

INDIANA TRAUMATIC SPINAL CORD & BRAIN INJURY RESEARCH

ACTIVITY-BASED THERAPY PROGRAM

an initiative funded by the

INDIANA DEPARTMENT OF HEALTH
IN ACCORDANCE WITH INDIANA CODE IC 16-41-42.2

Submission Deadline: November 4, 2024

INFORMATION FOR APPLICANTS

GENERAL INFORMATION

The State of Indiana established the research fund known as Indiana Spinal Cord and Brain Injury Research (ISCBIR) effective July 1, 2007. This fund, established under Indiana Code (IC) 16-41-42-4, will consist of appropriations, gifts and bequests, fees deposited in the fund under IC 9-29-5-2, and grants received from the federal government and private sources to: (1) Establish and maintain a state medical surveillance registry for traumatic spinal cord and brain injuries. (2) Fulfill the duties of the board established by section 5 of this chapter. (3) Fund research related to the treatment and cure of spinal cord and brain injuries, including acute management, medical complications, rehabilitative techniques, and neuronal recovery. Research must be conducted in compliance with all state and federal laws. (4) Concerning spinal cord injuries, fund at least ten percent (10%) and not more than fifteen percent (15%) of money in the fund for: (A) post acute extended treatment and services for an individual with a spinal cord injury; or (B) facilities that offer long term activity based therapy services at affordable rates to an individual with a spinal cord injury that requires extended post acute care. (5) Concerning brain injuries, funding of at least ten percent (10%) and not more than fifteen percent (15%) of money in the fund for: (A) post acute extended treatment and services for an individual with a brain injury; or (B) facilities that offer long term activity based therapy services at affordable rates to an individual with a brain injury that requires extended post acute care. (6) Develop a statewide trauma system. However, not more than fifty percent (50%) of money in the fund may be used for purposes of developing a statewide trauma system.

Effective July 1, 2015 this fund was supplemented and additionally authorized by legislation to consider applications and make grants to health care clinics that:

- (A) are exempt from federal income taxation under Section 501 of the Internal Revenue Code;
- (B) employ physical therapists licensed under IC 25-27; and
- (C) provide in Indiana long term activity based therapy services at affordable rates to individuals with spinal cord injuries or brain injuries that require extended post-acute care.

This application package is designed proposals to be funded under points 4) and 5) above. For the purposes of this RFA, "activity based therapy services" refers to specialized interventions that activate the neuromuscular system, involving intense, repetitive physical activity performed with the goal of retraining the nervous system to recover specific motor tasks.

This application package is designed for individuals in such organizations (eligibility criteria below) wishing to submit proposals for projects / programs to be funded under the activity based approach noted above. Start-up organizations are encouraged to apply as long as they meet criteria and are able to deliver care. Funding decisions for all proposals submitted under this program will be made by the Indiana Spinal Cord and Brain Injury Research Board (ISCBIRB), consisting of eleven members as defined in section 5(a) of IC 16-41-42.2. The Board will make these decisions after receiving input from an independent advisory panel. This advisory panel will review proposals for merit and matching required criteria and make recommendations to the Board. However, final funding decisions will be based upon the application meeting the priorities of the ISCBIRB with regards to activity-based therapy as it relates to traumatic spinal cord injury and traumatic brain injury.

The overall objective of this program is to foster and encourage activity-based therapy programs for the treatment of spinal cord and traumatic brain injuries, including acute management, medical complications, rehabilitative techniques, and neuronal recovery. For the purposes of this RFA "Activity Based Therapy" refers to functional and task-specific activities with the goal to promote neuroplasticity and recovery following neurologic injury due to brain injury or spinal cord injury.

Collaborations are encouraged between Indiana-based organizations as well as with organizations located outside the state of Indiana, including organizations in other countries. Even though the Indiana statute encourages collaborations with organizations outside of Indiana, the care should be Indiana-based. Salary support for collaborators outside of Indiana will be limited. Programs must be conducted in compliance with all state and federal laws.

FUNDING MECHANISMS INCLUDED IN THIS INITIATIVE

The initiative for funding activity based therapy programs, established under Indiana Code (IC) 16-41-42-4, consists of **two** funding mechanisms: 1) an RFA for programs providing rehabilitative clinical care and employing "activity based" approaches for persons with traumatic spinal cord injury and 2) an RFA for programs providing rehabilitative clinical care and employing "activity based" approaches for persons with traumatic brain injury.

Applications for each RFA may be submitted for up to a **maximum requested amount of \$150,000 for the total duration of the project**. All applications should be limited to a two-year duration. Because the nature and scope of the program proposed may vary, it is anticipated that the size of each award may also vary. Applications should include only those expenses directly applicable to the program. All applications must be limited to a two-year duration. (Note: funding is sequential and dependent upon adequate progress reports which will be reviewed and approved by the ISCBIRB). Awards pursuant to each of these RFAs is contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

WHO MAY APPLY

Eligible lead Institutions / organizations that are located within Indiana and fall into one or more of the following categories: public/state controlled Institution of higher education; private institution of higher education; nonprofit with 501(c)(3) IRS status (other than institution of higher education); nonprofit without 501(c)(3) IRS status (other than institution of higher education); small business; for-profit organization (other than small business); state government; U.S. territory or possession; Indian/Native American Tribal Government (Federally Recognized); Indian/Native American Tribal government (other than federally recognized); Indian/Native American Tribally Designated Organization; non-domestic (non-U.S.) entity (foreign organization); Hispanic-serving institution; historically black colleges and universities (HBCUs); Tribally Controlled Colleges and Universities (TCCUs); Alaska Native and Native Hawaiian Serving institutions; regional organization eligible agencies of the federal government; and faith-based or community based organizations.

Eligible organizations must be based in Indiana and have staff with the education, skills, knowledge, and resources necessary to carry out the proposed program. Organizations may simultaneously hold an award from each RFA but may not simultaneously hold more than one award for the same project. A subsequent application for either RFA must include outcomes data and programmatic enhancements.

RESTRICTIONS / ALLOWABLE EXPENSES

It is expected that funding from either of these two mechanisms will be used to launch programs or therapeutic approaches that will be sustainable within two years or for the purchase of equipment. Other expense criteria are below:

- 1. Successful applications will be relative to the topic of activity-based therapy for traumatic spinal cord OR activity-based therapy for traumatic brain injury. Applications are expected to have high scientific merit.
- 2. A separate proposal may be submitted for each RFA during each cycle if an award for that population is not currently held. However, if a proposal is submitted for each of the TBI and SCI populations, the proposals must fully address the relevant population in each submission (e.g. the same proposal should not be submitted twice).
- 3. The program director and all staff must be employed by an Indiana-based organization.
- 4. All applicants who have received prior ISCBIR funding are eligible, depending on the demonstrable progress from the prior awards.
- 5. Requested grant funding period cannot exceed 24 months and <u>may begin no earlier than</u> July 1, 2025.
- 6. Budget request may not include indirect costs.
- 7. Travel budget requested must be limited to those expenses necessary to carry out the specific aims of the proposed project. TRAVEL TO CONFERENCES / SEMINARS IS NOT AN ALLOWABLE EXPENSE.
- 8. Staff salaries and therapeutic equipment are deemed allowable expenses.
- 9. Creation of an endowment is not an allowable expense.
- 10. Funding cannot be used for reimbursable expenses that can be billed to a third party.
- 11. Scholarships intended to relieve financial burdens for persons undergoing therapy that have non reimbursable expenses are allowable but the selection criteria for such persons must be fully delineated and justified.

MECHANISM FOR APPLICATION SUBMISSION

Submission deadline: November 1, 2024

Application forms are available at: http://www.in.gov/isdh/23657.htm and CTSI ABT Link

Upload submission using the application and via the "Start a submission" link here: **CTSI ABT Link**

For questions about this program and about submitting a competitive application, please contact Julie Driscol at the Indiana CTSI (<u>judrisco@iu.edu</u>).

APPLICATION FORMAT

Applications should be single spaced on 8.5 x 11 inch white paper with at least 0.5 inch margins and not to exceed **15 pages**, including figures and tables but excluding resumes / CVs. Type size must be clear and readily legible and at least 11 point font.

Sequence:

- **Page 1** Face page: Specifies the title of the proposal, program director and his/her institutional/organizational affiliation, where work will be performed, the targeted RFA, and the total budget.
- Pages 2-3 Budget pages: See budget sheet in application packet. Additional sheets may be added to provide justification. List the direct costs for all personnel. Supplies and other costs must relate directly to performance of the project. Travel should be limited to the amount necessary to achieve the aims of the project. TRAVEL TO CONFERENCES AND SEMINARS IS NOT AN ALLOWABLE EXPENSE. All costs should be specifically justified. See Allowable Expenses.
- Pages 4-15 Proposed Program Description: Applications MUST describe the proposed program's ability to address each of the criteria described below under Review Criteria. Applicants should provide a narrative that allows reviewers to see a complete picture of the proposed program and how it will benefit the individuals being treated.

Prior Submission (limit 1 page):

- <u>Unfunded</u>: If the organization has previously submitted to this funding mechanism, the application must address how this proposal has been revised / is different from the previously submitted application.
- <u>Funded:</u> If the organization has received a prior award the application MUST include outcomes data and evaluatory evidence of a successful ABT program (see review criteria below)
- Resumes / CVs / Biosketches: The resume, CV, or biosketch (following NIH format) of the program director and any applicable collaborators should be included. These do not count as part of the page limit.
- <u>Additional Documentation</u>: If this is a resubmission, include the prior reviews as part of this submission

REVIEW CRITERIA

Applications should respond to the following criteria, which also serve as the review criteria:

- 1. The health care clinic in which the program resides must:
 - a. Be exempt from federal income taxation under Section 501 of the Internal Revenue Code;
 - b. Employ physical therapists licensed under IC 25-27;
 - c. Provide Indiana long term activity-based therapy services at affordable rates to individuals with traumatic spinal cord injuries OR traumatic brain injuries that require extended post-acute care.
- 2. The application's efficacy in providing significant and <u>sustained</u> improvement to individuals with traumatic spinal cord injuries OR traumatic brain injuries. To address this criterion, applications should describe the following features of the proposed program:
 - a. Staffing to include descriptions of:
 - i. Expertise and experience of staff in activity based therapy;
 - ii. Ratio of staff to projected number of persons served.
 - b. Client selection process including:
 - i. Medical evaluation to include diagnosis, co-morbidities, and contraindications to activity based therapy;
 - ii. Other evaluation(s) as needed.
 - c. A person-centered program that includes:
 - i. Involvement of the person served and, as appropriate, family involvement in goal-setting,

- planning and decision-making;
- ii. Education about the therapy process for the person served and, as appropriate, family;
- iii. Information for the person served and, as appropriate, family regarding the potential of the person served to achieve identified goals and the expected timeline for goal attainment.
- d. A process for initial and ongoing evaluations to include:
 - i. Standardized measurement of progress and outcome;
 - ii. Criteria for terminating therapy;
- e. Satisfaction of the person served with the therapy process and outcome.
- f. Access to needed medical services and adjunctive therapy services to include, but not limited to, response to emergent medical needs.
- g. Adequate space, equipment and facilities.
- 3. The application's efficacy in describing the method for determine "affordable rates"
- 4. The application's efficacy in providing a detailed selection of persons receiving scholarship funding (where applicable)
- 5. The application's efficacy in describing the need, client population, access, impact and benefit for the equipment purchase (where applicable)

Final funding decisions remain with the ISCBIR Board and will be based upon the recommendations of the review committee, in addition to the considerations below:

- 1. Documentation of productivity or results from prior awards if an organization was previously funded
- 2. If a number of meritorious applications are received, those applications that represent applications from previously unsupported organizations will be given priority

POST AWARD REQUIREMENTS

- 1. Complete a progress report during each of the two years of the award. Please note: If a one year no cost extension is given, then the project will require an additional progress report.
- 2. Present ongoing work / findings to-date at a poster session during an ISCBIR Board conference
- 3. Notify the ISCBIR Board in writing if the program director leaves the institution before funding is complete
- 4. Obtain prior approval from the ISCBIR Board for the project to be transferred to another director.

Requests for approval from the ISCBIR Board may be made by contacting trnsldev@iu.edu

NO COST EXTENSION REQUEST PROCESS

The ISCBIR Board will only consider a no cost extension **IF IT IS RECEIVED BY THE THIRD MONDAY IN APRIL OF THE YEAR THE FINAL ACCOUNT WILL CLOSE**. No extensions will be made for a time greater than 12 months following the official closing date of the grant, nor will additional extensions be granted. An approved no cost extension also necessitates an additional annual progress report for the Director.

The following process for requesting a no cost extension **must** be followed to be considered:

 A letter or email, requesting a no-cost extension for a period of no more than 12 months following the official closing date of the grant should be sent to the CTSI using trnsldev@iu.edu and MUST BE RECEIVED BY THE THIRD MONDAY IN APRIL of the year the final account will be closing.

- 2. Details of what to include in a no cost extension request may be found here: https://indianactsi.org/translational-research-development/no-cost-extension/
- 3. The Indiana CTSI will notify Directors whether the request was approved and if approved, a contract amendment from the ISDH to the representative institution will be initiated. This amendment must be signed and returned with an original signature prior to the official closing date of the grant.