4000-01-U

DEPARTMENT OF EDUCATION

Disability and Rehabilitation Research Project; Traumatic Brain Injury Model Systems Centers

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

ACTION: Notice.

Overview Information:

Proposed priority--National Institute on Disability and Rehabilitation Research--Disability and Rehabilitation Research Projects and Centers Program--Disability and Rehabilitation Research Project--Traumatic Brain Injury Model Systems Centers.

CFDA Number: 84.133A-5

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority under the Disability and Rehabilitation Research Projects and Centers Program administered by the National Institute on Disability and Rehabilitation Research (NIDRR). Specifically, this notice proposes a priority for Disability and Rehabilitation Research Projects (DRRPs) to serve as Traumatic Brain Injury Model Systems (TBIMS) Centers. The Assistant Secretary may use this priority for

competitions in fiscal year (FY) 2012 and later years. We take this action to focus research attention on areas of national need. We intend this priority to contribute to improved outcomes for individuals with traumatic brain injury.

DATES: We must receive your comments on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Address all comments about this notice to Marlene Spencer, U.S. Department of Education, 400 Maryland Avenue, SW., room 5133, Potomac Center Plaza (PCP), Washington, DC 20202-2700.

If you prefer to send your comments by e-mail, use the following address: marlene.spencer@ed.gov. You must include "Proposed Priority for Traumatic Brain Injury Model Systems (TBIMS) Centers" in the subject line of your electronic message.

FOR FURTHER INFORMATION CONTACT: Marlene Spencer. Telephone: (202) 245-7532 or by e-mail: marlene.spencer@ed.gov.

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

This notice of proposed priority is in concert with NIDRR's currently approved Long-Range Plan (Plan). The Plan, which was published in the Federal Register on February 15, 2006 (71 FR 8165), can be accessed on the Internet at the following site: http://www2.ed.gov/legislation/FedRegister/other/2006-1/021506d.pdf.

Through the implementation of the Plan, NIDRR seeks to: (1) improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of expertise, information, and training to facilitate the advancement of knowledge and understanding of the unique needs of traditionally underserved populations; (3) determine best strategies and programs to improve rehabilitation outcomes for underserved populations; (4) identify research gaps; (5) identify mechanisms of integrating research and practice; and (6) disseminate findings.

This notice proposes a priority that NIDRR intends to use for a DRRP competition in FY 2012 and possibly later years. However, nothing precludes NIDRR from publishing additional priorities, if needed. Furthermore, NIDRR is under no obligation to make an award for this priority.

The decision to make an award will be based on the quality of applications received and available funding.

Invitation to Comment: We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priority, we urge you to identify clearly the specific topic that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from this proposed priority. Please let us know of any further ways we could 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 notice in room 5133, 550 12th Street, SW., PCP, Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record

for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under FOR FURTHER INFORMATION CONTACT.

Purpose of Program: The purpose of the Disability and Rehabilitation Research Projects and Centers Program is to plan and conduct research, demonstration projects, training, and related activities, including international activities, to 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, especially individuals with the most severe disabilities, and to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended (Rehabilitation Act).

Disability and Rehabilitation Research Projects

The purpose of NIDRR's DRRPs, which are funded through the Disability and Rehabilitation Research Projects and Centers Program, are to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended, by developing methods, procedures, and rehabilitation technologies that advance a wide range of

independent living and employment outcomes for individuals with disabilities, especially individuals with the most severe disabilities. DRRPs carry out one or more of the following types of activities, as specified and defined in 34 CFR 350.13 through 350.19: research, training, demonstration, development, dissemination, utilization, and technical assistance.

Program Authority: 29 U.S.C. 762(g) and 764(a).

Applicable Program Regulations: 34 CFR part 350.

PROPOSED PRIORITY:

This notice contains one proposed priority.

Traumatic Brain Injury Model Systems (TBIMS) Centers.

Background:

The Centers for Disease Control and Prevention (CDC) report that each year in the United States at least 1.7 million people sustain a traumatic brain injury (TBI). Of these, approximately 52,000 die, 275,000 are hospitalized, and 1.3 million are treated and released from emergency departments (CDC, 2010; Faul, Xu, Wald, & Coronado, 2010). These estimates do not include those individuals who sustained a TBI and did not seek medical care, those seen only in private doctors' offices, or those treated in military or veteran health care facilities. The leading causes of TBI are falls (35.2 percent), motor

vehicle/traffic collisions (17.3 percent), struck by/against events (16.5 percent), and assaults (10 percent) (Faul et al., 2010). Blasts are a leading cause of TBI among active duty military personnel serving in war zones (Defense and Veterans Brain Injury Center, 2011a). The number of TBIs experienced by members of the U.S. Armed Forces between the start of 2000 and the end of the second quarter of 2011 is reported to be 220,430 (Defense and Veterans Brain Injury Center, 2011b).

Common disabilities resulting from TBI include problems with cognition, sensory processing, communication, and behavioral or mental health; and some TBI survivors develop long-term medical complications (National Institute of Neurological Disorders and Stroke, 2011). Direct medical costs and indirect costs such as lost productivity associated with TBI totaled an estimated $76.5 billion in the United States in 2010 (CDC, 2011). Despite the prevalence of TBI and the disabilities that often follow, less than 20 percent of the management guidelines for TBI are supported by either Class I (prospective, randomized, controlled trials with masked outcome assessment, in a representative population) or Class II (prospective matched group cohort study in a representative population with

masked outcome assessments) research evidence (Maas, Roozenbeek, & Manley, 2010).

The Traumatic Brain Injury Model Systems Centers (TBIMS Centers) program was created by NIDRR in 1987 to demonstrate the benefits of a coordinated system of neurotrauma and rehabilitation care and to conduct innovative research on all aspects of care for those who sustain TBI. The mission of the TBIMS Centers is to improve the lives of persons who experience TBI, and of their families and communities, by creating and disseminating new knowledge about the natural course of TBI and rehabilitation treatment and outcomes following TBI. The influence of the program was expanded in the current grant cycle through numerous TBI interagency initiatives with the U.S. Departments of Veterans Affairs and Defense, the National Institute of Neurological Disorders and Stroke, the Centers for Disease Control and Prevention, and the Defense and Veterans Brain Injury Center.

NIDRR currently funds 16 TBIMS Centers, which are located throughout the United States. These centers provide comprehensive systems of brain injury care to individuals who sustain TBI and conduct TBI research, including clinical research and the analysis of standardized data in collaboration with other related

projects. Since 1989, the TBIMS Centers have collected and contributed information on common data elements for a centralized TBIMS database, which is maintained through a NIDRR-funded grant for a National Data and Statistical Center for the TBIMS Centers. (Additional information on the TBIMS database can be found at http://tbindsc.org). The TBI National Data and Statistical Center for the TBIMS Centers coordinates data collection, manages the TBIMS database, and provides statistical support to the model systems projects. As of December, 2011, TBIMS Centers have contributed 10,631 cases to the TBIMS database, with follow-up data available to date for 8,136 participants at 1 year post injury; 6,889 at 2 years post injury; 4,425 at 5 years post injury; 1,834 at 10 years post injury; and 484 at 20 years post injury.

Through this priority, we seek to fund new TBIMS Centers that will continue to provide a coordinated, multidisciplinary system of rehabilitation care specifically designed to meet the needs of individuals with TBI. These services would span the continuum of treatment from acute care through community re-entry. Under this priority, TBIMS Centers would engage in initiatives and new approaches and maintain close working relationships with other governmental and non-profit institutions and

organizations to coordinate scientific efforts, encourage joint planning, and promote the interchange of data and reports among TBI researchers. As part of these cooperative efforts, TBIMS Centers would participate in collaborative research projects that range from pilot research to more extensive studies.

A committee consisting of the individual TBIMS project directors has, since its inception, guided the TBIMS Centers program. This group meets bi-annually in Washington, DC, and, in consultation with NIDRR, develops and oversees the policies of the TBIMS Centers. NIDRR intends to form such a committee with the project directors awarded grants under this proposed priority.

References:

Centers for Disease Control and Prevention. (2010). Injury prevention & control: Traumatic brain injury. Retrieved December 2, 2011, from www.cdc.gov/traumaticbraininjury/statistics.html.

Centers for Disease Control and Prevention. (2011). Severe traumatic brain injury. Retrieved December 2, 2011, from www.cdc.gov/TraumaticBrainInjury/severe.html.

Defense and Veterans Brain Injury Center. (2011a). TBI facts: What is a traumatic brain injury? Retrieved

December 2, 2011, from www.dvbic.org/TBI---The-Military/TBI-Facts.aspx.

Defense and Veterans Brain Injury Center. (2011b). DOD worldwide numbers for TBI – Archives. Retrieved December 2, 2011, from www.dvbic.org/Archive-of-DoD-Numbers-for-TBI.aspx.

Faul, M., Xu, L., Wald, M. M., & Coronado, V. G. (2010). Traumatic brain injury in the United States: Emergency department visits, hospitalizations, and deaths 2002-2006. Atlanta (GA): Centers for Disease Control and Prevention, National Center for Injury Prevention and Control.

Maas, A. I. R., Roozenbeek, R., & Manley, G. T. (2010). Clinical trials in traumatic brain injury: Past experience and current developments. Neurotherapeutics, 7, 115-126.

National Institute of Neurological Disorders and Stroke (NINDS). (2011, April). Traumatic brain injury: Hope through research. Bethesda, MD: National Institute of Health. NIH Publication No. 02-2478. Retrieved December 2, 2011, from www.ninds.nih.gov/disorders/tbi/detail_tbi.htm.

Proposed Priority:

The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority for the funding of Traumatic Brain Injury Model Systems (TBIMS) Centers under the Disability and Rehabilitation Research Projects (DRRP) program. The TBIMS Centers must provide comprehensive, multidisciplinary services to individuals with traumatic brain injury (TBI) and conduct research that contributes to the development of evidence-based rehabilitation interventions and clinical and practice guidelines.

For purposes of this priority, the term traumatic brain injury or TBI is defined as damage to brain tissue caused by an external mechanical force as evidenced by loss of consciousness or post-traumatic amnesia due to brain trauma or by objective neurological findings that can be reasonably attributed to TBI on physical examination or mental status examination. Both penetrating and non-penetrating wounds that fit this criteria are included, but, primary anoxic encephalopathy is not.

The TBIMS Centers must generate new knowledge that can be used to improve outcomes of individuals with TBI in one or more domains identified in NIDRR's currently approved Long Range Plan, published in the Federal Register on February 15, 2006 (71 FR 8165): health and function,

community living and participation, technology, and employment. Each TBIMS Center must contribute to this outcome by:

(a) Providing a multidisciplinary system of rehabilitation care specifically designed to meet the needs of individuals with TBI. The system must encompass a continuum of care, including emergency medical services, acute care services, acute medical rehabilitation services, and post-acute services;

(b) Continuing the assessment of long-term outcomes of individuals with TBI by enrolling at least 35 subjects per year into the TBIMS database, following established protocols for the collection of enrollment and follow-up data on subjects (found at http://www.tbindsc.org/);

Note: TBIMS Centers will be funded at varying amounts up to the maximum award based on the numbers of TBIMS database participants from whom TBIMS Centers must collect follow-up data. TBIMS Centers that have previously been TBIMS grantees with large numbers of database participants will receive more funding within the specified range than TBIMS Centers with fewer participants, as determined by NIDRR after applicants are selected for funding. Applicants must include in their budgets specific estimates of their costs for follow-up data collection. Funding will be determined

individually for each successful applicant, up to the maximum allowed, based upon the documented workload associated with the follow-up data collection, other costs of the grant, and the overall budget of the research project.

(c) Proposing and conducting at least one, but no more than two, site-specific research projects to test innovative approaches to treating TBI or to assess outcomes of individuals with TBI. Site-specific research projects must focus on outcomes in one or more domains identified in the Plan: health and function, community living and participation, technology, and employment;

Note: Applicants who propose more than two site-specific research projects will be disqualified.

(d) Participating as research collaborators in at least one module project. Module projects are research collaborations with one or more TBIMS Centers on topics of mutual interest and expertise. Such module projects must be carried out as part of the TBIMS Centers' activities. They must not be part of a current TBIMS Multi-Site Collaborative Project, which the Department funded under a separate priority (see the notice inviting applications, published in the Federal Register on February 1, 2008 (73 FR 6162) and the associated notice of final priority,

published in the Federal Register on February 1 2008 (73 FR 6132).

Note: Applicants should not propose a specific module project in their application. While all TBIMS Centers grantees are required to participate as research collaborators in at least one module project, they are not required to develop any module project on their own. Immediately following the announcement of awards under this priority, TBIMS Centers that are interested in proposing module projects may identify module topics, identify potential collaborators from among the other TBIMS Centers, and propose research protocols for the potential modules. At the first TBIMS Centers Project Directors' meeting, Project Directors will review, discuss, and decide upon specific module projects to implement. NIDRR staff will facilitate this post-award discussion and negotiation among TBIMS Centers grantees. Once these module projects are agreed upon by the Project Directors, each TBIMS Center must participate in at least one of them;

(e) Demonstrating, in its application, its capacity to successfully engage in multi-site collaborative research on TBI. This capacity includes access to research participants, the ability to maintain data quality, and the ability to adhere to research protocols;

(f) Spending at least 15 percent of its annual budget on participating in a module project, as described in paragraph (d) of this priority;

(g) Spending $5000 of its total budget towards the costs of a state-of-the-science conference to be planned and executed with input and participation by the TBIMS Centers;

(h) Coordinating with the NIDRR-funded Model Systems Knowledge Translation Center (MSKTC; http://www.msktc.org/) to provide scientific results and information for dissemination to clinical and consumer audiences;

(i) Addressing the needs of individuals with TBI, including individuals from one or more traditionally underserved populations; and

(j) Ensuring that the input of individuals with TBI is used to shape TBIMS research.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the Federal Register. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Final Priority:

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 additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does not solicit applications. In

any year in which we choose to use this priority, we invite applications through a notice in the Federal Register.

Executive Orders 12866 and 13563:

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is "significant" and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action likely to result in a rule that may--

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities in a material way (also referred to as an "economically significant" rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency--

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account--among other things and to the extent practicable--the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental,

public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives--such as user fees or marketable permits--to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency "to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include "identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes."

We are taking this regulatory action only on a reasoned determination that its benefits justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes

that this proposed priority is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits of this regulatory action. The potential costs associated with this regulatory action are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

The benefits of the Disability and Rehabilitation Research Projects and Centers Programs have been well established over the years in that similar projects have been completed successfully. This proposed priority would generate new knowledge through research and development. Another benefit of this proposed priority is that the establishment of new DRRPs would improve the lives of individuals with disabilities. The new DRRP would generate, disseminate, and promote the use of new information that would improve the options for individuals

with disabilities to perform activities of their choice in the community.

Intergovernmental Review: This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or computer diskette) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., room 5075, PCP, Washington, DC 20202-2550. Telephone: (202) 245-7363. If you use a TDD, call the FRS, toll free, at 1-800-877-8339.

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Dated: March 2, 2012

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Alexa Posny,
Assistant Secretary for Special Education and Rehabilitative Services.

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