

Justification B
Longitudinal Investigation of Gender, Health and Trauma (LIGHT) Study
OMB FORM 2900-XXXX

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Provide a numerical estimate of the potential respondent universe and describe any sampling or other respondent selection method to be used. Data on the number of entities (e.g., households or persons) in the universe and the corresponding sample are to be provided in tabular format for the universe as a whole and for each strata. Indicate expected response rates. If this has been conducted previously include actual response rates achieved.

It is estimated that approximately 4,336,630 Veterans between the ages of 18-50 live in the United States as of September 30, 2016. We will be sampling a random section of these Veterans. We will oversample for women veterans, racial and ethnic minorities, veterans living in high crime areas, and rural veterans to ensure participation of these groups of Veterans. We will contact a sample of 14,000 Veterans (11,000 female and 3,000 male) between the ages of 18 and 50 obtained from VA DoD Identity Repository (VADIR), with the ultimate goal of achieving a baseline sample of ~4,000 Veterans (~3,000 female and ~1,000 male), which accounts for a 30% response rate and adjusts for potentially unusable or ineligible records (estimated at ~8%). The table below shows the population and sample of Veterans stratified by gender.

Samples of male and female OEF/OIF veterans

Male		Female	
Population	Sample	Population	Sample
3,562,883	3,000 (contacted)	773,746	11,000 (contacted)

The rationale for a target sample size of 4,000 (enrolled) is to enable us to detect differences on rarer *understudied* reproductive health outcomes impacted by violence such as infertility and negative birth outcomes.

- 2. Describe the procedures for the collection of information, including:**
- **Statistical methodology for stratification and sample selection**
 - **Estimation procedure**
 - **Degree of accuracy needed**
 - **Unusual problems requiring specialized sampling procedures**
 - **Any use of less frequent than annual data collection to reduce burden**

A sample of 14,000 Veterans (11,000 female and 3,000 male) between the ages of 18-50 will be obtained from the VA DoD Identity Repository (VADIR). Veterans with residency in high crime communities, racial and ethnic minority status, and residency in rural communities will be oversampled. A contracted research firm will check the accuracy of addresses and conduct the mailings on VA Boston’s behalf. VA Boston will establish a data use agreement with this vendor in order to ensure that the contracted research firm protects the identifying information at all stages, from initial transfer of the information to the completion of the last mailing. The contracted research firm will label each sent survey with a unique code that contains no identifying information. A list linking participant information with this code will be kept separate from all other participant data.

Our recruitment strategy will involve a modified Dillman Tailored Design Method (TDM; Dillman, D. A., Smyth, J. D., & Christian, L. M. (2009). *Internet, Mail, and Mixed Mode Survey: The Tailored Design Method*. Hoboken: NJ: John Wiley & Sons), which is based on social exchange theory to maximize survey response rates. We will make a series of contacts with individuals selected for study invitation using USPS mail. The methodology for data collection will be identical for Time 1, 2 and 3 of data collection. The recruitment strategy at each time point entails a total of three sequential mailings to recruit study participants from the drawn sample.

- **Stage 1:** Mail cover letter, study fact sheet, a Veteran resources handout, survey instrument, \$5 pre-incentive payment, postage-paid/pre-stamped reply envelope (for completed surveys), and an opt-out form participants can return to indicate if they are not interested in being contacted again, to each participant's address via USPS 1st Class Mail. Participants whom mail back a completed survey will receive an additional \$20 incentive mailed directly to their address.
- **Stage 2:** Mail reminder postcards via USPS 1st Class Mail 1.5 weeks after the initial mailing to all participants who have not returned their surveys or the opt-out form indicating that they are not interested in being contacted again.
- **Stage 3:** Occurring 1.5 weeks after Stage 2 contact, we will mail a second cover letter, informed consent fact sheet, a Veteran resources handout, survey, and postage-paid/pre-stamped reply envelope via USPS 1st Class Mail to participants who did not respond to Stage 1 and 2 contacts.

The initial invitation will contain an informed consent fact sheet, which describes the purpose of the research, assures the confidentiality of all responses, emphasizes the voluntary nature of participation, states the estimated time to complete the survey instrument, provides information on risks and benefits, and provides our Help Desk phone number. This letter will conform to standards for the protection of human subjects. An opt-out form will also be included in this mailing to allow potential participants to indicate that they do not wish to be contacted again. Consistent with evidence that incentives to all potential participants are more effective at enhancing response rates than reimbursement to only those participants who complete the study (Singer, E., Van Hoewyk, J., & Maher, M. P. (2000). *Experiments with Incentives in Telephone Surveys*. *Public Opinion Quarterly*, 64(2), 171-188), this initial mailing will also include an incentive in the amount of \$5 as a token of appreciation. Potential participants will be instructed that they may keep the incentive regardless of their decision to participate. Those that return the survey will receive an additional \$20 incentive. The invitation will also include a handout that describes national resources available to Veterans.

Data collection will take place over approximately 1 year and participants will be surveyed 3 times approximately 3 months apart.

Data entry will be overseen by contracted research firm. All data will be double entered and verified. Participants will be instructed not to place their names on their surveys. Responses in the database will be coded only with a participant identification number assigned by research firm; participant contact information for mailings will be stored separately from survey data and securely stored in password protected files.

3. Describe methods to maximize response rate and to deal with issues of non-response. The accuracy and reliability of information collected must be shown to be adequate for intended uses. For collections based on sampling, a special justification must be provided for any collection that will not yield "reliable" data that can be generalized to the universe studied.

Obtaining a good response rate is one of our highest priorities. We've taken a number of steps aimed at attaining the highest response rate possible. First, we are aware that survey length can influence participation. In constructing the survey, we have balanced the need to obtain information that will allow us to address our specific aims with the need to keep the survey as short as possible. We have eliminated items not central to research questions, will format the instrument to make it as easy to complete as possible, and included skip patterns to reduce respondent burden. (Edwards, P., Roberts, I., Clarke, M., DiGuseppi, C., Pratap, S., Wentz, R., Kwan, I. & Cooper, R. [2007] Methods to increase response rates to postal questionnaires. *Cochrane Database of Systematic Reviews*, 4.) To this end, males and females will receive different survey versions so that they only receive questions that are relevant to them. Second, an incentive of \$5 will be sent with the survey mailing at each time point with an additional \$20 awarded if they complete the survey. Sending an incentive has been shown to double the odds of response and sending an unconditional incentive (i.e., an incentive sent with the initial survey and not based on survey return) has been shown to increase the odds of response by 61% (Edwards et al, 2007). Third, the cover letter will be personalized with each respondent's name. This small gesture has been shown to increase the likelihood of response by 16% (Edwards et al, 2007). Fourth, as stated above in section 2, a reminder card and an additional survey will be sent to participants at each time point to give them multiple chances to participate. This is a widely used and accepted strategy, considered to be one of the most effective methods of increasing response to mail surveys (James, J.M. & Bolstein, R. [1990] The effect of monetary incentives and follow-up mailings on the response rate and response quality in mail surveys. *Public Opinion Quarterly*, 54, 346-361).

While data collection is occurring, there will be regular review and trouble shooting of the process by the research firm and study team, so that patterns and problems in mailings and response rates can be detected and quickly addressed. Weekly meetings will be held with the study management staff to discuss any problems that may arise related to non-response.

Because this study will be using random sampling to select participants from the population of interest and has minimal inclusion/exclusion criteria, our results will be generalizable to a large population of veterans. The major generalizability issue when conducting a mail survey is non-response bias – that is that those who do not respond to the survey differ from those who do respond. We address this issue by giving careful consideration to survey methodology prior to the start of the study, and ensuring that procedures are in place to obtain the highest response rate possible. Additionally, nonresponse bias weights will be applied in analyses to help ensure results are generalizable to the population originally contacted.

4. Describe any tests of procedures or methods to be undertaken. Testing is encouraged as an effective means of refining collections to minimize burden and improve utility. Tests must be approved if they call for answers to identical questions of 10 or more individuals.

The survey instrument will be administered to a small number of individuals prior to the formal initiation of data collection; refinements then can be made as needed. This pilot testing of the questionnaire will involve 9 or fewer participants.

5. Provide the name and telephone number of individuals consulted on statistical aspects of the design and the name of the agency unit, contractor(s), grantee(s), or other person(s) who will actually collect and/or analyze the information for the agency.

All decisions about statistical aspects of the design were made by the Principal Investigators, Dr. Tara Galovski, PhD (857-364-4129), Director of the Women's Health Sciences Division of the NCPTSD (NCPTSD-WHSD) at VA Boston Healthcare System and Yael Nillni, PhD (857-364-4637), Clinical

Research Psychologist in the NCTPSD-WHSD at VA Boston Healthcare System. Both of these investigators have experience conducting large-scale studies, including statistical design and analyses.