

2021 APPLICATION GUIDE

SCI RESEARCH ON THE TRANSLATIONAL SPECTRUM

Craig H. Neilsen Foundation



This guide provides information on the Spinal Cord Injury Research on the Translational Spectrum (SCIRTS) grants. It is the Principal Investigator (PI)/Fellow/Applicant's (hereafter referred to as "Applicant") responsibility to carefully review the current application guide. Submissions that do not adhere to the most current guidelines, deadlines and/or required documentation will be disqualified without review.

CURRENT DEADLINES	
May 11, 2020 5:00 p.m. (Eastern Time)	Letter of Intent (LOI) Due via proposalCENTRAL
August 2020	Notification of LOI Results
October 14, 2020 5:00 p.m. (Eastern Time)	Full Grant Application (FGA) Due via proposalCENTRAL
March 2021	Notification of FGA Reviews
June 2021	Grant Awards Announced
July 2021	Awarded Grants to be Funded

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PART 1: OVERVIEW OF FUNDING

A. About the Neilsen Foundation

Established in 2002 as a private foundation, the Craig H. Neilsen Foundation is dedicated to spinal cord injury (SCI) research and quality of life programs for people living with SCI. Mr. Neilsen lived with a high level spinal cord injury for 21 years until his passing in 2006. He was a visionary with an entrepreneurial spirit who led his companies with inexhaustible passion. Craig Neilsen wanted his foundation to contribute in a significant way to SCI research and to offer those with SCI the quality of life they deserve.

Mission

Craig H. Neilsen Foundation's funding is dedicated to supporting both programs and scientific research to improve the quality of life for those affected by and living with spinal cord injury.

Vision

Individuals with spinal cord injuries, and those who care for them, live full and productive lives as active participants in their communities.

Values

Our values are inspired by our Founder, Craig Neilsen, who overcame barriers during his lifetime, empowered others to do the same, and created this organization to impact the field today and expand solutions for tomorrow. We value excellence, leadership, accountability, innovation, and collaboration.

NEILSEN FOUNDATION SCI FUNDING PORTFOLIOS

Research Grants:

- Spinal Cord Injury Research on the Translational Spectrum (SCIRTS): The goal of the portfolio is to address gaps in the field and advance novel approaches to improving function and developing curative therapies after SCI. This research is designed to improve understanding and advance the treatment of acute and chronic SCI and includes mechanistic, preclinical, translational and/or clinical studies.
- Psychosocial Research (PSR): The goal of the portfolio is to develop sound data to inform and disseminate best practices that produce better outcomes, improving quality of life for people living with SCI. This research explores the interrelation of behavioral, social and psychological factors that influence participation, health practice, lifestyle, and support systems in community and clinical settings.

Programmatic Grants:

- Creating Opportunity & Independence (CO&I): The goal of the portfolio is to support organizations that provide programs and services that enhance quality of life for individuals and families living with SCI. These grants cover diverse efforts that include discrete projects, program support and capacity building.

Education Grants:

- Spinal Cord Injury Medicine Fellowships (SCIMF): The goal of the portfolio is to support clinical training and to ensure that a sufficient number of physicians are attracted to the field to meet the needs of patients with SCI. SCIMF grants are awarded to ACGME-accredited programs to train physicians specifically in the field of SCI care.

- Neilsen Scholarship Program (NSP): The goal of the portfolio is to support students with SCI in their pursuit of higher education. Funding to selected academic institutions provides scholarships to qualified students in the curriculum of their choice. The Neilsen Foundation supports tuition and fees, as well as providing supplemental support funds to remove barriers to academic progress related to the students' SCI-associated needs.

Please visit the Neilsen Foundation website at www.chnfoundation.org for application guides, deadlines and information on previously funded grants.

B. SCIRTS Portfolio Funding

PORTFOLIO SPECIFIC OBJECTIVES

The Neilsen Foundation funds projects that are designed to improve and advance current treatments for acute and chronic spinal cord injury. This portfolio emphasizes SCI (vs. spinal cord disease or related disorders) and is intended to fill gaps in the field and to further develop new strategies to restore function resulting from SCI. The Neilsen Foundation does not intend to provide continuous funding to individual labs but to fund novel research throughout the translational spectrum.

SCIRTS Grants support research projects that include, but are not limited to, the following areas:

Mechanistic Research, including the development of novel strategies aimed at:

- Neuroprotection and/or elucidation of the pathological mechanisms that occur after SCI;
- Pathophysiology of the injured spinal cord;
- Promotion of neuronal survival, axonal regeneration, synaptogenesis, myelination, and functional connectivity after SCI;
- Transplantation strategies for SCI recovery;
- Pharmacological therapies to improve function after SCI;
- Bioengineering solutions to improve function in persons with SCI; and
- Chronic SCI treatment and issues related to aging with SCI.

Preclinical, Translational Research that will enable future clinical trials, such as:

- The effects of SCI and novel interventions on sensory and motor function;
- Use of preclinical models of SCI to develop interventions to alleviate complications of SCI including bowel, bladder, sexual and other autonomic dysfunctions, respiratory dysfunction, neuropathic pain, pressure sores, osteoporosis and the effects of aging with SCI; and
- Trial-enabling studies, e.g., to confirm the mechanism of action for novel therapeutics, dosing, toxicity, etc.

Clinical Research, such as:

- Studies to establish the natural history and progression of functional outcomes over time after SCI;
- Efforts to develop and validate outcome measures needed to facilitate definitive clinical trials in SCI populations; and
- Testing of innovative rehabilitation strategies and devices in persons with SCI.

NOTE: Early phase clinical trials of novel investigational drug or cell/biologic interventions under regulation by the U.S. Food and Drug Administration are limited to the Senior Grant category. Postdoctoral fellows may participate in an approved trial supported by the Mentor's other funding.

This Application Guide is intended specifically for the following grant funding categories:

- SCIRTS Postdoctoral Fellowships
- SCIRTS Pilot Research Grants
- SCIRTS Senior Research Grants

C. Eligibility and Other Requirements

ELIGIBILITY

The following applies to all funding categories:

- Applicants must have a doctoral degree or an equivalent terminal professional degree (e.g., PhD, MD, DVM). Non-fellowship applicants must demonstrate appropriate experience to serve as an **independent Principal Investigator (PI)**. The Neilsen Foundation encourages submissions from eligible PIs who represent a wide range of disciplines; however, it is required that **relevant SCI expertise** is represented on the proposed research project team.
- The grantee must be a **nonprofit academic/research institution or rehabilitation facility located in the United States or Canada** with a demonstrated capability to conduct grant-funded research.
- The Applicant is not required to be a citizen of the United States or Canada; however, the Applicant must be employed by an eligible grantee institution.
- Neilsen Foundation grants are not awarded to individuals, private foundations or non-functionally integrated Type III supporting organizations.
- The Applicant named in a grant application must be deemed eligible by his/her organization to apply for a grant and is expected to be responsible for conduct of the research. Each application must include the appropriate endorsement of an institutional official who is responsible for the administration of grant funds (hereafter known as the “Grants Administrator”).
- A PI may submit only one application in a given cycle in this portfolio (see CONCURRENT GRANTS section under PART 2, SECTION F., below).
- The Neilsen Foundation does not allow Co-Principal Investigators on its research grants. If two or more investigators are working together on a research project, one must serve as the PI; the other(s) should be listed as collaborator(s). Collaborators and/or consultants do not need to be affiliated with the same institution as the PI; a subcontract may be used to support a domestic or international collaborator or consultant.
- Multiple PIs from an institution may submit concurrent, independent applications in a given grant cycle. In such cases, each project must be distinct, with non-overlapping Aims.
- The Neilsen Foundation discourages Postdoctoral Fellows and their mentor(s) from submitting concurrent applications *with overlapping Aims* to multiple funding categories within this portfolio.
- It may not be necessary to provide preliminary data. Neilsen Foundation funding may be sought to allow the Applicant to obtain data to establish a line of research if the proposal provides strong rationale (e.g., support from the literature or use in an indication other than SCI) that justifies testing the hypotheses with the proposed experimental design. However, if feasibility issues add an unacceptable risk of failure, reviewers may note that preliminary data to address this risk should be provided.

OTHER REQUIREMENTS

- All application materials and communications (including IRB/IACUC approvals, where applicable) must be written in English and budgets must be in U.S. dollars.
- Applicants should carefully review additional requirements specific to each funding category (see instructions below) to ensure they meet the relevant, specific requirements before submitting either a Letter of Intent (LOI) or Full Grant Application (FGA).
- Grants from the Neilsen Foundation may be multi-year awards. Funding for each subsequent year will be contingent on a favorable review of annual progress and expenditure reports. Approval of final research and expenditure reports will be required at the end of the grant term to receive final payment.
- Perceived or real conflicts of interest must be disclosed in all stages of the application process (e.g., shareholder in a company providing a device for a proposed study or program).
- The grantee organization will retain title to Intellectual Property developed through the study or program/project.
- Human interventional studies funded by the Neilsen Foundation are required to register on [ClinicalTrials.gov](https://clinicaltrials.gov).
- The Neilsen Foundation strongly encourages data sharing and open access. Grantees are asked to make all scientific reports openly accessible (through the journal website or PubMed Central) no later than one year after publication.

SCIRTS POSTDOCTORAL FELLOWSHIPS

Overview:

- This funding is designed to encourage specialization in the field of SCI; Postdoctoral Fellowships are intended to provide mentored training in SCI research to early-career investigators. The Applicant (Fellow) should be mentored (or co-mentored) by an investigator experienced in SCI research.
- Fellows must have attained their doctoral degree or an equivalent terminal professional degree by the LOI submission deadline and have held that degree no longer than five years before the FGA submission deadline. For Fellows with an MD, the five-year eligibility period begins after completion of the residency program.
- Criteria for Fellowships include qualifications of the Fellow, how the training plan and environment provided by the mentor(s) will enhance the Fellow's research career, scientific merit of the proposal, and relevance of the project to the Neilsen Foundation and the SCIRTS portfolio.
- A two-page Training Plan is required when submitting an FGA.
- Funding for each year of the two-year project is up to \$75,000 for a maximum total cost of \$150,000.

Details for This Funding Category:

- Postdoctoral Fellowships are intended to support the Fellow directly. The proposal should be written by the Fellow, with input from the mentor(s).

- **Personnel Costs:** Fellowship budgets should cover 100% of the salary and fringe support for the Fellow. No funding for other personnel (e.g., technical staff) is allowed.
- **Non-Personnel Costs:** The purpose of allowing non-personnel costs in this category is to support the advancement of the Fellow's career. Non-personnel costs may be budgeted to further the Fellow's development in SCI research. The Neilsen Foundation will allow up to \$30,000 over the course of the two-year grant for non-personnel costs, provided the Fellow's salary and fringe are fully covered and total costs do not exceed \$75,000 per year. It is expected that the mentor(s) will make available necessary general office equipment and supplies; however, funds for travel, publication costs, supplies and/or equipment can be expended in the categories listed below.
 - **Travel:** Funds may be used for professional development-related travel for the Fellow. Travel for other personnel is not allowed.
 - **Publication Costs:** Funds may be used to develop the Fellow's manuscript preparation skills. Publication costs are allowed where the Fellow is a contributing author. Allowable costs include open-access fees.
 - **Supplies:** All items (e.g., glassware, chemicals, animal costs, electrodes, etc.) other than those described below in Equipment are allowed. A computing device or computer software is considered a supply if the acquisition cost is less than \$5,000, regardless of the length of its useful life.
 - **Equipment:** An item having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit is considered equipment. All requests must be justified by including a description of how the piece of equipment will support the advancement of the Fellow's career.
- **Indirect Costs:** The Neilsen Foundation does not allow indirect costs (i.e., administrative, overhead, per capita infrastructure costs, etc.) on its Postdoctoral Fellowships.

SCIRTS PILOT RESEARCH GRANTS

Overview:

- This funding is intended to support pilot studies that lay essential groundwork, allow the PI to test the feasibility of novel methods and procedures and/or collect new data that can lead to or enhance larger-scale studies.
- Applicants must have a doctoral degree or other equivalent terminal professional degree and hold an independent faculty position beyond the postdoctoral level (i.e., Instructor, Assistant Professor or equivalent research position) at the time of the FGA submission.
- Criteria for Pilot grants include the scientific merit of the project, the innovative nature of the proposed research and the likelihood that success will move the SCI field forward.
- Funding for each year of the two-year project is up to \$150,000 for a maximum total cost of \$300,000.

Details for This Funding Category:

- Applicants must be independent investigators, actively employed at the grantee institution at the time of FGA submission, and can be at any stage of their research career.

- Junior investigators should demonstrate evidence of a strong research background that is relevant to the proposed study. As independence is an important component for investigators who are not in a tenure track position (e.g., Instructor, Research Assistant, etc.), a letter of support from the institution's Director or Department Chair is recommended at the LOI and FGA stage. The letter should indicate that the applicant is an independent investigator and that necessary space and equipment are available for this research.
- Established investigators' proposals should demonstrate a new direction in SCI research that is considered "high risk" balanced by high potential impact. While new directions may be explored in both Pilot and Senior categories, in cases where preliminary evidence is being developed to show that new approach is worth pursuing, a Pilot grant is the appropriate category.

Allowable budget categories include:

- PI Salary: The amount requested for the PI's support (salary plus fringe benefits) may be up to 25% of the total yearly cost of the grant.
- Collaborator(s): A collaborator is an individual who will make a significant contribution or play a significant role in the conduct of the research project. In most cases, the collaborator provides certain expertise, such as a specific type of SCI research experience. Collaborators do not need to be affiliated with the same institution as the PI; a subcontract may be used to support a collaborator at a different institution. Collaborators named in the proposal may be paid or unpaid. If paid, the total amount requested for each collaborator's support (salary plus fringe benefits) should not exceed 10% of the total yearly cost of the grant. Support for collaborators beyond this limit may be requested, with strong justification.
- Other Personnel: This category includes other key project staff (e.g., project coordinator, statistician, community interviewer, etc.) who will contribute directly and substantively to the project. There is no restriction on the percentage of salary support for other positions. Calculation of fringe benefit rates exceeding 40% of salary must be fully explained. The Neilsen Foundation does not fund graduate student tuition or fees; however, stipends/salaries for graduate students can be included.
- Consultants: Consultant costs are allowed, and there is no limit on the amount requested. Consultants are generally independent contractors who offer advice or work on specific aspects of a project for a limited period of time.
- Subcontractors: A subcontract may be established by the grantee institution with another site to carry out selected activities of the proposed project. If a subcontract is included in the grant, the combined indirect cost amount for the PI's institution *and* the subcontractor's institution may not exceed 10% of the total cost of the grant.
- Supplies: All items (e.g., glassware, chemicals, animal costs, electrodes, etc.) other than those described below in Equipment are allowed. A computing device or computer software is considered a supply if the acquisition cost is less than \$5,000, regardless of the length of its useful life.
- Equipment: Requests for equipment are not encouraged but are allowed if justification is provided. Equipment cannot exceed \$10,000 for the two-year project. An item having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit is considered equipment.

- **Travel:** Support for conference travel is limited to \$6,000 during the grant term. Adequate justification is required for any additional project-related travel support (e.g., research participant travel, travel to a collaborating site, etc.).
- **Publication Costs:** Up to \$4,000 is allowed during the grant term. Allowable costs include open-access fees.
- **Indirect Costs:** The maximum amount allowed for indirect costs (i.e., administrative, overhead, per capita infrastructure costs, etc.) is 10% of the total cost of the grant. For example, if an applicant requests the maximum funding available, the total *indirect cost* allowed is \$15,000 per year.
- **Per Capita Infrastructure Costs:** These costs cannot be charged as direct costs (e.g., IT, network, communications or other charges not specific to the research Aims); indirect costs may be used to defray these charges, subject to the 10% of the total indirect cost cap.

SCIRTS SENIOR RESEARCH GRANTS

Overview:

- This funding is for individuals who are senior, independent investigators (equivalent to Associate Professor or above), employed at the grantee institution, at the time of the FGA submission.
- The grant category focuses on highly innovative projects by established PIs exploring new areas of SCI research or filling important gaps in the SCI field. The goal is not to substitute for federal funding, but to use Neilsen Foundation funds to encourage cutting-edge ideas and approaches that have great potential, despite some additional risk. The importance of the research goal should balance the risk due to the early stage of innovation.
- Criteria include the innovative nature of the proposed research, the likelihood that success will move the field forward, and a history of productivity and significant contributions by the investigator. Applicants should carefully consider their qualifications and the relevance of their Aims to the Neilsen Foundation before applying for a Senior Research Grant.
- Funding for each year of the three-year project is up to \$200,000 for a maximum total cost of \$600,000.

Details for This Funding Category:

Allowable budget categories include:

- **PI Salary:** The amount requested for the PI's support (salary plus fringe benefits) may be up to 20% of the total yearly costs of the grant.
- **Collaborator(s):** A collaborator is an individual who will make a significant contribution or play a significant role in the conduct of the research project. In most cases, the collaborator provides certain expertise, such as a specific type of SCI research experience. Collaborators do not need to be affiliated with the same institution as the PI; a subcontract may be used to support a collaborator at a different institution. Collaborators named in the proposal may be paid or unpaid. If paid, the total amount requested for each collaborator's support (salary plus fringe benefits) should not exceed 10% of the total yearly cost of the grant. Support for collaborators beyond this limit may be requested, with strong justification.

- **Other Personnel:** This category includes other key project staff (e.g., project coordinator, statistician, community interviewer, etc.) who will contribute directly and substantively to the project. There is no restriction on the percentage of salary support for other positions. Calculation of fringe benefit rates exceeding 40% of salary must be fully explained. The Neilsen Foundation *does not* fund graduate student tuition or fees; however, stipends/salaries for graduate students can be included.
- **Consultants:** Consultant costs are allowed, and there is no limit on the amount requested. Consultants are generally independent contractors who offer advice or work on specific aspects of a project for a limited time.
- **Subcontractors:** A subcontract may be established by the grantee institution with another site to carry out selected activities of the proposed project. If a subcontract is included in the grant, the combined indirect cost amount for the PI's institution *and* the subcontractor's institution may not exceed 10% of the total cost of the grant.
- **Supplies:** All project-related items (e.g., glassware, chemicals, animal costs, electrodes, etc.) other than those described below in Equipment are allowed. A computing device or computer software is considered a supply if the acquisition cost is less than \$5,000, regardless of the length of its useful life.
- **Equipment:** Requests for equipment are not encouraged but are allowed if justification is provided. Equipment cannot exceed \$10,000 for the three-year project. An item having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit is considered equipment.
- **Travel:** Support for conference travel is limited to \$9,000 during the grant term. Adequate justification is required for any additional project-related travel support (e.g., research participant travel, travel to a collaborating site, etc.).
- **Publication Costs:** Up to \$6,000 is allowed during the grant term. Allowable costs include open access fees.
- **Indirect Costs:** The amount allowed for indirect costs (i.e., administrative, overhead, per capita infrastructure costs, etc.) is 10% of the total cost of the grant. For example, if an applicant requests the maximum funding available, the total *indirect cost* allowed is \$20,000 per year (\$60,000 total).
- **Per Capita Infrastructure Costs:** These costs cannot be charged as direct costs (e.g., IT, network, communications or other charges not specific to the research Aims); indirect costs may be used to defray these charges, subject to the 10% of the total cost cap.

PART 2: APPLICATION PROCESS

A. Submission Requirements

For each cycle, the application process begins with an LOI. FGAs will only be accepted from Applicants invited through the most recent LOI competition.

The Neilsen Foundation uses the web-based grants system, proposalCENTRAL (<https://proposalCENTRAL.altum.com>), to review and manage its grants.

TIMELY SUBMISSION

All application deadlines, dates and times are strictly enforced. The online system, proposalCENTRAL, will automatically close at the cycle's stated deadline date and time.

We strongly recommend that you begin the application process in proposalCENTRAL well in advance of all deadlines. *Late submissions will not be considered.*

NOTE: Do not wait until the last day to submit your grant application and any required documentation. Technical difficulties will not be accepted as an explanation for late submissions.

NEILSEN FOUNDATION TEMPLATES

The Neilsen Foundation requires that all Applicants use the most recent templates provided in proposalCENTRAL for the LOI and FGA processes. *It is important to note that Applicants **may not modify** any Neilsen Foundation template.* Examples of disallowed modifications include changing margins, deleting template text (including instructions), changing form font sizes, etc. **If an Applicant modifies or fails to use a current Neilsen Foundation template or exceeds page limits, the LOI or FGA will be automatically disqualified for the current cycle.**

NOTE FOR MAC USERS: All Neilsen Foundation documents are created in Microsoft Word or Excel. Mac users may experience difficulties; it is strongly recommended that Applicants allow ample time to create and submit proposal materials. If you experience difficulty with the templates, contact your local IT support.

PDF ATTACHMENTS

If a document is required to be submitted as a portable document format (PDF) attachment and assistance is needed in converting documents to PDF, select "Download Templates & Instructions" (located in the navigation bar), click on the link at the bottom of the page "Click here for a list of PDF generators" to view "Converting Your Documents to PDFs." If assistance is needed, contact proposalCENTRAL Customer Service at (800) 875-2562 or via email at pcsupport@altum.com.

APPLICANT CONTACT INFORMATION

Contact information entered in proposalCENTRAL must include a current email address for the Applicant.

The Neilsen Foundation relies on contact information located in proposalCENTRAL to contact its Applicants and grantees. In order to receive important updates, it is the Applicant and grantee organization's responsibility to keep his/her proposalCENTRAL contact information current. This includes current information for the organization's grants administrator, signing official and financial officer.

The Neilsen Foundation recommends that Applicants check the "Auto Notify" box in the "Enable Other Users to Access this Proposal" section in proposalCENTRAL, for at least one other contact at the organization. The "Permissions" access level for other contacts can be set as view, edit or administrator.

NOTE: If the contact information in proposalCENTRAL is outdated, and we are unable to contact the Applicant, we will assume that he/she is no longer interested in funding from the Neilsen Foundation. This includes all significant information, from notification of a grant award to reporting deadlines.

INFORMATION CONSISTENCY AND ACCURACY

- Respond to all sections of the templates. If a section or question does not apply to the application, enter “N/A.”
- It is suggested that the Applicant carefully proofread all sections of the LOI or FGA materials for consistency and accuracy before submitting in proposalCENTRAL.
- The Applicant must verify that all PDF documents are legible.
- Inaccurate or incomplete submissions will be disqualified without review.

TECHNICAL ASSISTANCE

For technical questions regarding the online submission process, contact proposalCENTRAL Customer Service at (800) 875-2562 or via email at pcsupport@altum.com, during business hours, Monday–Friday, 8:30 a.m.–5:00 p.m. (Eastern Time). *There is no technical support available on weekends or holidays.*

ProposalCENTRAL also has a tutorial section on its website that may be helpful in completing the application (<https://proposalCENTRAL.altum.com/help.asp>).

B. Letter of Intent (LOI) Submission and Review

DEADLINE

Refer to page one of this Application Guide for the LOI deadline. The proposalCENTRAL online submission system will automatically close at 5:00 p.m. (Eastern Time) on the due date. *Late submissions will not be considered.*

FORMAT

All LOI applications must be submitted online, via proposalCENTRAL. The current LOI template in proposalCENTRAL (<https://proposalCENTRAL.altum.com>) must be used. Further instructions and page limitations will be provided on the LOI template. The Neilsen Foundation LOI template may not be modified by the Applicant. **All original text and formatting must remain on the submitted LOI.**

REQUIRED INFORMATION TO INCLUDE IN THE LOI APPLICATION

- Hypotheses and project Aim(s).
- Overview of the experimental design/methods.
- Relevance to the Neilsen Foundation.
- Brief preliminary budget for the entire project period. At the LOI stage, the budget should be broadly categorized. Eligible project costs, such as personnel, supplies, equipment, travel, etc., should directly support the project Aims.

- The Neilsen Foundation accepts submissions from eligible individuals across a wide range of disciplines; however, it is strongly encouraged that relevant SCI and technical expertise are represented on the project team.
- The PI must submit a Biosketch as described in the FGA section below. For Postdoctoral Fellowships, Biosketches are required for both the PI and mentor(s). Biosketches from any major collaborator who provides essential expertise are not required at the LOI stage but are encouraged. Each Biosketch should be provided as a separate PDF.
- Resubmissions: Applicants are allowed one resubmission of a previously reviewed but not funded FGA. Up to a half-page of additional text may be included at the end of the LOI to respond to reviewer comments; this half-page does not count in the three-page limit.
- A bibliography is not required at the LOI stage. If the PI chooses to provide references, these can be included as a single page appended at the end of the completed LOI template, in one PDF file.

EVALUATION CRITERIA FOR LOI

LOIs will be reviewed based on relevance of the proposed Aims to the Neilsen Foundation, potential impact to the field of SCI research, innovation and specific requirements of the funding category.

See Appendix 1 for a full list of LOI review criteria.

NOTIFICATION OF LOI RESULTS

Applicants will be notified via email whether they are invited to submit an FGA, or if the LOI has been declined. An LOI must be approved by the Neilsen Foundation in order for the Applicant to move to the next step of the grants process, submitting an FGA.

C. Full Grant Application (FGA) Submission and Review

Only Applicants invited to apply through the current cycle's LOI process may submit a FGA. Refer to page one of this Application Guide for the FGA deadline. All FGAs must be submitted online, via proposalCENTRAL. *The proposalCENTRAL system will not allow an application to be submitted until all required documents are uploaded. To check for any missing required information or files before submitting an application, click on the "Validate" button under the "Validate" section (located in the navigation bar).* The proposalCENTRAL online submission system will automatically close at 5:00 p.m. (Eastern Time) on the due date. *Late submissions will not be considered.*

FORMAT

The FGA template in proposalCENTRAL (<https://proposalCENTRAL.altum.com>) must be used. Further instructions and page limitations will be provided on the application templates. The Neilsen Foundation application templates may not be modified by the Applicant. **All original text and formatting must remain on the submitted FGA.**

IMPORTANT NOTICE FOR FGAS

In the proposalCENTRAL online application under Proposal Sections, select "Signature Page(s)" (located in the navigation bar), press the "Print Signature Pages" button and **print only page one (Grant Application) of the PDF file.** Once this page is signed by the PI/Applicant AND the Signing Official, upload the PDF in the "Proposal Narrative & Other Attachments" section.

It is important that the Applicant view the uploaded documents to ensure all PDFs are legible. In the online Proposal Section, return to “Signature Page(s)” and click on the “Print Signature Pages with Attachments” button to view the uploads.

APPLICATION REQUIREMENTS

It is strongly advised that Applicants review additional instructions under Proposal Sections (located in the navigation bar) and templates provided in proposalCENTRAL. Note the following:

Postdoctoral Fellowships

At the FGA stage, Postdoctoral Fellowship applicants must provide: 1) a research plan; 2) a Biosketch for the Fellow; 3) a Biosketch for the mentor(s); 4) a Training Plan; 5) a letter of recommendation from the mentor(s); and 6) two additional recommendation letters.

- Letters of Recommendation

A letter of recommendation from the Fellow’s mentor is required. If the applicant has co-mentors, one letter of recommendation should be provided and signed by both mentors. Two other letters of recommendation must be submitted with the application. It is the Fellow’s responsibility to ensure that the letters of recommendation are submitted by the deadline. The Neilsen Foundation recommends that the Fellow notify his/her references of the deadline and follow up to be sure that the letters are submitted in a timely manner. The proposalCENTRAL system will allow an application to be submitted with only one letter of recommendation uploaded; however, the Neilsen Foundation will not review an application without three reference letters.

- Postdoctoral Fellowship Training Plan

All postdoctoral applications **MUST** include a two-page Training Plan designed to enhance the postdoctoral experience through a program of structured activities focused on acquiring, expanding, and/or enhancing knowledge and expertise in SCI. The plan should delineate activities, opportunities and experiences that align with the Fellow’s long-term career goals. The Fellow’s contribution to the mentor’s research program(s) should also be addressed. Additional instructions are provided in proposalCENTRAL as a downloadable PDF document. The plan should be developed collaboratively by the Fellow and mentor(s). The Training Plan document must be signed by both the Fellow and mentor; if co-mentors are listed, their signatures or a letter indicating agreement should also be included. It is the Fellow’s responsibility to ensure that this document is **signed and submitted by the deadline**.

Biosketch(es)

The PI must submit a Biosketch using the NIH Biosketch format; no other Biosketch templates are allowed. Use of the personal statement to circumvent page limits by adding specific information on the proposed research plan is not allowed. **For Postdoctoral Fellowships**, the mentor(s) also **must** provide a Biosketch.

Biosketches for all collaborators and other key personnel must be submitted with the FGA. Key personnel are defined as the PI, collaborators and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not salary or compensation is requested.

Each Biosketch must be provided as a separate PDF.

Subcontractors

If the proposed research requires work to be carried out by another institution, the relationship must be disclosed in the Proposal Narrative and Budget sections of the application.

Other Research Support

The PI and collaborators must provide information for all current and pending grants. **For Postdoctoral Fellowships**, both the Fellow *and* the mentor(s) must provide this information. Other key personnel are not required to provide other research support information.

After submitting an application, the PI is required to immediately notify the Neilsen Foundation if he/she submits an application to another funding source or is notified by another funding source that his/her application has been **conditionally approved** for funding. **Failure to report other funding applications, pending or approved, will jeopardize the applicant's current Neilsen Foundation grant application status.**

EVALUATION CRITERIA FOR FGA

FGAs are peer-reviewed by members of the Neilsen Foundation's Review Board. The critique and evaluation of an FGA will be based on scientific merit, innovation and relevance to the Neilsen Foundation. Reviewer comments and a summary statement, if applicable, will be available to the Applicant after the current grant cycle results are announced.

See Appendix 2, 3, and 4 for a list of FGA review criteria.

D. Notification of FGA Results and Award Process

The Neilsen Foundation will notify Applicants whether the application has been approved or declined for funding, via email, approximately five months after the FGA deadline. Only approved FGAs will proceed to the award process.

Applicants whose FGA is approved for funding will be required to submit additional documentation before grant funds are issued to the grantee. The additional documentation will include but is not limited to: 1) signed Grant Agreement; 2) Grantee Verification of Tax-Exempt Status including a copy of the organization's IRS Determination letter; 3) Notice of Other Funding & Conflict of Interest; and 4) IRB/IACUC Approval (see below). Instructions for executing the additional documentation will be included in the award notification.

INSTITUTIONAL REVIEW BOARD/INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE APPROVALS

Prior to receiving funding for an award, the PI must provide documentation of IRB/IACUC approval for use of human or animal subjects. For multicenter clinical studies, use of a single IRB of record or a central IRB is strongly encouraged.

Important: The IRB/IACUC approval notification must be in English or with an English translation provided. The approval notification must be sent from the IRB or IACUC committee and list the expiration date of the approval, the PI's or other key personnel name(s), and include the Neilsen

Foundation project title. If the IRB/IACUC approval is for a broader protocol and the title on the approval notification differs from the Neilsen Foundation title, the notification must mention that the approval also covers the project funded by the Neilsen Foundation. If multiple IRB/IACUC approvals are required from multiple institutions, PIs must provide each approval notification as a separate PDF file.

NEILSEN FOUNDATION DUE DILIGENCE

Per the United States Pension Protection Act of 2006, private non-operating foundations are required to verify the nonprofit status of all prospective grantees. When submitting an application, the PI/Applicant will also need to provide the following:

United States-based organizations:

- A copy of the organization's U.S. IRS Determination letter, which proves the entity's 501(c)(3) designation or tax-exempt status under Internal Revenue Code Section 170(c)(1).
- *An organization classified as a public charity under Section 509(a)(3) should refer to IRS Notice 2006-109 (dated 12/18/2006) titled "Interim Guidance Regarding Supporting Organizations and Donor Advised Funds," and its subsequent modification in IRS Notice 2014-4. The organization will be required to provide the additional information and documentation specified in Section 3.01 of IRS Notice 2006-109. The Neilsen Foundation does not issue grants to non-functionally integrated Type III supporting organizations.*

Canadian-based organizations:

- The Neilsen Foundation prefers to make grants to (i) a Canadian organization that holds a U.S. IRS Determination letter, or (ii) a Canadian organization's U.S.-based "friends of" charity, which holds a U.S. IRS Determination letter. If a Canadian organization can satisfy either of these requirements, it must provide a copy of the U.S. IRS Determination letter for such entity (include all pages).
- If a Canadian organization cannot satisfy either of the requirements above, it must be a "registered charity" with the Canada Revenue Agency (CRA) and provide a copy of the CRA website page that lists the entity's registration. *If a grant is approved for funding, the Neilsen Foundation will require additional information in order to make a determination that the Canadian organization is the equivalent of a U.S. public charity.*

Do not upload copies of tax returns, EIN letters, W-9s, internal documents noting the organization's nonprofit status, etc., in lieu of, OR in addition to, the IRS Determination letter. Only copies of the official IRS Determination letter will be accepted.

DISBURSEMENT OF GRANT FUNDS

Once the required documentation is received and accepted by the Neilsen Foundation and our due diligence process is complete, funds will be disbursed to the grantee organization by the start date of the grant.

FINAL REPORT

At the end of the grant period, Applicants will be required to report on final progress and expenditures. Applicable templates are available in the Deliverables section in proposalCENTRAL. Applicants that do not comply with this requirement, or submit unsatisfactory reports, will not be eligible for future Neilsen Foundation funding until receipt of acceptable required report(s).

E. Resubmission

Applicants are permitted one resubmission of a revised FGA that was favorably reviewed but not funded in a prior grant cycle. A new LOI is required for the resubmission, but does not guarantee that the LOI will be invited to submit a revised FGA. The LOI must briefly indicate how the PI plans to respond to the previous critiques. This may be up to a half-page and is not counted in the standard LOI page limit.

If the original submission was a SCIRTS Pilot Research Grant, it cannot be “re-submitted” as a Senior Research Grant, which would require significant modification and expansion of the Aims and scope of the work. If the original submission was in the Senior Research Grant, category, it may be “re-submitted” as a Pilot grant, with similar Aims but decreased scope.

Aims that were unsuccessful in a resubmission may be submitted in a new grant application in a subsequent cycle, using the standard template (i.e., no response to reviewer comments). A new LOI is required and previous acceptance of similar Aims does not guarantee approval for invitation as an FGA.

F. Concurrent Grants Across Neilsen Foundation Portfolios

- Applicants may hold only one Neilsen Foundation grant within any portfolio at one time. To be eligible for the current cycle, a grantee must fulfill the obligations of a current grant (submission of the Final Report and Final Expenditure Report) before the FGA deadline noted on page one.
- **All Neilsen Foundation portfolios:** Non-trainee Applicants may apply for one grant per cycle per Neilsen Foundation portfolio (i.e., SCIRTS, PSR and CO&I), and may hold up to one grant in each of the three portfolios at a time. Such applications will be evaluated independently, according to each program’s timelines, guidelines and review criteria.
- **Fellowship/Training grants:** Postdoctoral Fellows may not apply for a non-training Neilsen Foundation grant. Foundation Fellowship budgets are intended to cover 100% of the salary and fringe support for the Fellow so they may focus on a defined training program specific to the needs of their research interests. Postdoctoral Fellows may not hold multiple concurrent grants in different Neilsen Foundation portfolios; however, funded Fellows may be listed as participants on other grants, within or outside the Neilsen Foundation, without salary or fringe support on those grants.

G. Additional Information

APPLICATION SUBMISSION CONTACTS

- For technical questions regarding the online submission process, contact proposalCENTRAL Customer Service at (800) 875-2562 or via email at pcsupport@altum.com, during business hours, Monday–Friday, 8:30 a.m.–5:00 p.m. (Eastern Time). *There is no technical support available on weekends or holidays.*
- ProposalCENTRAL also has a tutorial section on its website that may be helpful in completing an application: <https://proposalCENTRAL.altum.com/help.asp>.
- For questions regarding an application’s submission status, contact Ehrica Hernandez, Grants Management Associate, at ehrica@chnfoundation.org.
- For questions regarding this portfolio contact BOTH:
Tracey Wheeler, PhD (SCIRTS Program Officer) at tracey@chnfoundation.org.
Jacob Shreckengost, PhD (SCIRTS Program Associate) at jacob@chnfoundation.org.
- For information about all Neilsen Foundation portfolios, visit our website, www.chnfoundation.org.

Note: Applicants are strongly discouraged from contacting any Neilsen Foundation Review Board member regarding an application once it has been submitted. Such contact will result in disqualification of the LOI or FGA.

APPENDIX 1: LETTER OF INTENT REVIEW CRITERIA

SCI RESEARCH ON THE TRANSLATIONAL SPECTRUM

Craig H. Neilsen Foundation



The Letter of Intent (LOI) review process is intended to identify those LOIs that should be invited to submit a full proposal. To that end, we look at general criteria that apply to all LOIs, specific criteria relevant to each category of applicant (Postdoctoral, Pilot and Senior) and, to a limited extent, scientific merit. **Your evaluation of an LOI should be based primarily on relevance to the Neilsen Foundation, innovation and gaps in the field of spinal cord injury (SCI); any notable feasibility issues** should also affect LOI scoring. As the LOI format does not allow PIs to provide a great deal of information on methodology, reviewers should not focus on experimental detail, which will be evaluated in the invited grant applications.

GENERAL CRITERIA

1. The proposed research must be within the scope of the Spinal Cord Injury Research on the Translational Spectrum (SCIRTS) portfolio, which covers mechanistic research applied to SCI; pre-clinical and translational research; and clinical research. The portfolio is further defined in the Application Guide. If an LOI is not within this scope and is better suited to the Psychosocial Research (PSR) Program (studies the interrelation of behavioral, social and other quality of life factors that will benefit individuals living with SCI), the applicant should apply to the PSR program.
2. LOIs in which the template text or margins have been modified, or the page limits exceeded, will be rejected. The maximum allowable length is three pages (one tabular page, two of LOI text), not including references. An additional half-page is allowed for a resubmission of a previously reviewed but unfunded full grant application, specifically for a response to reviewer concerns.
3. Applicants must have a doctoral degree or an equivalent terminal professional degree at the time of the LOI submission. Undergraduates and predoctoral candidates are not eligible. Non-fellowship applicants must demonstrate appropriate experience to serve as an independent Principal Investigator (PI). The Neilsen Foundation encourages submissions from eligible PIs who represent a wide range of disciplines; however, it requires that relevant SCI expertise is represented on the proposed research team.
4. Applications must be from a nonprofit institution/organization located in the U.S. or Canada. If there are any questions about an institution/organization's status, contact Kim Cerise, Director of Grants Management (kim@chnfoundation.org).

PROGRAMMATIC CRITERIA

IMPACT AND INNOVATION

What is the likelihood that the project will exert a sustained, powerful influence in the field of SCI, based on the following criteria?

1. Significance

The extent to which the project, if successful, will make an original and important contribution to research in SCI, including:

- a. Does the study address an unsolved problem or important issue for persons with SCI?
- b. Does the study have the potential to improve clinical practice or quality of life for persons with SCI and/or establish novel areas of investigations in this field?
- c. Is the proposed research innovative versus incremental?

2. Relevance

The extent to which the project is relevant to the Neilsen Foundation, the field of SCI, and stated goals of the grant program to which it is applied.

APPROACH

The extent to which the conceptual framework provided for the studies to be proposed will test the stated hypotheses and is appropriate to the Aims of the project.

1. Feasibility

- a. Is the scope of work feasible within the project period, given the investigators' experience and expertise, past progress, and available resources?

RESEARCH DESIGN

1. Hypothesis

- a. Are the hypotheses clearly stated?
- b. Do the study objectives/Aims address the hypotheses?

2. PI/Preliminary Data

- a. Does the application support the PI's and other personnel's familiarity and competence with the proposed techniques, activities and issues relevant to SCI?

3. Research Plan

- a. Is the general design appropriate for solving the stated problems?
- b. For clinical research: What is the scope and type of the planned study and is it likely to be feasible within the resources provided by the Neilsen Foundation program? Is it a randomized clinical trial of a novel drug or biologic (*not allowed for Pilot Grants*)?

PRESENTATION

Is the application clearly written, within the page limits and free of typographical errors?

Are supporting materials (e.g., graphs, micrographs, etc.) legibly sized and used appropriately?

¹ Trials conducted under IDE are allowed in all categories.

BUDGET

Is the initial budget estimate appropriate to the nature and scope of the study?

RESUBMISSIONS

At the LOI stage, applicants are allowed a half-page response to reviewer's comments from a previously reviewed full grant application (FGA). To view the previous reviewer comments, click on the blue "R" on the left side of the reviewer screen. Please note whether the applicant has adequately indicated how they will respond to reviewer comments at the FGA stage in your review.

CATEGORY-SPECIFIC CRITERIA

POSTDOCTORAL (\$150,000 over two years):

1. Key evaluation criteria are: training opportunity, qualifications/strength of applicant, environment, mentorship (with SCI research experience), scientific/merit and Foundation relevance. Will this training period, mentor and project increase the skill set of the applicant to further their career path in SCI research?
2. Eligibility: doctoral degree completed by LOI submission due date (May 11, 2020) but not to exceed five years by FGA deadline (October 14, 2020). Applicant must have completed their degree by October 14, 2015 or later. If the Biosketch only lists the month, any month on or after October 2015 is acceptable, any dates prior to that render the applicant ineligible.

PILOT (\$300,000 over two years):

1. Key evaluation criteria are: strength of investigator, feasibility, innovation, and impact on the field.
2. This category is for relatively junior investigators (Instructor, Assistant Professor or equivalent research position at the time of the FGA) OR established investigators proposing high risk/high gain projects. Will this project help establish a junior PI's research program (if applicable)? If the PI is established, does the project have the potential for "high gain" to balance risk and/or develop key preliminary data?
3. If the applicant is not in a tenure track position, does he/she have appropriate experience, independence and access to needed resources?
4. Novel interventional drug/biologics or clinical trials are not allowed in the Pilot award category.

SENIOR (\$600,000 over three years):

1. Key evaluation criteria are: strength of investigator (history of success/productivity), feasibility, innovation, and impact on the field. The extent to which this project proposes cutting-edge ideas and approaches that have great potential, despite some additional risk, or projects that are critical to the field that might be difficult to fund through other sources.
2. Applicant must be at the level of Associate Professor (at the time of the FGA) or above to be eligible.
3. This is the largest and most competitive award. Thus, LOIs in this category should represent unique opportunities to fill an important gap in the field, not funded by other agencies at this stage.

APPENDIX 2: POSTDOCTORAL FELLOWSHIPS CRITERIA SCI RESEARCH ON THE TRANSLATIONAL SPECTRUM

Craig H. Neilsen Foundation



The main goal of Postdoctoral Fellowship Grants is to provide training opportunities. Funding for each year of the two-year project is up to \$75,000 for a maximum total cost of \$150,000.

OVERALL IMPACT

After considering the review criteria, summarize the significant strengths and weaknesses of the application and associated training plan, then state the likelihood that Neilsen Foundation funding of this project will allow this Fellow to become an important contributor to the field of SCI research.

SIGNIFICANCE

1. If the Aims of the project and training plan goals are achieved, how will the postdoctoral fellow's scientific knowledge, technical capability, and/or clinical skills improve?
2. Does the project address an important problem or a critical barrier to progress in the field of SCI?
3. Does the proposal identify a significant research area, supported by appropriate evaluation of the literature?

RELEVANCE

1. How is this project relevant to the Neilsen Foundation?
2. Does the proposal identify how this work will be translated to and/or the potential impact on, individuals with SCI?

INVESTIGATOR(S)

1. Does the applicant have the potential to develop as an independent and productive scientist and does the research training plan provide individualized, supervised experiences and appropriate research skills to foster this development?
2. Is the applicant's research experience of high quality?
3. Are the PI and mentors/co-mentors' expertise well-suited to the proposed SCI research?
4. Are the mentor's qualifications, including research support and track record of mentoring, appropriate for the proposed fellowship?
 - a. Is there evidence of a match between the research interests of the fellow and the mentor/sponsor?
 - b. Is there a demonstrated ability and commitment to assist in assuring the fellow's success?

INNOVATION

1. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

APPROACH

1. Is the research plan of high scientific quality and does it relate to the applicant's training plan?
2. Are the overall strategies, methodologies, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
3. Are potential problems, alternative strategies, and benchmarks for success presented?
4. If the project involves clinical research: a) are the plans for protection of human subjects properly described? b) are the plans for recruitment appropriate?

ENVIRONMENT

1. Is the institutional environment for the scientific development of the fellow of high quality?
2. Are the research facilities, resources (e.g., equipment, laboratory space, computer time, subject populations), and training opportunities adequate and appropriate for the project as proposed?
3. Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

NON-SCORED CRITERIA

Provide any important or relevant comments on each of the non-scored criterion below.

1. Budget
2. Ethics/Safety; protection of human subjects, including safety and data monitoring
3. Other/Additional Comments for the Applicant
4. Resubmission: When reviewing a resubmission, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project, but basing its final score on the overall merits of the current proposal.

APPENDIX 3: PILOT RESEARCH GRANTS CRITERIA SCI RESEARCH ON THE TRANSLATIONAL SPECTRUM

Craig H. Neilsen Foundation



Neilsen Pilot Research Grants cultivate new lines of research and novel projects conducted by either new or established PIs. Funding for each year of the two-year project is up to \$150,000 for a maximum total cost of \$300,000.

OVERALL IMPACT

After considering the review criteria, summarize the significant strengths and weaknesses of the application. Please state the likelihood that the project scope suits the Pilot funding level and will exert a powerful influence on the field of SCI research.

SIGNIFICANCE

1. Does the project address an important problem or a critical barrier to progress in the field of SCI? Is the evaluation of the literature comprehensive and appropriate?
2. If the Aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice improve?
3. Will successful completion of the Aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? If so, how?

RELEVANCE

1. How is this project relevant to the Neilsen Foundation?
2. Does the proposal adequately identify how this work would be translated to and/or the potential impact on, individuals with SCI?
3. For established investigators, is the proposal high risk/high gain? Does it pursue essential pilot data needed to obtain future funding?

INVESTIGATOR(S)

1. Are the PIs, collaborators, and other researchers well-suited to the project? Does the team have expertise in SCI mechanisms, models, and/or outcome measures? If the project involves clinical research a) is SCI clinical expertise sufficient (PI and/or collaborators)? b) is clinical research training for other staff described and is it sufficient?
2. If the PI is an established investigator, has he/she demonstrated an ongoing record of accomplishments that have advanced the field(s)?
3. Or, if the PI is a junior investigator, does he/she have appropriate experience, training and facilities to do the proposed work? Will the work facilitate establishment of the PIs research program?

INNOVATION

1. Does the application challenge and seek to shift current research or clinical practice paradigms? For example, does it utilize novel theoretical concepts, approaches or methodologies? Is the investigator incorporating ideas from another field?
2. For established investigators, is this a new direction for the PI?

APPROACH

1. Are the overall strategies, methodologies, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
2. Are potential problems, alternative strategies, and benchmarks for success presented?
3. If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed adequately?
4. If the proposal involves clinical research, does the project timeline include plans for study start-up time and sufficient subject recruitment?
 - a. Does the start-up plan adequately address regulatory approval, if required?
 - b. Will the National Institute of Neurological Disorders and Stroke, Common Data Elements be used? If not, is justification provided?

ENVIRONMENT

1. Are institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?
2. Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?
3. For non-tenure track applicants: Does the application adequately address the PI's independence and access to necessary resources to conduct the work? (Letter from institution is recommended but optional)

NON-SCORED CRITERIA

Provide any important or relevant comments on each of the non-scored criterion below.

1. Budget
2. Overlapping Funding
3. Ethics/Safety; protection of human subjects, including safety and data monitoring
4. Other/Additional Comments for the Applicant
5. Resubmission: When reviewing a resubmission, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project, but basing its final score on the overall merits of the current proposal.

APPENDIX 4: SENIOR RESEARCH GRANTS CRITERIA SCI RESEARCH ON THE TRANSLATIONAL SPECTRUM

Craig H. Neilsen Foundation



Senior grants focus on innovative projects by established contributors. Funding for each year of the three-year project is up to \$200,000 for a maximum total cost of \$600,000. The goal is not to substitute for federal funding, but to use Neilsen Foundation funding to encourage cutting-edge ideas and approaches that have great potential, despite some additional risk.

OVERALL IMPACT

After considering the review criteria, summarize the significant strengths and weaknesses of the application and state the likelihood that Neilsen Foundation funding of this project will exert a sustained, powerful influence on the field of SCI research.

SIGNIFICANCE

1. Does the project address an important problem or a critical barrier to progress in the field of SCI? Is the evaluation of the literature comprehensive and appropriate?
2. If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice improve?
3. Will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? If so, how?

RELEVANCE

1. How is this project relevant to the Neilsen Foundation?
2. Does the proposal adequately identify how this work will be translated to and/or the potential impact on, individuals with SCI?
3. Does Neilsen Foundation support of this project represent an exceptional opportunity (compared to federal or other funding)?

INVESTIGATOR(S)

1. Are the PIs, collaborators, and other researchers well-suited to the project? Does the team have expertise in SCI mechanisms, models, and/or outcome measures? If the project involves clinical research a) is SCI clinical expertise sufficient (PI and/or collaborators)? b) is clinical research training for other staff described and is it sufficient?
2. Is the PI an established investigator who has demonstrated an ongoing record of accomplishments that have advanced the field(s)?
3. Is this study appropriate for the grant category, career level and experience of the PI?

INNOVATION

1. Does the application challenge and seek to shift current research or clinical practice paradigms? For example, does it utilize novel theoretical concepts, approaches or methodologies? Is the investigator incorporating ideas from another field?
2. Is this a new direction for the PI?
3. Does the project fill an important research or translational gap? If so, how?

APPROACH

1. Are the overall strategies, methodologies, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
2. Are potential problems, alternative strategies, and benchmarks for success presented?
3. If the project is in the early stages of development, will the strategy establish feasibility?
4. If the proposal involves clinical research, does the project timeline include plans for study start-up time and sufficient subject recruitment?
 - a. Does the start-up plan adequately address regulatory approval, if required?
 - b. Will the National Institute of Neurological Disorders and Stroke, Common Data Elements be used? If not, is justification provided?

ENVIRONMENT

1. Are institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?
2. Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

NON-SCORED CRITERIA

Please provide any important or relevant comments on each of the non-scored criterion below.

1. Budget
2. Overlapping Funding
3. Ethics/Safety; protection of human subjects, including safety and data monitoring
4. Other/Additional Comments for the Applicant
5. Resubmission: When reviewing a resubmission, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project, but basing its final score on the overall merits of the current proposal.

APPENDIX 5: SUPPLEMENTAL INFORMATION RESOURCES AND CONSIDERATIONS FOR CLINICAL PROPOSALS

Craig H. Neilsen Foundation



In addition to the requirements and review criteria in the Application Guide, this document provides resources to consider in support of clinical study preparation and execution. The applicability of these resources and considerations will vary, based on clinical trial design. Any websites listed herein are not endorsed by the Neilsen Foundation, but are provided as examples of available resources.

1. **Overview:** The following article provides an overview of the “basics” of investigator sponsored trials, “Investigator Initiated Trials Made Easy”:
<https://www.iqvia.com/-/media/iqvia/pdfs/ap-location-site/iit-made-easy.pdf>
2. **Study Start-up:** There are many things to consider during study start-up and execution phase to enhance the chance of a successful study. Consider the following when planning clinical trials.
 - a. **Central IRB:** The use of a single IRB of record or a central IRB may decrease study start-up time, resulting in cost savings. Further discussion of the advantages of central IRBs and links to central IRBs can be found on the web. One example can be found on the NCATS link below (under SMART IRB).
 - b. **Protocol:** Development of a clear, well thought out and comprehensive study protocol is essential. Many protocol templates are available on the web and may be modified to suit the needs of individual studies. Examples can be found on the NIDCR and OSP links below.
 - c. **Outcome Measures:** Identifying appropriate outcome measures is critical. The National Institute of Neurological Disorders and Stroke (NINDS) identified Common Data Elements (CDEs) for use in spinal cord injury studies.
 - <https://www.commondataelements.ninds.nih.gov/Spinal%20Cord%20Injury>

Additional information about instruments listed in the NINDS CDEs, such as appropriateness based on acuity and level of injury, instructions for measurement and scoring, available languages, and summaries of measurement properties can be found at these websites:

- American Physical Therapy Association, Evidence Database to Guide Effectiveness (APTA EDGE), spinal cord injury specific:
<http://www.neuropt.org/professional-resources/neurology-section-outcome-measures-recommendations/spinal-cord-injury>
- Spinal Cord Injury Research Evidence (SCIRE), spinal cord injury specific:
<https://scireproject.com/outcome-measures/>
- Rehabilitation Measures Database:
https://www.commondataelements.ninds.nih.gov/sites/nindscde/files/Doc/SCI/F1723_Rehabilitation_Therapies.docx

3. **Data and Safety Monitoring:** Data and safety monitoring should be addressed in the protocol and/or in a separate document. There are numerous guidelines for data and safety monitoring. The Harvard Clinical and Translation Science Center provides a Data and Safety Monitoring Guide, including algorithms for suggested levels of monitoring.
 - https://catalyst.harvard.edu/pdf/regulatory/DSMB-P_Guidance.pdf

4. **Training:** Training is an important consideration for the Principal Investigator and study personnel. Depending on the study, various training activities may be included. Examples are listed below.
 - a. **International Standards for Neurological Classification of Spinal Cord (ISNCSCI):**
The American Spinal Injury Association (ASIA) offers web-based or in person trainings on the ISNCSCI exam.
 - <http://asia-spinalinjury.org/learning/>
 - b. **Good Clinical Practice (GCP):** An understanding of GCP is essential prior to undertaking clinical research and is now required for NIH funded investigators. GCP training is offered through the Collaborative Institutional Training Initiative (CITI) and some NIH institutes. One example can be found on the NCATS link below (under GCP).
 - c. **Investigator's Meeting:** For multi-center studies, an Investigator's Meeting prior to study start, including key personnel from all study sites (either in-person or electronically), provides the opportunity to train and review personnel on all study procedures and modify the Manual of Procedures, if needed.

5. **Additional Resources:** The resources below provide toolkits, templates and additional information. Although specific to the different Institutes within the NIH, these documents may be helpful and can be modified, as needed.
 - <https://www.nidcr.nih.gov/Research/toolkit/>
 - <https://ncats.nih.gov/expertise/clinical>
 - <https://osp.od.nih.gov/clinical-research/clinical-trials/>

REACT (Rehabilitation Research Resource to Enhance Clinical Trials) is NIH-supported to provide the medical rehabilitation research community with training, consultation, funding and tools to catalyze high-impact, interdisciplinary clinical trials.

- <https://react.center/>