evidence for the unique predictive validity of each of the deployment factors in accounting for scores on PTSD and other health problems.

A final set of hierarchical regressions will be conducted to account for any multicollinearity across deployment timeframes. For these analyses, significant pre-deployment, deployment, and post-deployment predictors from the previous set of analyses will be entered into a series of regression analyses predicting

each of the health measures, in turn. For each health measure, the set of significant pre-deployment factors will be entered first, followed by the set of significant deployment factors, and then by the set of significant post-deployment factors (preceded by measures of self-report bias if necessary). To the extent that each set of variables is determined to account for significant variance in the outcome, partial regression coefficients will be examined for each predictor. Secondary analyses will involve examining results separately for men and women and for Active Duty versus National Guard/Reservists to explore the extent to which scales perform similarly for these key military subgroups. These data will also be used to address secondary research questions of interest to the research team.

Confirmatory IRT analyses will next be conducted on the DRRI scales and this information will be used to identify two final sets of abbreviated items for each of the DRRI scales following recommended procedures in the literature (Embretson & Reise, 2000; Hambleton et al., 1991). Item information functions will again be generated for preliminary abbreviated scales. A final subset of approximately ten items for each DRRI construct that is best suited for research purposes and for clinical screening purposes will be identified.

Data collection will begin after the sample is obtained from Defense Manpower Data Center (DMDC). Approval has been obtained to draw a sample of OEF/OIF veterans from DMDC, which maintains automated files of military personnel with the necessary demographic information on gender and Active Duty versus National Guard/Reservist status to support the study. Importantly, this recruitment technique will allow contact with potential participants as private citizens rather than through their units while they are "on-duty."

Figure 1.	**Year 1**				**Year 2**			
Activity	Jul-Sep 2009	Oct-Dec 2009	Jan-Mar 2010	Apr-Jun 2010	Jul-Sep 2010	Oct-Dec 2011	Jan-Mar 2012	Apr-Jun 2012
Pre-investigation Tasks								
Recruit and hire research assistants	X							
Seek IRB approval for study	X							
Convene planning meetings with co-investigators	X							
Confer with project consultants	X							
Finalize survey instrument for study	X							
PHASE I								
Prepare survey materials for multi-stage data collection to N = 1154		X						
Create survey tracking program		X						
Develop data management system		X						
Coordinate with DMDC to select sample		X						
Secure veteran list from DMDC			X					
Multi-stage survey administration – Phase I			X					
Data entry – Phase I			X					
Compute initial item and scale properties				X				
Compute initial item response theory analyses				X				
Refine scales as needed				X				

PHASE II								
Prepare survey materials for N = 1154					X			
Multi-stage survey administration – Phase II					X			
Data entry – Part II					X			
Conduct final psychometric analyses on full scales						X		
Compute final item response theory analyses						X		
Confer with project consultants						X		
Develop abbreviated scales						X		
Finalize all scales							X	
Prepare conference presentations							X	X
Prepare manuscripts for publication							X	X
Develop manual to accompany DRRI and abbreviated scales								X

17. If seeking approval to omit the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

There are no requests for approval to omit the expiration date for the OMB approval of the information collection.

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB 83-I.

There are no exceptions.