INDIANA TRAUMATIC SPINAL CORD & BRAIN INJURY RESEARCH GRANT PROGRAM

AN INITIATIVE FUNDED BY THE

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

Submission Deadline: December 1, 2020

PLEASE BE ADVISED THAT THIS IS CONSIDERED AN EXTERNAL GRANT AND SHOULD BE ROUTED AND SIGNED BY THE APPROPRIATE INSTITUTIONAL OFFICIAL PRIOR TO UPLOADING

For IU / IUPUI / IUSM this means it must be routed through ORA
For Purdue and Notre Dame follow appropriate procedures

Please note that you will be submitting through the Indiana CTSI's grants management software WebCAMP. Please allow enough time to be familiar with this system.

The WebCAMP user's guide is also available under the funding announcement here:
https://indianactsi.org/translational-research-development/open-funding-opportunities/

For questions contact judrisco@iu.edu / 317-278-2822

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. These funds will be utilized 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) as it pertains to spinal cord 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 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) as it pertains to 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 (not more than fifty percent (50%) of money in the fund may be used for purposes of developing a statewide trauma system.

This application package is designed for all researchers wishing to submit proposals for research projects / programs to be funded under item 3 noted above. *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 scientific advisory panel. This advisory panel will review proposals for scientific merit only, 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 traumatic spinal cord and brain injury.*

The overall objective of this program is to foster and encourage research for the prevention, treatment and cure of traumatic spinal cord and brain injuries, including acute management, medical complications, rehabilitative techniques, and neuronal recovery. Collaborations are encouraged between Indiana-based researchers as well as with researchers located outside the state of Indiana, including researchers in other countries. Even though the Indiana statute encourages collaborations with researchers outside of Indiana, the primary research should be Indiana-based. Collaborations can be between Principal Investigators (PIs) at the same institution, different institutions, or a PI and a company. Salary support for collaborators outside of Indiana will be limited. Research must be conducted in compliance with all state and federal laws.

Because the nature and scope of the research proposed may vary, it is anticipated that the size of each award may also vary. Awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications. Applications to this program are considered small grants and should include only those expenses directly applicable to the research. M**aximum requested amount:**

- Basic science proposals may request up to $80,000 per year for two years
- Clinical research proposals (i.e. involving human subjects, human biological samples, or data from human subjects) may request up to $100,000 per year for two years
- Early commercialization proposals targeting new technologies (i.e. diagnostic or therapeutic drugs / devices) may request up to $100,000 for one year

(Note: funding is incremental and dependent upon adequate progress reports which will be reviewed and approved by the ISCBIRB.)

Priority will be given to:

- Junior investigators (within 5 years of their last training period at the time of submission)
- Researchers embarking on a new research direction
- Returning investigators whose prior awards have resulted in demonstrable movement along the translational spectrum (e.g. from in vitro to in vivo) and/or led to extramural research support
- Early commercialization research that is reasonably expected to lead to future funding (SBIR/STTR, private investment)

ELIGIBILITY

Eligible lead Institutions / organizations 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.
A small business applying for funding under this mechanism for commercialization of a product / device must be eligible to apply for an NIH SBIR (see https://sbir.nih.gov/about/eligibility-criteria)

Eligible principal investigators must be based in Indiana and have the education, skills, knowledge, and resources necessary to carry out the proposed research. This is typically commensurate with a position of Assistant Research Scientist or above. Postdoctoral fellows are also considered eligible to apply if approved to serve as a PI by the institution's central research office. Collaborations with other individuals and institutions throughout the United States and internationally are allowed, but a single communicating principal investigator must hold an appropriate position in the State of Indiana.

RESTRICTIONS / ALLOWABLE EXPENSES

1. Successful applications will be relative to the topic of traumatic spinal cord and brain injury and have high scientific merit. Ischemic injury is not an appropriate topic for this mechanism.
2. The principal investigator(s) must be employed by an Indiana-based research institution / organization.
3. Requested grant funding period cannot exceed 24 months.
4. Budget request may not include indirect costs.
5. 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 unless directly necessary to accomplish one or more specific aims of the project.
6. PI salaries and publication fees are deemed allowable expenses.
7. All PIs who have received prior ISCBIR funding are eligible, depending on the demonstrable progress from the prior awards.

APPLICATION SUBMISSION PROCESS AND AWARD TIMELINE

Applications will be considered one time per year. **Submission due date is December 1, 2020.**

Applications will be reviewed in early 2021. Awards will be announced in April 2021 and the contracts distributed thereafter. Therefore, the start date of the project period must be no earlier than July 1, 2021.

Application forms are available at http://www.in.gov/isdh/23657.htm OR **CTSI ISCBIR Link**

Application submission via the "Start a submission" here: CTSI ISCBIR Link

For questions about this program, areas of emphasis including commercialization, and submitting a competitive application, please contact Julie Driscol at the Indiana CTSI (judrisco@iu.edu; 317-278-2822).

APPLICATION FORMAT

Applications should be single spaced on 8 ½ x 11 white paper with at least 0.5 inch margins and not to exceed **12 pages,** including figures and tables. 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, principal investigator and his/her institutional affiliation, where work will be performed, and the total budget. Signature of the Institutional Officer signifies approval and support of the time and effort specified by the PI on the application.

FOR IU/IUPUI/IUSM PIs: PI MUST FILE APPLICATION AFTER RECEIVING INSTITUTIONAL SIGNATURE.

Pages 2-3 **Budget pages**: Lists 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 (limit justification to 1/2 page for each budget year).

Page 4 **Abstract & Keywords:** Provide a brief (one paragraph) summary of your project and five (5) keywords that describe the research content of your project

Priority Application: If you are applying for priority consideration (see page 1) include up to one-half page describing why you are eligible (e.g. for research embarking in a new direction provide a description of your previous research and your new focus.)

Page 5 **Specific Aims:**
State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Pages 6-11 **Research Strategy:**
The **Research Plan** should ***not exceed 6 pages*** and should address the project period

and funding requested, show the scope of the overall project and justify how the proposed project will aid in finding a treatment or cure for traumatic spinal cord and brain injury. It is to the applicant's advantage to focus and establish priorities for the proposed project period. These priorities should be made clear in all relevant sections of the Research Strategy.

Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading – **Significance**, **Innovation**, **Approach**. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section.

A. <u>Significance</u>:

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
- For commercialization projects, describe the critical unmet medical need and how the technology / device addresses that need and the commercial potential.

B. <u>Innovation</u>:

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.
- For commercialization projects describe how this new product or service fits within the current market structure (e.g., first in class, improvement upon current products or services)

C. <u>Approach</u>:

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.
- Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- **For early commercialization projects, indicate any participation in a university or federally funded commercialization program that provided guidance for the**

development of ideation, market analysis, and / or business model development.

- If the study(s) involves human subjects, you are expected to explain how relevant biological variables are important to the proposed experimental design and analyses. The sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion on inclusion and justify the proposed proportions of individuals (such as males and females) in the sample.
- If the study(s) involve human subjects or vertebrate animals, explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.
- For early commercialization projects, describe the critical success factors for development of the new product including the time frame required for successful commercialization of the envisioned product.

NOTES:

- For multiple Specific Aims, the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.
- Include preliminary studies, data and or experience pertinent to this application in one of the above-mentioned sections.

Page 12 **Future Directions**: Briefly describe planned next steps for the data from this project (e.g. an R type grant / SBIR / STTR, clinical trial, etc.)

References

Additional Required Pages (not included in proposal or appendix total)

Prior Submission (1 page): If you have previously been awarded any ISCBIR funding or your current project was previously submitted to the ISCBIRF funding mechanism you **MUST** address one of the scenarios below on a single page:

- Funded projects: For PIs with previously funded ISCBIR projects, you must address the overlap or the lack of overlap to this current project as well as providing a summary of the previously funded project's progress to date. Discuss whether this is a new direction for your science or whether this is an extension of your previous work and how it builds on prior awards.
- Unfunded projects: For PIs with previously submitted, unfunded, projects, you must address how this proposal has been revised / is different from, the previously submitted application(s).

Facilities (1 page): Describe the facilities available for this project including laboratories, clinical resources, office space, animal quarters, etc. List major items of equipment available for this work.

Collaborative Arrangements (1/2 page): If the proposed project requires collaboration of the PI with other investigators, describe the collaboration and provide evidence to assure the reviewers that the other collaborators agree to the arrangements (letters of support in the appendix).

Protection of Human Subjects and/or Vertebrate Animals: The appropriate details, where applicable, must be addressed. If unclear what to address in this section please see below*. Commercialization projects may indicate NA if not applicable.

Biographical sketches: Principal investigator and any senior / key personnel in the NIH format (5-page maximum for each individual).

Other Support: Principal investigator and any key personnel that are relevant to the proposed project; 3- page maximum for each individual.

Additional Appendices: Up to six additional pages**,** are allowed and may contain such items as letters of agreement from collaborators, letters of support from inside / outside the applicant institution, and additional scientific materials.

***Detailed Requirements for Protection of Human Subjects and/or Vertebrate Animals**

Human Subjects

1. *Risks to the subjects*
   a. Human subjects involvement and characteristics
   b. Sources of material
   c. Potential risks

2. *Adequacy of protection against risks*
   a. Recruitment and informed consent
   b. Protection against risk

3. *Potential benefits of the proposed research to the subject or others*

4. *Importance of the knowledge to be gained*

Vertebrate Animals

1. *Description of Procedures*. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the "Research Strategy" section. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed provide the source of the animals.

2. *Justifications*: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro).

3. *Minimization of Pain and Distress*: Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain, and injury.

4. *Euthanasia*: State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

REVIEW PROCESS

A copy of the review criteria may be found here: **ISCBIR Review Criteria**

Final funding decisions remain with the ISCBIRB and will be based upon the recommendations of the review committee, in addition to the funding priorities (see page 3):

POST AWARD REQUIREMENTS

1. Complete an annual progress report during each of the two years of the award.
2. Complete a progress report annually for five years following the completion of funding. (Please note: If a one year no cost extension is given, then the project will require an additional progress report.)
3. Present ongoing work / findings to-date at a poster session during the ISCBIR Board annual meeting
4. Notify the ISCBIR Board in writing if you leave your institution before the project is complete
5. Obtain prior approval from the ISCBIR Board for the project to be transferred to another PI.
6. For basic science and research proposals: the PI will submit at least 1 grant application and 2 peer-reviewed publications – generally reported on the annual progress reports which occur 2+ years following completion of study.
7. For commercialization projects: the PI will complete the customer discovery program (e.g,. IU Quarry, Notre Dame Commercialization Engine or Purdue Foundry) from an appropriate academic institution and submit for an SBIR / STTR. The PI or company will submit at least one SBIR / STTR grant application within 2 years of completion of the study.

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

NO COST EXTENSION REQUEST PROCESS

The ISCBIR will only consider a no cost extension **IF IT IS RECEIVED BY NO LATER THAN 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. Approval of a no cost extension also necessitates an additional annual progress report for the PI.

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

1. 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 NO LATER THAN THE THIRD MONDAY OF 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 PIs 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.