SUMMARY STATEMENT

PROGRAM CONTACT: **(Privileged Communication)** ***Release Date:*** **02/19/2014**

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Application Number: **1 R21 MH102570-01A1**

Principal Investigators (Listed Alphabetically):
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Applicant Organization: COLUMBIA UNIVERSITY HEALTH SCIENCES

Review Group: **BGES**
Behavioral Genetics and Epidemiology Study Section

Meeting Date: **02/03/2014** ***RFA/PA:*** **PA13-303**
Council: **MAY 2014** ***PCC:*** **AD-TS**
Requested Start: **07/01/2014**

Project Title: **Posttraumatic Stress Disorder and Cognitive Decline in Women**

SRG Action: **Impact Score: 20 Percentile: 5 +**
Next Steps: **Visit http://grants.nih.gov/grants/next_steps.htm**
Human Subjects: **44-Human subjects involved - SRG concerns**
Animal Subjects: **10-No live vertebrate animals involved for competing appl.**
Gender: **2A-Only women, scientifically acceptable**
Minority: **1A-Minorities and non-minorities, scientifically acceptable**
Children: **3A-No children included, scientifically acceptable**
Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1	150,000	263,792
2	125,000	219,827
TOTAL	275,000	483,619

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1R21MH102570-01A1 KOENEN, KARESTAN

PROTECTION OF HUMAN SUBJECTS UNACCEPTABLE

RESUME AND SUMMARY OF DISCUSSION: The effect of posttraumatic stress disorder (PTSD) and its associated dysregulated stress response on subsequent cognitive health, independent of depression, will be evaluated in middle-aged women using a brief computerized cognitive battery to assess current cognitive function and to obtain preliminary data on rates of cognitive decline, with evaluation of specific elements influencing the association as potentially modifiable mediators of PTSD-related cognitive change. The effect of PTSD on cognitive aging is an important but poorly understood issue that the proposed research will address. There are many positive aspects of the study design, including novel use of online testing in a non-clinical population that has extensive prior information about PTSD in a cohort that has been followed longitudinally. In this resubmission, the investigators have decisively and effectively addressed most of the concerns raised in the previous review. There is confidence that the online cognitive test battery will be effective. The potential for comorbid depression to affect cognitive performance will be addressed explicitly. The follow-up time span of 18 months remains an issue as being too short to investigate change in this relatively young group, since cognitive decline over 18 months has been demonstrated primarily in an older sample, but reviewers recognized that even the short period could lay important groundwork for a more comprehensive future study with a longer time span. Limited representation of minorities remains an issue for generalizability but is an unavoidable consequence of using longitudinal data from an existing cohort that was representative of the original target population of registered nurses. This exceptionally strong study with essentially no remaining weaknesses will have a high impact on characterizing the effect of PTSD on cognitive performance and change and understanding the mechanisms underlying this effect.

DESCRIPTION (provided by applicant): Posttraumatic stress disorder (PTSD) is a pervasive and debilitating mental disorder in the U.S. population and particularly common among women: 1 in 9 women will meet criteria for the diagnosis during their lives. PTSD is the sentinel stress-related mental disorder and is characterized by hypothalamic-pituitary-adrenal axis and neuroendocrine dysregulation; animal models and human correlational studies have linked such dysregulation in the HPA axis and neuroendocrine function to alterations in multiple cognitive processes, brain structure, and function. However, questions remain as to whether PTSD and its associated dysregulated stress response produce cognitive decrements as extant studies report conflicting results. Understanding the relation of PTSD and cognitive health -- including elements influencing an association, such as duration and intensity of symptoms and mechanisms underlying an association, such as sleep quality, health status, cardiovascular disease -- could inform interventions aimed at mitigating any risks PTSD may pose for cognitive health. We propose to examine PTSD and subsequent cognitive function within 54,282 women age 48-65 years from the Nurses' Health Study II, who are part of a sub-cohort followed since 1989 with detailed data on PTSD. Women are currently age 48-65 years. Our primary aim is to evaluate if PTSD, independent of depression, is associated with worse cognition in middle-aged women and to collect preliminary data on cognitive change. In accomplishing this aim, we will utilize a brief, validated, computerized cognitive battery (CogState), allowing highly efficient data collection in these computer-savvy nurses. As a secondary aim we will evaluate specific elements of any relation of PTSD to cognition, including factors acting as mediators and effect modifiers, which could be targeted for interventions. Prior work on PTSD and cognition has focused on small samples from specific populations, such as Holocaust survivors or larger samples of primarily male military personnel or veterans. This application represents a unique opportunity to begin to leverage a large, existing cohort of women to understand the larger scope of effects of PTSD in the broader-based population - at very modest cost. Women's risk of PTSD is twice that of men' risk and, therefore, understanding the impact of PTSD on cognition in women of great public health importance. Finally, in addition to directly addressing our Aims, we will generate important data for planning future research on PTSD, and other areas of interest as well; for example, preliminary data on rates of cognitive change in this age group

will allow us to appropriately design prospective studies of the mechanisms driving the relation between PTSD and cognition, including other health, mental health and lifestyle variables.

PUBLIC HEALTH RELEVANCE: Posttraumatic stress disorder (PTSD) is a pervasive and debilitating mental disorder in the U.S. population and particularly common among women: 1 in 9 women will meet criteria for the diagnosis during their lives. The overall goal of this proposal is to examine whether PTSD is associated with decrements is cognitive function in middle-aged women and to identify modifiable mechanisms underlying the association. The results of this study will inform research, policy and practice by identifying malleable and robust risk factors for PTSD-related cognitive decrements and will inform interventions aimed halting cognitive decline in women with PTSD.

CRITIQUE 1:

Significance: 3
Investigator(s): 2
Innovation: 2
Approach: 3
Environment: 1

Overall Impact: PTSD is a relatively frequent “stress disorder” which is not yet fully understood. Females are at higher risk for PTSD, with lifetime prevalence being 1 in 9 women. The proposed study, based on a large sample (over 50,000 nurses) with rich prior longitudinal data on PTSD, aims to evaluate whether PTSD, while controlling for depression, is associated with worse cognitive performance in middle-aged women. Results would help shed light on the effect of PTSD on cognitive performance, and will generate important data for planning future research on PTSD. Preliminary data on rates of cognitive change in this age group will help inform and design prospective studies of mechanisms driving the relation between PTSD and cognition. Results could “inform research, policy and practice by identifying malleable and robust risk factors for PTSD-related cognitive decrements” that could lead to effective interventions to reduce or halt cognitive decline in women.

1. Significance:
Strengths

- PTSD is a relatively frequent “stress disorder,” and is more prevalent in women (over 10%). Its effects on cognitive aging are not well understood, and the proposed study (and subsequent R01) aims to fill this important gap in the literature.
- Building on an existing longitudinal study with extensive prior data on PTSD, the proposed study will provide important preliminary data on cognitive decline in middle-aged women, which will help inform and design future prospective studies.
- Identifying malleable risk factors for PTSD-related cognitive decline will help inform future interventions.

Weaknesses

- None noted.

2. Investigator(s):
Strengths

- The contact Multiple Principal Investigator (Koenen) is a highly productive researcher, a licensed developmental psychologist and epidemiologist with considerable expertise in PTSD.
- The non-contact Multiple Principal Investigator (Grodstein) has been leading research on cognitive function in the Nurses’ Health Study for over 15 years.

Weaknesses

- Although they have been colleagues on the Nurses' Health Study for many years, the two Multiple Principal Investigators do not appear to have listed any joint publications. Nonetheless, the research team is well qualified to conduct this research.

3. Innovation:
Strengths

- Prospective study of cognitive decline in a population-based cohort of women with extensive prior longitudinal data.
- Use of computerized tests of cognitive performance is relatively rare, and provides an efficient way to conduct this large-scale research.

Weaknesses

- None noted.

4. Approach:
Strengths

- Large sample with rich prior longitudinal data: 54,282 women (age 48-65) from Nurses' Health Study II, who have been followed since 1989 and have detailed data on PTSD.
- Use of validated, computerized cognitive battery to assess cognitive performance via the internet.
- In response to reviewer concerns about comorbid depression, aims were revised to include depression as a covariate to control for this.

Weaknesses

- Causal effects of PTSD on cognitive decline cannot be unequivocally established using this design. Those more prone to cognitive decline in the first place might be more vulnerable to stress reactions. Given the impossibility of manipulations, however, these prospective longitudinal data can help illuminate the associations between PTSD and cognitive decline while statistically controlling for various confounding variables.
- One minor concern is whether the inclusion of depression as a covariate might actually overcorrect any potential cognitive decline, since depression might actually be the result of PTSD in some cases. It would seem preferable to use depression PRIOR to PTSD onset as the covariate, or look separately at PTSD with and without depression.
- It would also seem feasible to test for the effects of depression on cognitive decline, independently of PTSD. Such analyses could presumably be done.
- The comorbidity between depression and PTSD is not specified in the application.

5. Environment:
Strengths

- Excellent environment at both Columbia University as well as Brigham and Women's Hospital (where Nurses' Health Study is housed).

Weaknesses

- None noted.

Protections for Human Subjects:
Acceptable Risks and/or Adequate Protections

- no concerns

Inclusion of Women, Minorities and Children:
G2A - Only Women, Acceptable
M1A - Minority and Non-minority, Acceptable
C3A - No Children Included, Acceptable

Vertebrate Animals:
Not Applicable (No Vertebrate Animals)

Biohazards:
Not Applicable (No Biohazards)

Resubmission:

- The application was highly responsive to previous criticisms, and the resubmitted application is strengthened. Previous criticisms and responses are as follows:
- 1. Limited depth of cognitive assessment, especially verbal ability, which might compromise the sensitivity for detecting longitudinal cognitive change. The resubmitted application provides more details on CogState including its validity and sensitivity to changes in memory and learning in studies of dementia, providing a strong argument for the utility of this instrument for assessing cognitive decline.
- 2. Inadequate handling of correlated measures in analyses. The resubmitted application describes new and more sophisticated analyses based on SEM with latent variables; LGM also added.
- 3. Short duration of follow-up. Details now provided on sensitivity of CogState to detect changes over a 12 month period; will be administer 4 times over 18 months, with excellent power to detect differences in slope of decline (n>23,000 with 4 time points)
- 4. Sample bias, attrition. Added analyses to evaluate attrition (differences between responders and non-responders); will now use raw ML in order to make use of all data; and will use censored weights in regression models.
- 5. Potential confounding effects of comorbid depression. Aims revised to include depression (measured on multiple occasions in NHSII), including DEP as another latent variable and treat as covariate. One concern is whether this adequately addresses this issue, as it might overcorrect any possible decline, since DEP might be a RESULT of PTSD in many cases (see above notes under Approach).

Budget and Period of Support:
Recommend as Requested

CRITIQUE 2:

Significance: 1
Investigator(s): 1
Innovation: 2
Approach: 2
Environment: 1

Overall Impact: Posttraumatic stress disorder (PTSD) is a potentially debilitating disorder that afflicts over 10% of women over their lifetime. As it is essentially a stress related disorder and as chronic stress can impose cognitive impairment, it is logical to ask whether PTSD is associated with greater cognitive decline than in unaffected persons. The study will target PTSD and cognitive function among 54,282 women aged 48-65 years from a sub-cohort of the Nurses' Health Study 2 (NHSII), with detailed data on PTSD (3,750 women with PTSD are eligible; N= > 30,000 women without PTSD who are exposed or not exposed to trauma). Primarily, the study will compare current cognitive function and, secondarily, rates of cognitive decline over an 18-month follow-up in the NHSII sample. It will also analyze whether related factors such as age of onset, or health behaviors (e.g., BMI, smoking) mediate

the relation of PTSD to cognition. The study addresses important questions in a non-clinic based sample. It uses novel internet based cognitive testing that obviates the need for onerous in person cognitive tests. Based on the preliminary work, it has a high level of feasibility. Important cross-sectional data will be generated. The contact Principal Investigator is a well-qualified, productive individual. She has addressed most of the concerns raised in the previous review. Remaining concerns diminishing enthusiasm include the relatively short follow-up period (4 evaluations over 18 months) and to a lesser extent, the relatively low minority representation in the sample, thus reducing generalizability.

1. Significance:
Strengths
- Important question with substantial clinical impact.
- Identification of mediating factors in secondary aim could enable therapeutic interventions.

Weaknesses
- None noted.

2. Investigator(s):
Strengths
- Contact Multiple Principal Investigator Koenen has published widely on PTSD.
- Multiple Principal Investigator Grodstein is an expert in cognitive assessments.

Weaknesses
- None noted.

3. Innovation:
Strengths
- Novel question relating cognitive decline to PTSD
- Non-clinic based sample.
- Use of internet based questionnaires to assess cognitive function.

Weaknesses
- None noted.

4. Approach:
Strengths
- Analytic plan has been revised. Plan to use structural equation modeling (SEM) to create a single cognitive function latent variable defined by scores on the four CogState tasks from the first assessment. A PTSD latent variable will be defined by dichotomous indicators from the PTSD questionnaire. SEM will also enable analysis of key variables such as depression.
- Plan to evaluate cognitive function at four time points.
- Using conservative estimates, sample has 90% power to detect mean differences of <5% in cognitive function for each of the CogState tasks.

Weaknesses
- Relatively short follow up. Clinical experience suggests that decline over 18 months is unlikely to be substantial in a non-dementing illness.
- Study will not investigate women at the same stage of their illness. It is unclear whether cognitive decline, if it occurs is linear over the course of the illness.

5. Environment:
Strengths
- Excellent facilities for all aspects of the proposed work.

Weaknesses
- None noted.

Protections for Human Subjects:
Unacceptable Risks and/or Inadequate Protections

- The study addresses and important health related question. Efforts will be made to maximize confidentiality. CogState, the company administering the web-based cognitive evaluations will only have access to participant ages, because investigators will provide a separate ID to the company. However, it is stated that "Consent will be implied when participants choose to complete the computerized cognitive battery." It is unclear whether such "passive" consent is acceptable. This point needs to be clarified.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):
Acceptable

- Though not required, a DSMP will be in place.

Inclusion of Women, Minorities and Children:
G2A - Only Women, Acceptable
M1A - Minority and Non-minority, Acceptable
C3A - No Children Included, Acceptable

- The study is based on an ongoing longitudinal cohort, so its inclusion criteria are limited by the characteristics of that study. The NHS II cohort is relatively under-represented with regard to minorities, limiting its generalizability. As it is a nurses' cohort, no children were recruited. This is acceptable.

Vertebrate Animals:
Not Applicable (No Vertebrate Animals)

Biohazards:
Not Applicable (No Biohazards)

Resubmission:

- The prior review had cast doubts on the limited scope of the CogTest, questioned the relatively low anticipated response rate, queried analysis of co-morbid depression and substance abuse, and expressed concerns on the relatively brief follow up period and the under-representation of minorities. All concerns barring the last two have been addressed.

Budget and Period of Support:
Recommend as Requested

CRITIQUE 3:

Significance: 2
Investigator(s): 1
Innovation: 2
Approach: 3
Environment: 1

Overall Impact: While there is strong evidence for the development of cognitive decline associated with individuals diagnosed with PTSD, there are very few longitudinal studies of women with PTSD. Yet women have about double the incidence of PTSD. The present application proposes to address the underrepresentation of women in longitudinal studies of PTSD by taking advantage of the Nurses' Health Study II, which in addition to being very large has already amassed a wealth of important risk factor data and a very strong participation rate among the subjects. The brief computerized cognitive

assessment battery is a strength in that it is a brief and seemingly simple battery of test with mostly good psychometric properties, At the same time, it has weaknesses, in that it does not assess a wide range of cognitive functions and some areas left out are strong predictors of cognitive decline that might be important to include. The age of the sample too has both strengths and weaknesses. For a study seeking to identify risk factors for cognitive decline, it is desirable to measure potential risk factors at relatively early ages and this a clear strength of using the NHSII sample, but the cited study notwithstanding (focusing as it does on notably older subjects), it is not clear if the assessment will be able to identify cognitive decline over a relatively short period in a middle aged sample.

1. Significance:

Strengths

- There is good evidence for cognitive decline in PTSD, but relatively few longitudinal studies of women with the PTSD, despite a two-fold increased risk for the disorder among woman compared with men. The project is focused on this understudied group and could ultimately lead to identifying risk factors associated with cognitive decline in women with PTSD.

Weaknesses

- None noted.

2. Investigator(s):

Strengths

- This is a Multiple Principal Investigator project, and in combination they have the extensive experience and expertise required in this area.
- Dr. Rentz has experience with the computerized neuropsychology battery to be used. Dr. Sumner, a post-doctoral fellow and co-Investigator on the research team, too has appropriate experience for this project.

Weaknesses

- None noted.

3. Innovation:

Strengths

- It is moderately innovative to conduct a population-based study of cognition in women with PTSD.
- Also innovative, as well as economical, is the use of the Nurses' Health Study II sample, a large, important, and well-established longitudinal study of women.

Weaknesses

- None noted.

4. Approach:

Strengths

- The use of a large and well characterized population-based sample is far superior to studies that rely on smaller, clinic-based samples, which are far less representative of most women with PTSD.
- The application shows good evidence that the NHSII sample has been highly responsive to research, providing a basis for confidence that there will be relatively low subject attrition.
- A strength of this study is the availability of not only PTSD and no trauma groups, but a large number of trauma exposed women without PTSD as an additional comparison group.
- The NHSII cohort has a wealth of valuable information pertaining to health risk behaviors, the presence of medical conditions, and anthropometric measures.

Weaknesses

- Although the 48-65 age range of the sample is provided, no statistics are provided regarding the age distribution. This is an important consideration in a study of longitudinal cognitive decline. A

continuing concern is the extent of cognitive decline that will be observed in this still relatively young group.

- Related to the above concern is the stress given to the study by Darby et al., which found a small group (13 of 263 subjects) who showed greater than expected cognitive decline in a 12 month period using the CogState battery. In the four (of the 13) directly assessed with a follow up medical evaluation, none was found to have cognitive functioning outside normal limits, although three showed “excess accumulation of cortical amyloid on PET-amyloid imaging.” However, age range for the Darby et al. sample was age 50 to 86, and the mean age of the sample was 65 (SD=7). Thus the *average* age of subjects in the Darby sample was at that upper limit of the age range of the present sample.
- Working memory is included, but a direct measure of delayed recall would have been desirable as this has frequently been found to be a good early predictor of cognitive decline.

5. Environment:
Strengths

- Outstanding.

Weaknesses

- No concerns.

Protections for Human Subjects:
Acceptable Risks and/or Adequate Protections

- No concerns.

Inclusion of Women, Minorities and Children:
G2A - Only Women, Acceptable
M1A - Minority and Non-minority, Acceptable
C3A - No Children Included, Acceptable

- The NHSII sample includes minorities but the number included in the sample is very small. Given the use of this valuable and economical sample, this is the sample that the investigators have to work with.

Vertebrate Animals:
Not Applicable (No Vertebrate Animals)

Biohazards:
Not Applicable (No Biohazards)

Resubmission:

- The application states that revisions are indicated by a line on the left margin but no such lines were evident.
- The application addresses the relevance of the cognitive battery to other cognitive tests, but does not directly respond to the issue raised about the absence of an assessment of verbal ability.

Budget and Period of Support:
Recommend as Requested

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): UNACCEPTABLE
Upon discussion, reviewers expressed concern about lack of consent for the cognitive assessment, with implied consent that is assumed to be given when participants begin the online assessment instrument. Reviewers would prefer a more explicit informed consent even if it is something as simple and straightforward as a consent document to read online, with advancement to the assessment instrument after the participant reads it and clicks on an “agree” button.

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

+ Derived from the range of percentile values calculated for the study section that reviewed this application.

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-10-080 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-080.html.
The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

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Population Sciences and Epidemiology Integrated Review Group
CENTER FOR SCIENTIFIC REVIEW
BGES
February 03, 2014

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* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.