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**TITLE: Enrichment of Data Collection for the Boston Biorepository and Integrative Network for GWI: The Non-Exclusionary Wave (NEW BBRAIN) Cohort**

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**CONTRACTING ORGANIZATION: Boston University Medical Campus, Boston, MA**

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| <b>14. ABSTRACT</b><br>The primary objective of NEW BBRAIN is to develop a new cohort of 200 Gulf War veterans who have GWI chronic symptoms but would otherwise be excluded from GWI studies based on exclusionary medical and psychiatric conditions. This will be the "NEW BBRAIN" cohort and will be combined into the repository with the two existing BRAIN cohorts of the Principal Investigator's ongoing study (Boston Biorepository, Recruitment and Integrative Network ("BBRAIN"); GW170055; Principal Investigator: Sullivan). This prospective study will seek to collect data on up to 200 participants using a combination of in-person data collection and participant at-home procedures. Data collection will consist of neuropsychological testing, questionnaires, blood draw, saliva sampling, brief neurological examination, and home collection of urine and stool samples, and sleep quality and heart rate sampling through use of a Fitbit device. To date, we have begun enrollment and data collection of the first 16 study participants. We have also completed resurveys of 48 prior BBRAIN study participants. |                                    |                                     |                                 |                                   |                            |  |  |  |
| <b>15. SUBJECT TERMS</b><br>Gulf War Illness, Biorepository, consortium, CNS, innate immunity, cytokines, pesticides, DFP, sarin   |                                    |                                     |                                 |                                   |                            |  |  |  |
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**1. INTRODUCTION:**

The primary objective of NEW BBRAIN is to develop a new cohort of 200 Gulf War veterans who have GWI chronic symptoms but would otherwise be excluded from GWI studies based on exclusionary medical and psychiatric conditions. This is the “NEW BBRAIN” cohort and will be combined into the repository with the two existing BBRAIN cohorts of the Principal Investigator’s ongoing study Boston Biorepository, Recruitment and Integrative Network (BBRAIN) GW170055; Principal Investigator: Sullivan. This NEW BBRAIN prospective study seeks to collect data on up to 200 participants using a combination of in-person data collection and participant at-home procedures. Data collection consists of neuropsychological testing, questionnaires, blood draw, saliva sampling, neuropsychological examination, home collection of urine and stool samples, and sleep quality and heart rate sampling through use of a Fitbit device. There is also an online resurvey of prior BBRAIN participants planned for this study.

**2. KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Gulf War Illness, Biorepository Network, GW veterans, biomarkers

**3. ACCOMPLISHMENTS:**

**Major goals of the project.**

The approved statement of work lists the major goals of the project and the timeline for achieving each goal:

**Statement of Work: NEW BBRAIN Protocol**

| Tasks  | Timeline | Status  |
|--|----------|---------|
| <b>Major Task 1: Obtain IRB/OHRO approval</b>  | Months   |         |
| 1a: Submit new protocol application or amendments to the BU, NSU, Baylor College of Medicine and SFVA IRB committees   | 1-4      | X       |
| 1b. Submit OHRO approval for all study sites   | 4-5      | X       |
| Milestone Achieved: Regulatory reviews completed, IRB, and OHRO approval obtained  | 5        | X       |
| <b>Major Task 2: Preparation and Training for Clinical Study Procedures</b>  | Months   |         |
| 2a. BEDAC will create data collection forms, specimen tracking system and databases for NEW BBRAIN cohort to merge with BBRAIN infrastructure  | 1-5      | X       |
| 2b. Develop/update manuals for the neurological evaluation, smell test, cognitive testing, specimen collection protocols and recruitment screening procedures  | 1-5      | X       |
| 2c. Train researchers and staff on protocols and quality control measures for the clinical study and repository collection   | 1-5      | X       |
| Milestone (s) Achieved: Staff trained and all data bases and websites ready for subject recruitment and specimen tracking  | 5        | X       |
| <b>Major Task 3: Screening, Recruit, and assessment of GW veterans for the NEW BBRAIN cohort</b>   | Months   |         |
| 3a: Obtain informed consent from potentially eligible GW veterans  | 5-24     | Ongoing |
| 3b. Assess subjects by obtaining demographics, medical history, self-report questionnaires, neurological exam, smell test, neuropsychological testing, Fitbit tracker, blood draw and saliva samples from 200 study participants | 5-24     | Ongoing |

|  |        |         |
|--|--------|---------|
| 3c. Obtain participants urine and stool sample kits back by mail to BUSPH for biorepository storage  | 5-24   | Ongoing |
| 3d. Upload Fitbit sleep, heart rate variability, and blood pressure data to BUSPH BEDAC to merge with our datasets   | 5-24   | Ongoing |
| 3e. Score neuropsychological tests and upload summary data to BEDAC for entry, cleaning and analysis   | 5-24   | Ongoing |
| 3f. Send blood and saliva samples to Nova University for analysis of cytokine and chemokine panels and cortisol measurements and biorepository banking   | 5-24   | Ongoing |
| Milestone(s) Achieved: Obtained blood saliva, urine, stool, autonomic, demographic and cognitive data from 200 NEW BBRAIN participants for biorepository and analysis  | 24     | Ongoing |
| <b>Major Task 4: Resurvey all BBRAIN and NEW BBRAIN study participants</b>   | Months |         |
| 4a: Implement online chronic health conditions re-survey   | 5-24   | X       |
| 4b. Coordinate data cleaning and analyze information from NEW BBRAIN cohort to compare to existing BBRAIN groups   | 20-24  |         |
| <b>Major Task 5: Process, Store and Manage samples for a total of 200 new participants</b>   | Months |         |
| 5a. Process and store blood, saliva, urine and stool samples obtained at Boston recruitment site at two biorepository sites (NSU, BUSPH)   | 5-22   | Ongoing |
| 5b. Perform local laboratory analyses (CBC) for 200 participants   | 5-22   | Ongoing |
| 5c. Extract DNA and RNA from 500 saliva samples and store in repository  | 5-22   | Ongoing |
| 5d. Run batched assays for cortisol and cytokine results (18 plex cytokine assay)  | 5-22   |         |
| 5e. Provide sample request forms and tracking information regarding the use of samples   | 5-24   |         |
| 5f. Ship samples to requesting investigators   | 5-24   |         |
| Milestone(s) Achieved: Processed all newly collected NEW BBRIAN cohort samples into biorepository storage, ran cytokine and cortisol measurements, extracted DNA/RNA for repository  | 24     |         |
| <b>Major Task 6: Merge Data and Perform Interim Data Analyses</b>  | Months |         |
| 6a. Merge New BBRAIN data with ongoing BBRAIN study data for cognitive, demographic and health symptom report outcomes   | 5-24   |         |
| 6b. Discussion of results and reparation of abstracts for meeting presentations and initial manuscripts for publication  | 18-24  |         |
| 6c. Determine new case GWI criteria exclusions   | 20-24  |         |
| 6d. Annual reports of progress will be written   | 12-24  |         |
| Milestone(s) Achieved: Preliminary analysis of results and presentation of initial results at scientific meetings and potential publication. Possible changes to GWI criteria exclusions and early markers of neurodegeneration form analyses. | 24     |         |
| <b>Major Task 7: Perform Final Analysis, Prepare Manuscripts for Preparation and Finalize NEW BBRAIN Biorepository cohort for Sharing Samples</b>  | Months |         |
| 7a. Write annual and final reports   | 12-24  |         |
| 7b. Prepare manuscripts for publication  | 22-24  |         |
| Milestone(s) Achieved: Final Analyses completed and NEW BBRIAN samples and data available for sharing from the BBRAIN repository.  | 24     |         |

The statement of work for year 1 is inclusive of tasks 1-5 above. Major tasks 1 and 2 have been completed as all IRB and OHRO approval has been fulfilled. In addition, study staff members have been trained and databases have been prepared for in-person subject enrollment. Major task 3 has begun with recruitment of previously ineligible veterans and newly interested GW veterans. The NEW BBRAIN protocol has been implemented and completed on 16 participants to date. Participants have given blood, saliva, stool, and urine samples to be stored in the BBRAIN repository as outlined in major task 5. Participants have also completed surveys and

neuropsychological assessments. Major task 4 has been initiated with 48 BBRAIN participants completing the follow-up survey to date.

**Summary of NEW BBRAIN Clinical Assessments at the Boston Site**

|                                 | Year 1 |    |    |    | Year 2 |     |     |     |
|---------------------------------|--------|----|----|----|--------|-----|-----|-----|
| Target Enrollment (per quarter) | Q1     | Q2 | Q3 | Q4 | Q1     | Q2  | Q3  | Q4  |
| Boston (NEW BBRAIN)             |        |    | 30 | 30 | 35     | 35  | 35  | 35  |
| Target Enrollment (cumulative)  |        |    | 30 | 60 | 95     | 130 | 165 | 200 |

**Summary of NEW BBRAIN Online Surveys at all 4 study sites**

|                                 | Year 1 |    |    |    | Year 2 |     |     |     |
|---------------------------------|--------|----|----|----|--------|-----|-----|-----|
| Target Enrollment (per quarter) | Q1     | Q2 | Q3 | Q4 | Q1     | Q2  | Q3  | Q4  |
| Boston                          |        |    | 30 | 30 | 85     | 85  | 85  | 85  |
| Miami                           |        |    |    |    | 25     | 25  | 25  | 25  |
| Houston                         |        |    |    |    | 25     | 25  | 25  | 25  |
| San Francisco                   |        |    |    |    | 25     | 25  | 25  | 25  |
| Target Enrollment (cumulative)  |        |    | 30 | 60 | 220    | 380 | 540 | 700 |

**Accomplished under these goals:**

**TASK 1. OBTAIN IRB/OHRO APPROVAL (MONTHS 1-5)**

Institutional Review Board (IRB) approval and OHRO for Boston University has been obtained for new study protocol as well as the re-survey of existing BBRAIN participants. This included creating a new protocol with new exclusion/inclusion criteria for the study. Investigators from multiple study sites met to discuss and finalize new protocol details.

The San Francisco and NSU have obtained IRB approval for their re-survey of existing BBRAIN participants. Baylor University is submitting protocol of re-survey for Gulf War Illness Consortium participants to their IRB. OHRO approval has been obtained for all studies sites for the re-survey piece as well as for the in-person enrollment at Boston University.

**TASK 2: PREPARATION AND TRAINING FOR CLINICAL STUDY PROCEDURES (MONTHS 1-5)**

All milestones under this task have been completed. BEDAC has created and implemented a new REDCap project to collect data on in-person participants to be easily merged with already existing data from the BBRAIN study. They have also automated the process of re-surveying prior participants. Existing manuals were updated, and new manuals and standard operating procedures were created for added neuropsychological tests and re-survey piece. All research team members working on the protocol have been trained on tracking systems, data collection and study protocol.

**TAKS 3: SCREENING, RECRUIT, AND ASSESSMENT OF GW VETERANS FOR THE NEW BBRAIN COHORT (MONTHS 5-24)**

To date, 50 veterans have been screened for the NEW BBRAIN study. Of this, 16 participants have been enrolled and have completed the study protocol. 16 blood and saliva samples have been collected and shipped to Nova Southeastern University for storage in the BBRAIN repository. 16 stool and urine samples have been sent to BUSPH for storage in the biorepository. In addition, 16 health symptom surveys and neuropsychological test batteries have been collected into REDCap for the NEW BBRAIN cohort.

**Table 1. NEW BBRAIN Surveys**

| Name  | Description  |
|---|--|
| Demographics                                  | Subjects report information on age, education, gender, ethnicity, marital status, handedness, corrective lenses, hearing aid usage (SENSE), GW duty service (active vs. reserve/National Guard), military rank and current military status |
| SF36V   | Veterans' version of the SF36 which assesses functional health-related quality of life in 8 domains and provides overall summary scores for physical and mental health status.   |
| Kansas Gulf War and Health Questionnaire      | Queries veterans about demographics, military and deployment history, and chronic symptoms and diagnoses required to ascertain Kansas GWI and CMI case status.   |
| Medical Conditions                            | A checklist with 21 medical conditions that the subject is asked to rate if they have ever had the condition, how it was diagnosed (self or doctor) and when it was diagnosed.   |
| Current Medications list                      | A list of current medications which participants are taking listing the medication and what symptoms it is taken for.  |
| Profile of Mood States (POMS)                 | The POMS is a self-report assessment of current mood. The indicators of importance are current fatigue, confusion, tension and depression.   |
| 3 Question DVVIC TBI screening tool           | A 3 question screening for deployment related TBI causes and symptoms from the Defense and Veterans Brain Injury Center.   |
| American Academy of Neurology mTBI guidelines | Questions are asked regarding history of mild TBI (mTBI) during three time periods (before, during, after GW) and number of mTBIs.   |
| Kansas Gulf War Experiences and exposures     | A questionnaire that assesses veteran-reported experiences and exposures during their deployment to the 1991 Gulf War.   |

|   |   |
|---|---|
| Structured Neurotoxicant Assessment Checklist (SNAC)      | The SNAC assesses the degree of past and current exposure to neurotoxicants during civilian and military occupations and includes questions pertaining to recent occupational and environmental         |
| Pittsburg Sleep Quality Index (PSQI)                      | PSQI assesses sleep quality during the past month. It covers domains of sleep quality, latency, duration, efficiency, disturbances, medications and daytime dysfunction. Total global scores range from |
| Multidimensional Fatigue Inventory Questionnaire (MFI-20) | 20 item self-report fatigue instrument that covers general fatigue, physical fatigue, mental fatigue, reduced motivation and reduced activity.  |
| McGill Pain Questionnaire                                 | A pain questionnaire that includes 3 sections including what the pain feels like, change over time and strength of pain. Scores range from 0-   |
| Every day Cognition Scale                                 | A self-report survey measuring aspects of everyday cognition related to memory, language, visuospatial and executive functioning.   |
| Brief Pain Inventory (BPI) short form                     | The BPI is a brief 9 question self-report survey of severity, location and impact of pain on daily functioning.   |
| Visual Analog Pain and Fatigue Scales                     | Participants measure their pain and fatigue by drawing a vertical line on a horizontal scale from 'not at all' to 'worst pain or fatigue ever'.   |
| Fatigue Severity Scale                                    | A brief survey where statements of fatigue affecting daily activities is endorsed on a scale from 1 to 7 for disagree to completely agree.  |
| PTSD Checklist for DSM-5 (PCL-5)                          | A 20-item self-report measure that assesses the 20 <i>DSM-5</i> symptoms of PTSD. It screens and provides a provisional PTSD diagnosis.   |
| Center for Epidemiologic Studies Depression Scale (CES-D) | A 20-item scale which measures depressive feelings and behaviors during the past week. Provides a depression quotient.  |
| COVID-19 Questionnaire                                    | A 6 item questionnaire where the subject is asked to provide information on prior positive tests of COVID-19 and COVID-19   |

**Table 2. NEW BBRAIN Neuropsychological Tests**

| Test Name                                     | Description   | Outcome Measure  |
|---|---|--|
| <b>I. Executive System Functioning</b>        |   |  |
| Controlled Oral Word Association Test (COWAT) | Spontaneous generation of words from letters F, A and S and animals   | Total correct words generated                                      |
| D-KEFS Category switching                     | Number of correct words generated switching between two categories  | Total number of words<br>Total number of correct category switches |
| D-KEFS Color-Word Interference Test (Stroop)  | The Stroop is a test that measures the ability to inhibit competing responses in the presence of salient conflicting information. This ability can be called response inhibition, or behavioral inhibition. Secondly, the test also measures processing speed of verbal (words) | Total Errors<br>Self-corrected errors<br>Uncorrected errors        |
| D-KEFS Category switching                     | Number of correct words generated switching between two categories  | Total number of words<br>Total number of correct category switches |

| <b>II. Tests of Attention, Vigilance and Tracking</b>             |   |   |
|---|---|---|
| Trail-making Test<br>(Reitan & Wolfson, 1985)                     | Timed connect-a-dot task to assess attention and motor control requiring sequencing (A).  | Time to Completion<br>Self-Corrected errors<br>Uncorrected errors |
| Continuous Performance Test<br>(Connors' CPT3)                    | Target letter embedded in series of distractors; to assess sustained attention and reaction time.                                       | Reaction Time, Total Omission and Commission Errors               |
| <b>III. Tests of Motor Function</b>                               |   |   |
| Finger Tap Test   | Continuous tapping key with alternate hands; assesses simple motor speed.   | Number of taps  |
| Grooved Pegboard Test   | Placing grooved pegs into a small pegboard; assesses fine motor skills  | Number of correct pegs  |
| <b>IV. Tests of Visuospatial Function</b>                         |   |   |
| Rey-Osterrieth Complex Figure Test                                | Copy of a complex figure  | Total correct out of 36   |
| <b>V. Tests of Memory</b>   |   |   |
| California Verbal Learning Test<br>(CVLT- II; Delis et al., 2000) | List of 16 nouns from 4 categories presented over multiple learning trials with recall after interference; assesses memory and learning | Total Trials 1-5<br>Long Delay                                    |
| Rey-Osterrieth Complex Figure Test                                | Immediate and delayed recall of a complex figure  | Total recall out of 36  |
| <b>VI. Tests of Motivation and General Intellectual Ability</b>   |   |   |
| CVLT – Forced Choice Recognition                                  | Forced choice of word pairs for each of the 16 target items.  | Total correct   |
| Wide-Range Achievement Test - Reading                             | Measures word reading skills and word decoding through letter identification and word recognition.                                      | Total Correct<br>Scaled Score                                     |

#### **TASK 4: RESURVEY ALL BBRAIN AND NEW BBRAIN STUDY PARTICIPANTS (MONTHS 5-24)**

Yearly surveys have been sent to all eligible BBRAIN participants who agreed to re-contact for future studies and participated over a year ago. Details of surveys administered are included in table 3. We worked with our data coordinating center, also known as BEDAC, to create and automate the process for distribution and reminders of the yearly surveys. So far, the survey has been sent to 100 participants and 48 participants have completed the re-survey.

**Table 3. NEW BBRAIN Re-survey of Prior BBRAIN participants**

| <b>Name</b> | <b>Description</b> |
|-------------|--------------------|
|             |                    |

|   |   |
|---|---|
| SF36V   | Veterans' version of the SF36 queries functional health-related quality of life in 8 domains and summary scores for physical and mental health status |
| Kansas Gulf War and Health Questionnaire                  | Demographics, military and deployment history, chronic symptoms and diagnoses required to ascertain Kansas GWI and CMI case status.                   |
| Medical Conditions  | Checklist with 21 medical conditions rated for having the condition, how it was diagnosed (self or doctor) and when diagnosed                         |
| Current Medications                                       | A checklist of current medications participants are taking and what symptoms they are addressing.   |
| Pittsburg Sleep Quality Index (PSQI)                      | Assess sleep quality during the past month. It covers sleep quality, latency, duration, efficiency, disturbances, medications and daytime dysfunction |
| Multidimensional Fatigue Inventory Questionnaire (MFI-20) | 20 item self-report fatigue instrument that covers general fatigue, physical fatigue, mental fatigue, reduced motivation and reduced activity         |
| McGill Pain Questionnaire                                 | A pain questionnaire that includes 3 sections including what the pain feels like, change over time and strength of pain                               |
| Everyday Cognition Scale                                  | A self-report survey measuring aspects of everyday cognition related to memory, language, visuospatial and executive functioning                      |
| Fatigue Severity Scale of Sleep                           | A brief survey where statements of fatigue affecting daily activities is endorsed on a scale from 1 to 7 for disagree to completely agree             |
| PTSD Checklist for DSM-5 (PCL-5)                          | A 20-item self-report measure that assesses the 20 DSM-5 symptoms of PTSD. It screens and provides a provisional PTSD diagnosis.                      |
| Center for Epidemiologic Studies Depression Scale (CES-D) | A 20-item scale that measures depressive feelings and behaviors during the past week. Provides a depression quotient.                                 |
| Covid-19 Questionnaire                                    | Questionnaire to collect information such as participants' COVID 19 vaccination status and history, and symptom/diagnosis history                     |

### **TASK 5: PROCESS, STORE AND MANAGE SAMPLES FOR A TOTAL OF 200 NEW PARTICIPANTS (MONTHS 5-24)**

Biological samples for the first 16 participants have been processed and stored according to the protocol. Saliva and blood samples have been sent to NSU and are currently being analyzed for cytokines. Urine and stool samples have been sent to BUSPH for storage and logged in the biorepository.

### **TASK 6: MERGE DATA AND PERFORM INTERIM DATA ANALYSIS (MONTHS 5-24)**

This task has begun with the merging of data from the first 16 participants to BBRAIN data. In addition, data from the re-surveys have been merged with BBRAIN data to create a longitudinal database of GW health symptoms.

### **Opportunities for training and professional development:**

#### **Research Staff Training:**

Personnel who will be using the web systems for either direct data capture, participant tracking, or viewing reports have been trained to ensure uniformity of procedures, to achieve the ultimate aim of ensuring high quality protocol implementation and data collection. As a large academic community, Boston University also provides

opportunities for students to get real world experience. The NEW BBRAIN and BBRAIN studies can tap into this talent pool by taking practicum and intern students in the fields of health communication and promotion. Doctoral students in related fields can also be brought on to aid in this project.

**How results will be disseminated to communities of interest:**

Research staff will use some of the outreach structure already in place from the BBRAIN cohort. The research group Facebook page has over 3,000 followers, many of whom regularly interact with and share page content. This allows researchers to freely spread information among the already existing GW network on social media. BBRAIN also has a study website that will be used to disseminate information to the community. Boston University also has a very proactive media team that produces text and video news stories that get widely shared. Research staff will also be aided by the Veteran Working Group in getting news out about the NEW BBRAIN to fellow veterans and their communities. As the research team has done for BBRAIN, they will write professional publications that state what samples are available and who to contact. Our team has also attended local veteran events where we have announced the launch of our study and disseminated research findings to the community. These events included the Massachusetts Women Veterans Network 2023 Conference and the 2023 Veterans Fair in Quincy, MA.

**Plan for upcoming reporting period to accomplish goals:**

In the next reporting period, we plan to:

- Continue to obtain NEW BBRAIN study specimens and data to include in the BBRAIN repository
- Continue recruitment for the NEW BBRAIN study of 180 more interested Gulf War veterans
- Continue to re-survey BBRAIN participants yearly

**4. IMPACT:**

The addition of this third group of 200 NEW BBRAIN study participants to the BBRAIN repository will also allow for richer hypothesis testing across the GWI field. It will increase the total BBRAIN cohort of repository samples to 700 that would be available to the wider GWI research community. The BBRAIN repository is the largest compilation of data and various biological samples of veterans with GWI and GW veteran controls to date. This repository is freely available to the GWI research community and has already resulted in multiple publications and funding for data-mining studies. This NEW BBRAIN cohort allows for the assessment and re-evaluation of the current GWI case-criteria in a unique cohort that provides not only health symptom data but also biomarkers of many affected body systems in GWI. This will allow the field to better understand the sickest of GW veterans and to characterize if some of these veterans are more at risk for accelerated aging related to their chronic GWI status and/or general age related changes. We will also determine if this third group called the NEW BBRAIN cohort is similar with regard to overall symptoms as the GWI cases or distinctly different in their symptom and biomarker outcomes (i.e. subgroups of specific risk outcomes). It will also help to determine what changes need to be made to the current case criteria exclusions for biomarker and treatment trials.

This study also allows for the creation of an online brief health follow up survey of all 700 BBRAIN participants. Collectively, this will help determine if BBRAIN participants are developing neurodegenerative or other chronic health outcomes over time. This could allow for early detection and treatment of chronic diseases in this vulnerable group of veterans and allow for a more-clear picture of the chronic health effects of GWI. This study will also engage veterans who have long been excluded from participating in research studies because they are ‘too ill’ to participate but who may be the most in need of targeted treatments.

**Impact on other disciplines**

*Nothing to report.*

**Impact on technology transfer**

*Nothing to report.*

**Impact on society beyond science and technology**

*Nothing to report.*

**5. CHANGES/PROBLEMS:**

*Nothing to report.*

**6. PRODUCTS:**

*Nothing to report.*

**7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

**Individuals that have worked on the project:**

|                         |  |   |
|-------------------------|--|---|
| Name: Kimberly Sullivan | Project Role:                          | <i>PI of NEW BBRAIN and Biorepository Network</i>   |
|                         | Researcher Identifier (e.g. ORCID ID): | <a href="https://orcid.org/0000-0001-7940-6123">https://orcid.org/0000-0001-7940-6123</a> |
|                         | Nearest person month worked:           | <i>12</i>   |

|                    |  |  |
|--------------------|--|--|
|                    | Contribution to Project:               | <i>Oversee the biorepository at BUSPH; oversee the recruitment and participation of NEW BBRAIN (200 participants); oversee data and sample coordination of all prospective and retrospective BBRAIN sites.</i> |
|                    | Funding Support:                       | <i>NEW BBRAIN Award, W81XWH-22-1-0398</i>  |
| Name: Nancy Klimas | Project Role                           | <i>Co-Investigator, PI of BBRAIN Miami Site</i>  |
|                    | Researcher Identifier (e.g. ORCID ID): | <a href="https://orcid.org/0000-0003-1459-3268">https://orcid.org/0000-0003-1459-3268</a>  |
|                    | Nearest person month worked:           | <i>12</i>  |
|                    | Contribution to Project:               | <i>Oversee the resource site at the Miami VA medical center; oversee re-survey of BBRAIN participants (100 participants).</i>  |
|                    | Funding Support:                       | <i>NEW BBRAIN Award, W81XWH-22-1-0398</i>  |
| Name: Lea Steele   | Project Role                           | <i>Co-Investigator, PI of Baylor University site</i>   |
|                    | Researcher Identifier (e.g. ORCID ID): |  |
|                    | Nearest person month worked:           | <i>12</i>  |
|                    | Contribution to Project:               | <i>Oversee resurveying GWIC participants from Houston (100 participants)</i>   |
|                    | Funding Support:                       | <i>NEW BBRAIN Award, W81XWH-22-1-0398</i>  |
| Name: Linda Chao   | Project Role                           | <i>Co-Investigator, PI of San Francisco VA Site</i>  |
|                    | Researcher Identifier (e.g. ORCID ID): | <a href="https://orcid.org/0000-0002-8593-2434">https://orcid.org/0000-0002-8593-2434</a>  |
|                    | Nearest person month worked:           | <i>12</i>  |
|                    | Contribution to Project:               | <i>Oversee BBRAIN site in San Francisco and re-survey all BBRAIN participants(100 participants);</i>   |
|                    | Funding Support:                       | <i>NEW BBRAIN Award, W81XWH-22-1-0398</i>  |

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

*Nothing to report.*

- **Other organizations serving as partners:**

*Nothing to report.*

## **8. SPECIAL REPORTING REQUIREMENTS**

- **COLLABORATIVE AWARDS:**  
*Nothing to report.*

## **9. APPENDICES:**

- *Appendix A.* Inclusion Enrollment Report

# PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

OMB Number: 0925-0001

Expiration Date: 3/31/2020

**\*Study Title (must be unique):** Enrichment of Data Collection for the Boston Biorepository and Integrative Network for GWI: The Non-Exclusionary Wave (NEW BBRAIN) Cohort

\* Delayed Onset Study?  Yes  No

*If study is not delayed onset, the following selections are required:*

|  |  |   |
|--|--|---|
| <b>Enrollment Type</b>                       | <input type="checkbox"/> Planned             | <input checked="" type="checkbox"/> Cumulative (Actual) |
| <b>Using an Existing Dataset or Resource</b> | <input checked="" type="checkbox"/> Yes      | <input type="checkbox"/> No                             |
| <b>Enrollment Location</b>                   | <input checked="" type="checkbox"/> Domestic | <input type="checkbox"/> Foreign                        |
| <b>Clinical Trial</b>                        | <input type="checkbox"/> Yes                 | <input checked="" type="checkbox"/> No                  |

**NIH-Defined Phase III Clinical Trial**  Yes  No

**Comments:** Participants from this study will be 1991 Gulf War veterans who were primarily male and caucasian but we will oversample as much as possible for women veterans and other ethnic groups. Sixteen study participants have been recruited in person to date.

| Racial Categories                         | Ethnic Categories      |           |                       |                    |          |                       |                                |          |                       | Total     |
|---|------------------------|-----------|-----------------------|--------------------|----------|-----------------------|--------------------------------|----------|-----------------------|-----------|
|   | Not Hispanic or Latino |           |                       | Hispanic or Latino |          |                       | Unknown/Not Reported Ethnicity |          |                       |           |
|   | Female                 | Male      | Unknown/ Not Reported | Female             | Male     | Unknown/ Not Reported | Female                         | Male     | Unknown/ Not Reported |           |
| American Indian/ Alaska Native            | 0                      | 0         | 0                     | 0                  | 0        | 0                     | 0                              | 0        | 0                     | 0         |
| Asian                                     | 0                      | 0         | 0                     | 0                  | 0        | 0                     | 0                              | 0        | 0                     | 0         |
| Native Hawaiian or Other Pacific Islander | 0                      | 0         | 0                     | 0                  | 0        | 0                     | 0                              | 0        | 0                     | 0         |
| Black or African American                 | 1                      | 0         | 0                     | 0                  | 0        | 0                     | 0                              | 0        | 0                     | 1         |
| White                                     | 5                      | 10        | 0                     | 0                  | 0        | 0                     | 0                              | 0        | 0                     | 15        |
| More than One Race                        | 0                      | 0         | 0                     | 0                  | 0        | 0                     | 0                              | 0        | 0                     | 0         |
| Unknown or Not Reported                   | 0                      | 0         | 0                     | 0                  | 0        | 0                     | 0                              | 0        | 0                     | 0         |
| <b>Total</b>                              | <b>6</b>               | <b>10</b> | <b>0</b>              | <b>0</b>           | <b>0</b> | <b>0</b>              | <b>0</b>                       | <b>0</b> | <b>0</b>              | <b>16</b> |