

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

Open in September

Submission Deadline: December 8, 2017 (5:00 PM)

Review late January / early February

**PLEASE BE ADVISED THAT THIS IS CONSIDERED AN EXTERNAL GRANT AND
SHOULD BE ROUTED AND SIGNED BY THE APPROPRIATE INSTITUTIONAL
OFFICIAL PRIOR TO UPLOADING BY DECEMBER 8, 2017**

For IU/IUPUI this means it must be routed through ORA

Please contact the Indiana CTSI via icreate@iu.edu with questions

June 2017

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) fulfilling the duties of the board; and 3) funding research related to treatment, cure, and prevention of traumatic spinal cord and brain injuries.

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 with a **maximum requested amount of up to \$80,000 per year for basic science proposals and up to \$100,000 for proposals with research involving living human subjects.** All applications should be limited to a two-year duration. (Note: funding is incremental and dependent upon adequate progress reports which will be reviewed and approved by the ISCBIRB.)

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.

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.
6. PI salaries and publication fees are deemed allowable expenses.

APPLICATION SUBMISSION PROCESS AND AWARD TIMELINE

Applications will be considered one time per year. **Submission due date is Friday, December 8, 2017 at 5:00 pm.** Applications will be reviewed in early 2018. Awards will be announced by April 2018 and the contracts distributed thereafter. Therefore, the start date of the project period must be no earlier than July 1, 2018.

Application forms are available at <http://www.in.gov/isdh/23657.htm> or www.indianactsi.org/grants

Application submission: Upload online at www.indianactsi.org/grants.

For questions about this program, please contact Julie Driscoll at the Indiana Clinical and Translational Sciences Institute (CTSI) (jdrisco@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.

NOTE:

- If an application is not received five business days prior to the deadline it is assumed the principal investigator has waived administrative review rights; consequently, the proposal may be subject to administrative withdrawal if not compliant with guidelines.
- If font and formatting specifications are not followed, the application processing will be delayed or the application may be disapproved for review.

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 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:** Provide a brief (one paragraph) summary of your project

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. Significance:**
- 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.

B. Innovation:

- 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.

C. Approach:

- 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.
- 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.
- If your 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.
- 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.

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. collaboration with another PI; an R type grant; a foundation grant, etc.)

NOTE: Applications exceeding this page limit may be excluded from review.

- **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.
- **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).

Senior / Key Personnel listing

References

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 page 9 below*.

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

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.

REVIEW CRITERIA AND SCORING SYSTEM

- **Significance:** Does the project address an important problem or a critical issue in spinal cord

and/or brain injury research? If the project is successful and yields pilot data, how likely is it to attract federal funding for continuation or develop IP? What new information or important advance will result? Will the results ultimately have impact on human health and clinical outcomes?

- **Investigator(s):** Is the PI (and collaborator if proposed) well suited and well trained for the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? Note: Lower/better scores should not be given to established investigators in comparison to new investigators, simply because of the length of their research career. Each investigator should be judged respective to the single, applicable question noted above - based on the evidence provided in the application. If a collaboration is proposed, does it add significantly to what could be accomplished by one of the partners alone?
- **Innovation:** Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?
- **Approach:** Are the overall strategies, methodologies, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are the specific aims of the project appropriate for generating data that will result in external funding, IP, and/or improvement in human health or treatment outcomes? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
- **Environment:** Will the scientific / clinical environment in which the work will be done contribute to the probability of success? Does the collaboration, if proposed, provide an interdisciplinary dimension or synergistic interaction that significantly enhances the potential outcomes of an award? Are the institutional support, equipment and other physical resources available to the investigator(s) adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Are any logistical problems related to any collaboration adequately addressed?

These criteria are not scored, but considered in the scope of the overall application:

- **Budget:** Does the budget look reasonable? Are expenditures in line with the guidelines?

The NIH scoring system defined below will be used for the scored criteria and the overall impact score

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

<p>Minor Weakness: An easily addressable weakness that does not substantially lessen impact</p> <p>Moderate Weakness: A weakness that lessens impact</p> <p>Major Weakness: A weakness that severely limits impact</p>

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

1. Documentation of productivity or results on prior projects if a PI was previously funded
2. If a number of meritorious applications are received, those applications that represent research from previously unsupported investigators will be given priority

POST AWARD REQUIREMENTS

1. Complete a six month progress report during each of the two years of the award. Funding from this award is incremental and based on invoices accompanied by approved progress reports.
2. Complete a progress report annually for two 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. Request approval from the ISCBIR Board for a revised budget if expenses in a particular area of the project become 25%+ more or less than originally budgeted (as per NIH guidelines)
7. The PI will submit at least 1 grant application and 2 publications – generally reported on the annual progress reports which occur 2 years following completion of study.

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

NO COST EXTENSION REQUEST PROCESS

The ISCBIRF Board will only consider no cost extension requests that are made three months prior to account closure. 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 by the ISCBIRF Board 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 icreate@iu.edu and must be received at least three (3) months prior to the official closing date of the account. Approvals cannot be granted via email and must be approved at a Board meeting
2. Details of what to include in a no cost extension request may be found here: <https://www.indianactsi.org/funding/no-cost-extension/>
3. The ISCBIR Board 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.

***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.