INDIANA SPINAL CORD & TRAUMATIC BRAIN INJURY RESEARCH FUND GRANT PROGRAM

AN INITIATIVE FUNDED BY

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

Submission Due Date: December 9, 2016 (5:00 PM)

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 9, 2016

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

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

September 2016

INFORMATION FOR APPLICANTS:

GENERAL

The state of Indiana established the research fund known as the Indiana Spinal Cord and Brain Injury Research Fund (ISCBIRF) 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 spinal cord and brain injuries. The fund is expected to generate approximately $1.6 million per year, with the majority of money generated to be allocated to research projects.

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 Fund Board, consisting of eight 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 Indiana Spinal Cord and Brain Injury Research Fund Board with regards to Spinal Cord and Traumatic Brain Injury.*

The overall objective of this program is to foster and encourage research for the prevention, treatment and cure of spinal cord and traumatic 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.** 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 ISCBIRF Board.)

WHO MAY APPLY

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. *They must also not have been awarded more than 2 ISCBIRF grants during a 6-year time period.*

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 spinal cord and traumatic brain injury and have high scientific merit.

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.

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 <u>not</u> *scored*, but considered in the scope of the overall application.

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

Human and animal subjects or biohazards. Have the required regulatory approvals been submitted and/or approved?

Previously funded ISCBIRF grants. What were the accomplishments of previously

funded ISCBIRF grants?

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
Minor Weakness: An easily addressable weakness that does not substantially lessen impact **Moderate Weakness:** A weakness that lessens impact **Major Weakness:** A weakness that severely limits impact			

MECHANISM FOR SUBMISSION OF APPLICATION

Applications will be considered one time per year. **Submission due date is Friday, December 9, 2016 at 5:00pm.** Applications will be reviewed in January. Awards will be announced in February 2017, and the contracts distributed shortly thereafter. Therefore, the start date of the project period must be July 1, 2017.

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

For questions about this program, please contact Julie Driscol at the Indiana Clinical and Translational Sciences Institute (CTSI) CREATE Program (icreate@iu.edu; 317-278-2822).

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

Format Specifications.
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.

Please Note: Applications not following the formatting guidelines may be excluded from review.

Applications will follow this 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.

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 spinal cord and traumatic 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.

If an applicant has multiple Specific Aims, then 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.)

Additional Required Pages (not included in appendix total)

Prior Submission (1 page): If you have previously been awarded any ISCBIRF 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 any previously funded ISCBIRF 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 any previously submitted projects to the ISCBIRF mechanism, that were not funded, you must address how this proposal has been revised / is different from the previously submitted application.

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 (if applicable address the following points)

1. Risks to Human Subjects

a. Human Subjects Involvement, Characteristics, and Design

- Describe and justify the proposed involvement of human subjects in the work outlined in the Research Strategy section.

- Describe the characteristics of the subject population, including their anticipated number, age range, and health status, if relevant.

- Describe and justify the sampling plan, including retention strategies and the criteria for inclusion or exclusion of any subpopulation.

- Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that 'prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.

- If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subjects protection, describe and justify the selection of an intervention's dose, frequency and administration.

- List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data from the site(s) will be obtained, managed, and protected.

b. Sources of Materials

- Describe the research material obtained from living individuals in the form of specimens, records, or data.

- Describe any data that will be collected from human subjects for the project(s) described in the application.

- Indicate who will have access to individually identifiable private information about human subjects.

- Provide information about how the specimens, records, and/or data are collected, managed, and protected as well as whether material or data

that include individually identifiable private information will be collected specifically for the proposed research project.

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c. Potential Risks

- Describe all the potential risks to subjects posed by participation in the research (physical, psychological, financial, legal, or other), and assess their likelihood and seriousness to the human subjects.

- Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research.

2. Adequacy of Protection Against Risks

a. Recruitment and Informed Consent

- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.

- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver.

b. Protections Against Risk

- Describe planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness.

Vertebrate Animals (if applicable address the following points):

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.

Biographical sketches: Principal investigator and any senior / key personnel in newly published 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.

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

POST AWARD REQUIREMENTS

1. Complete a six month progress report during each of the two years of the award.

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 ISCBIRF Board annual meeting

4. Notify the ISCBIRF Board in writing if you leave your institution before the project is complete and/or if the project is transferred to another PI.

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.

2. The letter or email should:
   - State that no additional funds are being requested.
   - Describe the progress to date
   - Justify the need for an extension and briefly describe the plan for completing the project within the time frame requested (up to 12 months)

3. The ISCBIRF 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.