



Federal Register

**Tuesday,
March 5, 2002**

Part IV

Department of Education

**National Institute on Disability and
Rehabilitation Research; Notice**

DEPARTMENT OF EDUCATION**National Institute on Disability and Rehabilitation Research**

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice of proposed priority.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes funding a priority for a Traumatic Brain Injury Model Systems (TBIMS) Program under the Disability and Rehabilitation Research Projects (DRRP) Program for the National Institute on Disability and Rehabilitation Research (NIDRR) for fiscal year (FY) 2002. The Assistant Secretary takes this action to focus research attention on an identified national need. We intend this priority to improve the rehabilitation services and outcomes for individuals with Traumatic Brain Injury.

DATES: We must receive your comments on or before April 4, 2002.

ADDRESSES: Address all comments about this proposed priority to Donna Nangle, U.S. Department of Education, 400 Maryland Avenue, SW., room 3412, Switzer Building, Washington, DC 20202-2645. If you prefer to send your comments through the Internet, use the following address: donna.nangle@ed.gov.

FOR FURTHER INFORMATION CONTACT:

Donna Nangle. Telephone: (202) 205-5880.

If you use a telecommunications device for the deaf (TDD), you may call the TDD number at (202) 205-4475 or via the Internet: donna.nangle@ed.gov.

Individuals with disabilities may obtain this document in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION:**Invitation to Comment**

We invite you to submit comments regarding this proposed priority.

We invite you to assist us in complying with the specific requirements of Executive Order 12866 and its overall requirement of reducing regulatory burden that might result from the proposed priority. Please let us know of any further opportunities we should take to reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments

about this priority in room 3412, Switzer Building, 330 C Street SW., Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request, we will supply an appropriate aid, such as a reader or print magnifier, to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this proposed priority. If you want to schedule an appointment for this type of aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

We will announce the final priority in a notice in the **Federal Register**. We will determine the final priority after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing or funding additional priorities, subject to meeting applicable rulemaking requirements.

Note: This notice does *not* solicit applications. In any year in which we choose to use this proposed priority, we will invite applications through a notice in the **Federal Register**. When inviting applications we designate the priority as absolute, competitive preference, or invitational.

Disability and Rehabilitation Research Projects (DRRP) Program

The purpose of the DRRP program is to plan and conduct research, demonstration projects, training, and related activities to:

- (a) Develop methods, procedures, and rehabilitation technology that maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities; and
- (b) Improve the effectiveness of services authorized under the Rehabilitation Act of 1973 (the Act).

Description of Special Projects and Demonstrations for Traumatic Brain Injuries

The Traumatic Brain Injury Model Systems (TBIMS) program requires excellence in clinical care, rehabilitation research, and relevance to consumers, principally individuals with traumatic brain injuries and their families. Each TBIMS project funded under this program must have an integrated continuum of care to support the rehabilitation of persons with TBI, with linkage to a trauma system project

and community-based treatment settings. Each project must have capacity to enroll TBI subjects and conduct research on TBI.

The Department is particularly interested in ensuring appropriate expenditure of public funds. Not later than three years after the establishment of any TBI project, NIDRR will conduct one or more reviews of the activities and achievements of each project to ensure that the grantee is carrying out proposed activities and contributing to the advancement of knowledge. In accordance with the provisions of 34 CFR 75.253(a), continued funding depends at all times on satisfactory performance and accomplishment of stated objectives.

The New Freedom Initiative (NFI) emphasizes the importance of assistive and universal designed technologies, other employment initiatives, and promotion of full access to community-based living. The NFI can be accessed on the Internet at the following site: <http://www.whitehouse.gov/news/freedominitiative/freedominitiative.html>. NIDRR's published Long-Range Plan (the Plan), focusing on both individual and systemic factors that impact functional capability, includes the following elements: employment outcomes, health and function, technology for access, community integration and independent living, and associated activities such as development of outcome measures and disability statistics. The Plan can be accessed on the Internet at: <http://www.ed.gov/offices/OSERS/NIDRR/Products>.

Priority*Background:*

An estimated 5.3 million Americans currently live with disabilities resulting from TBI. The Centers for Disease Control (CDC) estimates that approximately 80,000 Americans experience the onset of disabilities resulting from traumatic brain injury each year. The three leading causes of TBI are motor vehicle crashes, violence, and falls, particularly among the elderly. Following TBI, individuals may have impairments in cognition, movement, and sensation (Thurman D.J., Alverson C.A., Dunn K.A., Guerrero J., Snizek, J.E., *Traumatic brain injury in the United States: A Public Health Perspective*, Journal of Head Trauma Rehabilitation. 1999, 14(6): 602-615). The CDC maintains a website on "Epidemiology of Traumatic Brain Injury in the United States" at <http://www.cdc.gov/ncipc/dacrrdp/tbi.htm>.

As stated in the 1998 National Institute of Health (NIH) Consensus Conference Proceedings, "TBI may result in lifelong impairment of an individual's physical, cognitive, and psychosocial functioning." In a 1995 review of the literature on TBI survivors, Morton and Wehman identified "significant" decreases in opportunities for social interaction and maintaining friendships as well as high levels of anxiety and depression lasting for prolonged periods following TBI (Morton M., Wehman P., *Psychosocial and Emotional Sequelae of Individuals with Traumatic Brain Injury: A Literature Review and Recommendations*, Brain Injury, 1995, Vol. 9, No. 1, 81–92). In the civilian population, it is estimated that fewer than 25% of persons experiencing TBI are "able to gain and maintain employment" (Kolakowsky-Hayner S., Kreutzer J.S., Miner K.D., *Validation of the Service Obstacles Scale for the Traumatic Brain Injury Population*, NeuroRehabilitation, 2000, Vol. 14, 151–158.) Other research has found high rates of rehospitalization after TBI, often for seizures and psychiatric difficulties (Marwitz J.H., Cifu D.X., Englander J., High W.M., *A Multi-System Project Analysis of Rehospitalizations Five Years After Brain Injury*, Journal of Head Trauma Rehabilitation, Aug. 16, 2001, No. 4, 307–17).

In 1987, NIDRR established the National Traumatic Brain Injury Model Systems (TBIMS) Program by funding four projects to provide comprehensive, multidisciplinary rehabilitation services to persons who experience TBI and to conduct research to foster advances in TBI rehabilitation. This number expanded to 17 projects in 1998. The TBIMS program is designed to study the course of recovery and outcomes following the delivery of a coordinated system of TBI care.

Contributions to the TBI National Data Center Project

From 1989 to present, the TBIMS projects have collected information on common data elements and contributed to a centralized TBI database (additional information on TBIMS can be found at <http://www.tbims.org>). The TBI National Data Center (TBINDC) project coordinates data collection, manages the TBI database, and provides statistical support to the model system projects. To date, TBI projects have contributed 2,553 cases to the national database, with follow up data currently extending to 12 years post injury. For purposes of the TBIMS, TBI is defined as damage to brain tissue caused by an external mechanical force as evidenced by: Loss

of consciousness due to brain trauma, post-traumatic amnesia (PTA), skull fracture, or objective neurological findings that can be reasonably attributed to TBI on physical examination or mental status examination. Penetrating wounds fitting the definition listed above are included. Lacerations or bruises on both of the scalp or forehead without other criteria listed above are excluded. Primary anoxic encephalopathy is excluded.

In the current TBIMS, participants must meet the following criteria: (a) Fit the above definition of TBI; (b) be 16 or older; (c) entered the Model System's acute care hospital emergency department within 24 hours of injury; (d) receive both acute hospital care and care on a designated inpatient rehabilitation unit within the model system; and (e) be able to understand and signs an informed consent form or, if unable, have a family or legal guardian who understands and sign the informed consent form. At the present time, TBIMS projects collect 429 data items on each individual during the initial hospitalization, and an additional 459 items during follow up.

TBI Rehabilitation

In recent years, medical and pharmacological therapies have shown promise for preserving and enhancing function for individuals with TBI. The availability of drugs capable of regulating neurotransmitter release or receptor function has led to research into neuroprotective intervention in TBI (Verma A., *Opportunities for Neuroprotection in TBI*, Journal of Head Trauma and Rehabilitation, 2000; 15(5): 1149–1161); (McIntosh T.K., Juhler M., et al., *Novel Pharmacologic Strategies in the Treatment of Experimental Traumatic Brain Injury*, Journal of Neurotrauma, Oct. 1998; 15(10): 731–69). Psychopharmacological agents such as amantadine have shown responsiveness to symptoms that include problems with short-term memory, attention, planning, problem solving, impulsivity, disinhibition, poor motivation, and other behavioral and cognitive deficits (Kraus M.F., Maki P.M., *Effect of Amantadine Hydrochloride on Symptoms of Frontal Lobe Dysfunction in Brain Injury: Case Studies and Review*, Journal of Neuropsychiatry and Clinical Neurosciences, Spring 1997; 9(2): 222–30).

Diagnostic data offer new promise for facilitating treatment interventions and impacting outcomes. For instance, evidence indicates that intracranial pressure (ICP) data can increase the confidence of outcome predictions that

are based on the clinical examination alone (Bullock R., Chesnut R.M., et al., *Guidelines for the Management of Severe Head Injury*, Brain Trauma Foundation, European Journal of Emergency Medicine (England), June 1996; 3(2): 109–27). Magnetic resonance imaging (MRI) may clarify the relationship between chronic symptoms such as headaches and irritability after TBI and MRI abnormalities. MRI also appears to be the most sensitive imaging method for assessing mild TBI (MTBI) (Voller B., Auff E., et al., *To Do or Not to Do? Magnetic Resonance Imaging in Mild Traumatic Brain Injury*, Brain Injury, Feb. 2001; 15(2): 107–15).

New technologies and therapeutic interventions have the potential to improve understanding and enhance access and function for individuals with TBI. Virtual reality (VR) technology can be used to assess TBI patients and enable them to relearn activities of daily living (ADL) in a safe, controlled, visually stimulating environment (Gourlay D., Lun K.C., et al., *Virtual Reality for Relearning Daily Living Skills*, International Journal of Medical Informatics, Dec. 2000; 60(3): 255–61). Tele-rehabilitation is being used to conduct follow-up psychological testing of individuals with TBI who live in rural areas. This technology may facilitate access for individuals who must travel long distances to see providers.

Research on improving employment outcomes has found that specific vocational interventions tailored to the needs of individuals with TBI may be effective despite significant neuropsychological impairments (Johnstone B., Schopp L.H., Harper J., Kosciulek J., *Neuropsychological Impairments, Vocational Outcomes, and Financial Costs for Individuals with Traumatic Brain Injury Receiving State Vocational Rehabilitation Services*, Journal of Head Trauma Rehabilitation, 1999, Vol. 14, 220–232). Yet other research finds that "significant service gaps remain, particularly in the area of employment outcomes" (Goodall P., Ghilone C.T., *The Changing Face of Publicly Funded Employment Services*, Journal of Head Trauma Rehabilitation, 2001, Vol. 16, No. 1, 94–106).

Despite the emergence of improved imaging techniques and psychopharmacologic treatments, the effectiveness of many rehabilitation interventions for persons with TBI has yet to be demonstrated conclusively. In work funded by the Agency for Health Care Policy and Research (now the Agency for Health Care Research and Quality), a panel of experts concluded that there is little evidence relating the

intensity of acute inpatient TBI rehabilitation to outcome. Research on TBI interventions must have methodological rigor that includes attention to study population, controls, hypotheses, appropriate measures, and appropriate statistical analysis methods (Evidence Report/Technology Assessment Number 2. Rehabilitation for Traumatic Brain Injury, AHCPR Publication No. 99–E006).

NIDRR recently completed a Summative Program Review of the current TBIMS projects. Participants in the review process observed that the comprehensive continuum of quality care should continue to be a requirement for participation in the TBIMS projects program. In addition, the review panels identified longitudinal data collection and innovative research as achievements of the TBIMS. Reviewers also noted that uniformly comprehensive, high quality care, together with a common data collection system and administrative infrastructure, make the TBIMS program a valuable platform for various collaborative studies, including multi-system project trials of therapies and technologies as well as community-based interventions. NIDRR will hold a separate competition to foster collaborative research to take advantage of the multi-site capacities of the TBIMS.

A committee consisting of the individual system project program directors has, since its inception, guided the TBIMS program. This group meets bi-annually in Washington, DC, and, in consultation with NIDRR, develops and oversees the policies of the TBIMS. It is anticipated that this mechanism will continue. In the current funding cycle, this governing body developed a set of strategic recommendations for the Model Systems. NIDRR intends to work through the system project directors to implement some of the recommendations of this group, including:

- Evaluation of the inclusion criteria and its impact on the population admitted to the model system;
- Systematic evaluation of the TBI longitudinal data set, with reduction in redundancy of data items and consideration of adoption of a minimal data set;
- Development of guidelines for public use of the data set, ensuring confidentiality of data; and
- Continued development of research management mechanisms that promote rigor in TBI studies.

Proposed Priority

The Assistant Secretary proposes to establish an absolute priority for Traumatic Brain Injury Model System projects for the purpose of generating new knowledge through research to improve treatment and services delivery outcomes for persons with TBI. A TBIMS project must:

(1) Have a multidisciplinary system of rehabilitation care specifically designed to meet the needs of individuals with TBI. This system must: (a) Encompass a continuum of care, including emergency medical services, acute care services, acute medical rehabilitation services, and post-acute services; and (b) demonstrate the ability to enroll adequate numbers of subjects in order to conduct rigorous research projects.

(2) Conduct no more than three research studies focused on areas identified in the NFI and the Plan, ensuring that each project has sufficient sample size and methodological rigor to generate robust findings. These studies may be done in collaboration with other TBIMS projects.

(3) Participate as directed by the Assistant Secretary in national studies of TBI by contributing to a national database and by other means as required by the Assistant Secretary, collect data on TBIMS participants, adhering to data collection and data quality guidelines developed by the TBINDC in consultation with NIDRR, and demonstrating capacity to maintain long-term retention of participants.

(4) Disseminate research findings to clinical and consumer audiences, using accessible formats, and evaluate impact of these findings on improved outcomes for persons with TBI.

(5) Collaborate, as appropriate, with other system projects in ongoing research and dissemination efforts, providing information on coordination mechanisms, quality control, and impact on overall management of the system project.

In carrying out these purposes, the TBIMS project may select one of the following research objectives related to specific areas of the NFI or the Plan:

• *Integrating Persons with Disabilities into the Workforce:* (1) Develop and evaluate strategies that improve the employment outcomes of persons with TBI, particularly focusing on job quality and job stability; and (2) Investigate the relationship between treatment in TBIMS and improved employment outcomes for persons with TBI.

• *Maintaining Health and Function:* (1) Study the impact of diagnostic innovations, such as use of ICP and fMRI, in acute management on

rehabilitation outcomes; (2) Identify pharmacologic interventions of psychoactive drugs and other pharmacologic agents to enhance cognitive and behavioral outcomes, (3) Design and test rehabilitation interventions that improve functional and long-term outcomes of persons with TBI; or (4) Examine treatment alternatives for depression and other affective disorders.

• *Assistive and Universally Designed Technologies:* (1) Evaluate the impact of selected innovations in technology or rehabilitation engineering or both on outcomes such as function, independence, and employment; or (2) Evaluate the impact of selected innovations in technology or rehabilitation engineering or both on service delivery to persons with TBI.

• *Full Access to Community Life:* (1) Develop and test strategies for improving the independent living/community integration outcomes of persons with TBI, including identifying predictors of community participation and interventions that may affect it; (2) Evaluate the role of family and social supports in facilitating the independent living/community integration outcomes of persons with disabilities; or (3) Examine the impact of environmental barriers on the outcomes of persons with TBI.

In carrying out these purposes, the system project must:

• Involve, as appropriate, individuals with disabilities and individuals from minority backgrounds in all aspects of the research as well as in design of clinical services and dissemination activities.

• Demonstrate knowledge of culturally appropriate methods of data collection, including understanding of culturally sensitive measurement approaches;

• Collaborate with other related projects, including the other funded TBIMS projects.

Applicable Program Regulations: 34 CFR part 350.

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Program Authority: 29 U.S.C. 762(g) and 764(b).
(Catalog of Federal Domestic Assistance Number 84.133A, Disability Rehabilitation Research Project.)

Dated: February 27, 2002.

Loretta L. Petty,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 02-5230 Filed 3-4-02; 8:45 am]

BILLING CODE 4000-01-P