CHRISTOPHER & DANA REEVE FOUNDATION
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spinal research
Curing paralysis together

Pre-Clinical Research Request for Applications

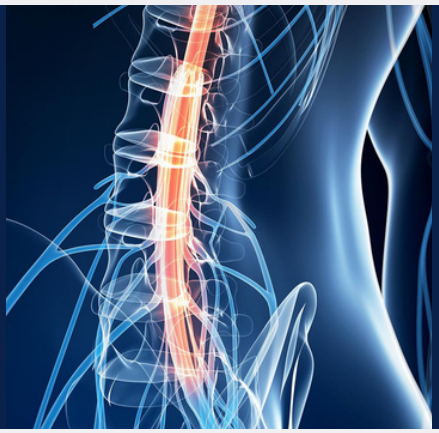
The Christopher & Dana Reeve Foundation and Spinal Research have partnered to fund pre-clinical research applications on paralysis caused by traumatic spinal cord injury in support of the mission of both organizations.

Request for Application (RFA) Overview
A critical step in the translational pipeline is that between discovery and Investigational New Drug (or Investigational Device) enabling studies. Therefore, this request for applications (RFA) encompasses early pre-clinical (non-human) to translational research to support pre-IND or pre-IDE studies in traumatic spinal cord injury (SCI).

Our goal is to promote an understanding of a proposed therapeutic that will encourage continued engagement and support to prepare for the next stages of scientific research and development. Studies of new or repurposed drugs and biologics, and non-clinical research for medical devices, gene therapy approaches, of neuroprotection, regeneration and plasticity are within the scope of the RFA. Full drug screens, IND enabling studies or clinical research are outside the scope of this RFA.

Deadlines

- RFA open: October 31, 2024
- Informational Webinar: November 12, 2024, 11AM ET
- Letters of intent due: December 12, 2024, 5PM ET
- Full grant application invitations: January, 2025 (deadline forthcoming)
- Full grant applications due: March 2025 (deadline forthcoming)
- Anticipated award announcement: June 2025
- Anticipated funding: August 2025



Please note: Applicants are encouraged to apply early in the event of issues with the submission process. Program staff will be unable to respond to queries in the two days prior to an application deadline; all queries must be sent prior to that time. Please do not request updates from program staff prior to timelines delineated above.

Pre-Clinical Research RFA Description

This RFA supports pre-clinical (non-human) research of new or repurposed drugs and biologics in the areas of neuroprotection, regeneration and plasticity, at the pre-IND or pre-IDE development stage. This RFA does not encompass full drug screens, IND/IDE enabling studies or clinical as the costs are beyond the scope of this RFA.

Suggested areas of focus (applicable areas for drugs, biologics and devices are within the scope of this RFA):

- Pre-clinical in vitro and/or in vivo studies.
- Assay development (including target based assays for drug screening, target engagement and potency assays), lead candidate optimization, studies confirming mechanism of action, evidence of target engagement and selectivity for spinal cord injury relevant mechanisms of action potency, selectivity screens, mechanistic studies, evidence on blood spinal cord penetrance.
- Proof of concept studies validating potential benefits of a therapeutic strategy in pre-clinical spinal cord injury models.
- Dose, timing, non-GLP toxicology, pharmacokinetics and pharmacodynamics, biomarker development in preclinical spinal cord injury studies.
- Medical devices in similar pre-clinical development stages and areas of focus (including benchtop studies).

Phenotypic drug development/targets will be considered if a mechanistic rationale is provided.

Pre-Clinical Research RFA Description

Eligibility and Requirements

- The Primary Investigator (PI) must have a doctoral degree or equivalent terminal professional degree (e.g. MD, DVM) and must be beyond the postdoctoral level.
- PIs from academic or private institutions or companies from any country may apply. Industry and academic partnerships are encouraged.
- A single PI must be identified who is responsible for the application, communications, and research conduct. Sub-investigators are allowed.
- PIs may only submit one application.
- Only one submission will be accepted from the same lab or company.
- Financial relationships of the PI with a corporate applicant must be disclosed.
- Industry and academic partnerships are encouraged for necessary drug development expertise.

Funding/Budget

- Duration: 1-2 years
- Amount: Up to $250,000
- All budgets must be in USD.
- Subcontracting to contract research organizations (CROs) is allowed and encouraged particularly where needed expertise is not otherwise available. Resources for CROs may be found at the NIH Blueprint website.

The total budget includes direct and indirect costs. Indirect costs are limited to 10% of the total budget.

Pre-Clinical Research RFA Description

Data Sharing and Publication

- Open access publications are encouraged and funds may be allocated within the budget for this purpose.
- Open data sharing of non-intellectual property is required and a plan for data sharing is part of the application process. If patent protection is being sought, investigators should explain what data may be shared at the time the grant is completed and how data will be shared after filing for patent protection to allow for both further research and the development of commercial products to advance.
- Any data repository may be used as long as FAIR (Findability, Accessibility, Interoperability, Reusability – Wilkinson et al., 2016, DOI: 10.1038/sdata.2016.18) share principals are observed. Investigator are strongly encouraged to set up data in a way that supports data sharing The Open Data Commons for SCI (an option for data sharing) has general guidelines for preparing data for sharing, which can be applied to other data bases.

Additional Requirements

- All applications must be in English with budgets in US dollars.
- Awards will be milestone based and subsequent funding will be contingent upon successful milestone completion. As drug discovery and development are high-risk, if awarded, milestones and communication will be frequent (no less than every six months) to enable problem solving between the PI and funding agencies and their experts. Continued funding is based on successful achievement of milestones or identification of alternative strategies. However, the Reeve Foundation and Spinal Research will work with applicants and provide expert resources where possible to address challenges that may arise.
- Intellectual property will be held by the grantee/organization undertaking the research.

Pre-Clinical Research Submission Process

This RFA will be a two-stage process with an initial LOI submissions and review, followed for an invitation only full grant application process.

All LOIs must be submitted through our online portal at: Pre-clinical RFA online submission portal . We strongly encourage applicants to view the screens in the online portal system before beginning a LOI. All communications and correspondence will be sent to the identified PI.

All submissions undergo an administrative and scientific review by individuals under a confidentiality agreement.

Applicants should ensure that submitted proposals fit the goals of the funding program, are clearly and logically written, with sufficient details to ensure that reviewers understand all critical aspects of the proposed project methods and plan. Given the length of the LOI (approximately two pages) it is not possible to provide the full scope of the methodological details but sufficient detail to assess strategy should be provided.

For questions about the letter of intent application process and the online system please contact Maria Fonseca, Grants Associate at FoundantHelp@Reeve.org. For questions about the scope of the application, please contact Linda Jones, PT, PhD, Reeve Senior Scientific Director Consultant at LJones@Reeve.org. Please note questions must be sent no later than 48 hours prior to the submission deadline.

The following sections are included in the online LOI:

Administrative Section (Required)

Applicant details, high level information on therapeutic, project team and budget summary. See online for details.

Pre-Clinical Research Submission Process

Letter of Intent Summary (Required)

Please label each section in the LOI summary section (10,000-character limit) per headings below and address the requested information under each heading.

Impact: Indicate how a successful outcome of the proposed plan would lead to future development efforts, including ultimate goals and estimated timeline for moving the therapeutic into the next stage of development.

Indication: Describe whether the proposed therapeutic is intended to address neuroprotection, regeneration, and/or plasticity, at what stage of SCI, and in what target SCI population (if known, e.g. severity, level of injury).

Therapeutic: Describe the specific therapeutic being developed, the mode of action, and how the therapeutic was identified. Please identify the strengths and weaknesses of the proposed therapeutic.

Target: Indicate the biological target and hypothesized mechanism and pathway for which you propose to develop a traumatic SCI therapeutic. If available, provide evidence of target engagement.

Stage of Development: Describe the current stage of development of the proposed therapeutic (e.g., high-throughput screening, hit-to-lead, lead optimization, or pre-clinical drug candidate nomination) and discuss relevant data (preclinical and/or clinical) that justifies the progression of the therapeutic to the next development stage (e.g., bioavailability, PK/PD relationships, safety). For drugs, as a guidance, you may refer to the Optional Appendix (Therapeutic Template Profile) Studies to collect gaps in the data can be proposed as part of your application.

Development Plan: Describe and justify the study(ies) you wish to complete to move the proposed therapeutic forward. How do these studies fit into the big picture of developing a therapeutic for persons with SCI?

Pre-Clinical Research Submission Process

IP/Competitive Landscape: Describe any intellectual property considerations and/or restrictions that may impact how further development of the proposed therapeutic will proceed (e.g., the existence of competing technologies or legal barriers to commercialization). Please note that if invited to submit a full grant application (FGA), applicants must describe what data can be shared considering IP.

Appendix (Optional)

This section contains a Therapeutic Template Profile which is optional for relevant therapeutics including for small molecules and antibodies (not needed for all types of therapeutics). You may complete any portion of this form for which you have information. Data for this section which has not yet been obtained, could be part of the requested funding.

Review criteria for Letters of Intent include the following:

Impact: Does the proposed therapeutic have the eventual potential to impact people living with SCI? Is it innovation or is it the critical next step in the development process?

Target viability: Is there supportive biological rationale/evidence for target viability and applicability in SCI?

Stage of Development: Does the investigative team have an understanding of the current stage of development and where that fits within a drug/biologic/device development pathway? Are the gaps in knowledge about the therapeutic agent understood? Are next steps elucidated?

Development plan: Are the proposed studies appropriate for development stage and feasible within a two-year award?

Intellectual Property: Are there significant barriers to IP?

Team: Does the proposed team have the knowledge and ability to execute next stages of drug therapeutic development?