

Office of Research and Development
Health Services Research and Development Service
Program Announcement
Request for Concept Papers to Evaluate TBI Screening Instruments and
Processes for Clinical Follow-up

1. Purpose: VA's Office of Research and Development Health Services Research and Development Service seeks concept papers for Service Directed Research (SDR) projects examining the quality, usefulness, and potential improvement of VA's screen for Traumatic Brain Injury (TBI). This research is needed to inform policy and practice involving the instrument used to screen all Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) veterans, the processes used for clinical follow-up, clinical co-morbidity (particularly psychiatric), and clinical outcomes. Epidemiology researchers and researchers with experience constructing and evaluating questionnaires are particularly encouraged to apply, even if they have no prior TBI related experience.

Because of the importance of research results derived from this program announcement to inform current VHA clinical practice, projects that propose secondary analyses and that utilize national or regional data are preferred (refer to "Background/Rationale" section, below). The maximum project duration is 24 months. Studies that propose primary data collection (combined with or independent of secondary data analyses) will be considered, but the feasibility of completing such projects within 24 months must be carefully supported.

Concept papers invited on issues related to the evaluation of TBI screening instruments include, but are not limited to:

- a. Evaluation of results of TBI screening among returning veterans, including variations in screening results related to timing and site of screening, veteran and other factors.
- b. Evaluation of the psychometric properties of the current VA TBI screen, including but not limited to its reliability, validity, sensitivity, and specificity, and predictive value. Studies that identify approaches to improve the TBI screening protocol as well as those that investigate the relationships between TBI and psychiatric symptoms and disorders are of particular interest.
- c. Evaluation of clinical assessment strategies following a positive or negative screen and variation in assessment strategies at the regional, facility, and practice level; examination of factors at the patient, provider, and facility level that are associated with variation in assessment strategies.
- d. Identification and evaluation of methods to improve follow-up assessment strategies for patients with positive and negative screening results, which should take into consideration the existence of co-occurring psychiatric conditions, including but not limited to PTSD.
- e. Description and analysis of the relationships between VA TBI screen elements and specific clinical pathways and practice patterns, accounting for the impact of co-occurring psychiatric conditions and other relevant factors.
- f. Description and analysis of the key characteristics and salient differences between veterans who have been screened and those who have not been screened.

2. Background/Rationale: TBI is a common form of injury in service men and women serving in OEF/OIF. As experience with this condition in OEF/OIF veterans accumulated, it became clear that screening for possible TBI in OEF/OIF veterans could contribute to ensuring that cases are identified and treatment implemented. The VA's Office of Research and Development is soliciting concept papers for SDR research proposals to contribute to the evidence base for clinical practice.

Data have been collected on more than 180,000 returning veterans from the screen that was implemented in April 2007. A data base of the results of the screen has been established in Patient Care Services. National data may be requested through the Veterans Health Administration Office of Patient Care Services by completing a Data Use Agreement with that office.

Investigators are encouraged to develop projects that combine TBI screening with other national and regional database information, and medical record review.

3. Eligibility: This solicitation is open to VA investigators with at least 5/8ths VA appointments. Investigators are encouraged to propose cross-service collaboration (e.g., with Clinical Science and/or Rehabilitation Medicine) and collaboration with Department of Defense investigators.

4. Response Format: A concept paper (2-3 pages) is due by September 15, 2008, via e-mail to Martha Bryan (Martha.bryan@va.gov) articulating in the following order:

1. Title: Response to Solicitation: TBI Screening Instruments and Processes for Clinical Follow-up
2. Name of Principal Investigator and Contact Information (e-mail, telephone)
3. Brief description of design and methods to be used and type(s) of analyses to be performed
4. List of key personnel, affiliation, role and articulate any special qualifications for conducting the study
5. Description of any other existing or anticipated partnerships that will facilitate conduct of this work
6. Timeline
7. Additional questions to be addressed (for example, cost-effectiveness data or other continuous quality improvement issues related to the assessment tools; adverse consequences of screening)
8. Expected total project duration and estimated total cost

5. Evaluation: Concept papers will undergo review by a selected group of VA program officials and scientists. Criteria for evaluation will include:

- a. Clarity and responsiveness of key questions being addressed
- b. Scientific merit of approach and design envisioned
- c. Feasibility of approach and design
- d. Team qualifications
- e. Responsiveness in terms of timeliness
- f. Short term value relative to costs
- g. Longer term value relative to costs
- h. Justification/defensibility of proposed 'Gold Standards', proxy measures, and other comparators

It is anticipated that investigators will be asked to develop a full proposal for merit review and potential funding within six weeks of the date of notification (November 14, 2008) that the concept paper is approved (notification is anticipated by October 1, 2008). The proposal is expected to follow standard HSR&D merit review instructions, available at:

<http://www.hsr.d.research.va.gov/funding/instructions-merit-review.pdf> with the exception that the proposal, like the concept paper, will be submitted electronically to Martha.bryan@va.gov as a PDF file. Proposal reviewers will be asked to identify any major conceptual or other flaws precluding funding and if there are none, to identify any steps needed to strengthen the project.

Questions/Concerns: Questions or concerns can be directed to Dr. Martha Bryan at 202-461-1505.

/s/

Joel Kupersmith, MD
Chief Research and Development Officer
Office of Research and Development