



ALS Canada-Brain Canada Hudson Translational Team Grant



Terms of Reference

I) OVERVIEW

The vision of ALS Canada is “By 2024, ALS will be a treatable disease.” To that end, ALS Canada's Strategic Plan for Research (2014-2017) established the goal to develop, through a national network, at least one novel therapeutic strategy to slow the progression of ALS and related neurological disorders, including primary lateral sclerosis, progressive muscular atrophy, and ALS/FTLD (ALS/frontotemporal lobar dementia). The ultimate goal of the ALS Society of Canada and Brain Canada (the Partners) is to prevent or cure these disorders, to slow their progression, and to improve the quality of life for those affected and their families. As a mechanism to achieve that goal, the Arthur J. Hudson Translational Team Grant has been established. The spirit of this program is to bring together researchers from across the country to accelerate therapeutic development by: 1) identifying and testing a relevant therapeutic target or candidate therapy and/or 2) addressing critical needs for early diagnosis and biomonitoring of clinical progression applied to clinical research. Research in all stages of development is welcomed, from basic/preclinical to phase I, II and III clinical trials. For all projects, an explanation of the translational intent of the research should accompany the work plan as well as an indication of next steps should the work be successful. While clinical trials are welcomed, they are not a requirement.

ALS Canada is partnering with Brain Canada for this program in order to leverage contributions made through the Ice Bucket Challenge for ALS. ALS Canada and Brain Canada (The Partners) are seeking applications from teams of independent investigators from multiple independent institutions proposing such a translational research approach with a sound and feasible rationale, supported by preliminary data. Here, translational research is defined as “basic or clinical research that may lead to discoveries that enhance human health and well-being. It focuses on iterative feedback loops between the basic and clinical research domains to accelerate knowledge translation from bench to bedside, and back again.”

Applications will be rated by an international peer review panel for scientific excellence, achievability and relevance to the program's goal of fostering collaborations among Canadian scientists and translating scientific discoveries into clinical practice. In general, the conditions of the grant will follow Tri-Council Guidelines for eligibility, research ethics, eligibility of expenses, and financial administration. Continued funding will be dependent upon review of year-end reports for acceptable achievement of milestones and continued feasibility of the project (as reviewed by ALS Canada and Brain Canada), as well as continued availability of funds.

II) QUALIFYING TEAMS

Qualifying teams will be composed of a minimum of three independent principal investigators (PI) from at least two different institutions. An independent PI is defined as a researcher who has a PhD or equivalent, or a health professional degree (*e.g.*, MD) with relevant research training, and holds an academic position at a qualifying Canadian institution, defined according to CIHR guidelines (<http://www.cihr-irsc.gc.ca/e/36374.html>). Postdoctoral fellows and research associates are not eligible to serve as PIs for this program.

Teams are strongly encouraged to use this opportunity to bring together PIs from different Canadian institutions, at different career stages and with different expertise. The term institution refers to a university and its affiliated/associated research centres and hospitals. There is no limit to the number of PIs that can be included in the team. International investigators will generally not be co-PIs on a Hudson grant. If this arrangement is deemed to be necessary, then an additional section of the grant must be submitted indicating why this International PI is required.

International collaborators with specific expertise, equipment or techniques may be proposed to strengthen proposals, but funds will not be directed from ALS Canada or Brain Canada to an institution outside of Canada. (International collaborators may be provided with a fee for service or reagents paid for by a Canadian PI's portion of the grant.)

While not required, teams are encouraged to engage pharma/biotech in their proposals through letters of support and/or provision of services or products "in-kind". Although it is the policy of ALS Canada that donor dollars cannot be used to fund development of private industry, grants may be used to leverage contributions from other public and private sources for ALS research and development.

A training component (for graduate, postdoctoral and/or postgraduate trainees) is required in the application.

One PI must be named (lead PI) who will assume the administrative and financial responsibility for the grant, which will be paid to that individual's institution (the Institution Paid).

III) GRANT DETAILS

- The Partners anticipate committing up to \$10M to support meritorious research proposals.
- Funding can be requested for one to five years, with no imposed constraints on the total budget requested to achieve the aims. However, the scope of the research proposed must be reasonable in consideration of the team and project's development, the resources available for the competition, and the intent to award funding to multiple teams. Applicants should identify "go/no go" points of the study, particularly for more ambitious projects with larger budgets. Teams awarded grants may also apply for supplementary funding in subsequent competitions to support additional components of the research, or the next stage of development of a successful project.

IV) USE OF FUNDS

- These grants may be used to support any aspect of the operating costs of the research project including: supplies and materials; provision of special services and user fees; maintenance of essential equipment; travel of team members and trainees for collaboration and presentation of results; publication costs; salaries for technical personnel; stipends of trainees; and purchase of equipment that is currently unavailable but essential for the project.
- For items of equipment costing over \$10,000 up to a maximum of \$50,000, a letter from the department head/institute director is required to indicate that the equipment is required, but not available for the project.
- Research projects must involve trainees in any appropriate health professional or scientific discipline.

- Salary payments to any team members who are eligible to apply for operating grants from the federal granting agencies are not permitted.
- The Partners do not provide institutional overhead.
- These grants are non-renewable.

V) APPLICATION PROCESS

Letter of intent (LOI): A LOI should be submitted via email to Dr. David Taylor, Director of Research, ALS Canada (dt@als.ca), as a single PDF file by 1:00 pm EST on March 23, 2015. The LOI template is downloadable from the ALS Canada website on the Arthur J Hudson Translational Team Grant page. The applicants must provide a summary of the rationale for the project, the scientific objectives and approach, the expertise and integration of the team members to achieve the objectives, and expected outcomes and significance to the program's objectives (limit 2 pages).

Review of LOI will be done by the International Peer Review Panel and additional individuals with relevant expertise identified in conjunction with Brain Canada. Letters will be reviewed for relevance to the terms of reference of the program and the overall mission of ALS Canada. Potential applicants will be informed by email on or before April 24, 2015 as to whether they are invited to submit a full proposal for the July 13, 2015 deadline.

Full Proposal: Complete applications should be submitted via email to Dr. David Taylor, Director of Research, ALS Canada (dt@als.ca). Applications will be accepted until 1:00 pm EST on July 13, 2015. A template will be provided by email. Applications should request delivery and read receipts. An email acknowledging receipt of the application will be sent.

Full Application Requirements:

- **Format:**
- Applications must be prepared as a single PDF file using standard type fonts (Arial-11 or Times Roman-12) with 0.5"/1.27 cm margins and numbered pages.
- **Required Documents:** Please include the following documents in the application in this order:
 - Signed and completed cover pages
 - Scientific summary (1 page)
 - Summary of progress (if applying for supplementary funding) (1 page)
 - Response to reviewers (for resubmissions or to LOI review) (2 pages)
 - Research Plan (limit 13 pages including figures and tables; see guidelines below*)
 - Research milestones and go/no go points (1 page; narrative or Gantt chart format)
 - Training opportunities - integration of trainees (undergraduate, graduate, postdoctoral and/or postgraduate) into the project to foster the next generation of ALS researchers; supervisory expertise of the team (1 page).
 - Budget by annum and budget justification; see guidelines below**)
 - Curriculum Vitae for each PI (NIH style abbreviated CV; see format***)
 - Conflict of Interest Disclosure Form
 - Supporting Documents (e.g., letters from colleagues who will provide resources critical to the success of the proposed research plan; letter of support from the pharma/biotech implicated in the proposal describing their role in the project, etc.).

***Research Plan:**

The total length of the research plan (including figures and tables) must not exceed 13 pages and should include the following headings:

- Biological and clinical rationale for the project, including hypothesis
- Specific aims
- Background: A comprehensive literature review is not expected. Please supply only the information that is required for reviewers who specialize in neurodegenerative disease to understand the proposal.
- Preliminary data: Supporting data is required, but this information can be provided in Rationale or Experimental Plan, or as a separate section.
- Experimental Plan: A clear and logical experimental plan that addresses the hypothesis and specific aims.
- The role of the individual investigators should be indicated where appropriate as well as a plan for how the team will communicate/exchange information.
- Statement of relevance to translational ALS strategies.
- Bibliography (please include titles and all authors of the referenced articles; excluded from page limit).

****Budget:**

- Total budget and duration of the grant will be at the discretion of the applicant based on need for successful execution of the project.
- Allowable expenses include: personnel, laboratory equipment, consumable supplies, laboratory animals, travel[#], necessary equipment[#], other (including service contracts, service charges, publication costs, etc).
- [#]Note: Budgets which include equipment over \$5000 and travel must be particularly well justified. For equipment over \$10,000, to a maximum of \$50,000, a letter from the department head/institute director is required to indicate that the equipment is required, but not available for the project.
- Indirect costs are not permitted.
- Other funding for the project (current, applied for, intent to apply for). Discuss overlap and any complementarity. Attach summary and budget pages for all grants/applications with any theoretical or experimental overlap with the current application. Although it is the policy of ALS Canada that donor dollars cannot be used to fund development of private industry, grants may be used to leverage contributions from other public and private sources for ALS research and development.

*****CV:**

CVs should take the form of an NIH-style abbreviated CV, including the following sections: Education and Training, Positions and Honours, Research Focus (one paragraph), Professional Activities and Awards, Peer-reviewed Publications relevant to the proposal, and Research Funding (last five years). Maximum 4 pages.

VI) EVALUATION

Full applications will be reviewed and rated by the International Peer Review Panel comprising basic and clinician scientists with expertise in ALS and/or related neurodegenerative neurological diseases. Panel members and future Chairs are selected by the current Panel Chair, the Director of Research, the chair of the Scientific and Medical Advisory Council of ALS Canada, and a Brain Canada representative and approved by the boards of ALS Canada and Brain Canada. The research plan will be assessed on scientific merit, potential impact, and feasibility with a particular emphasis on the translational capacity of the

proposal, as per the definition on page 1. The team will be evaluated for the suitability and qualifications of the individual members for the project and the value added for bringing together investigators from different institutions, from different career stages, training opportunities, and existing or potential partnerships with biotech/pharma and clinical trials networks (if relevant to completing the project).

Additional external reviewers may be solicited by the Chair, Director of Research and Brain Canada according to additional expertise required or work load of the Panel members. These external reviewers will provide ratings and detailed comments to inform the discussions at the in person Panel meeting.

The International Review Panel will provide its scores and rankings to the Director of Research and Brain Canada representative, who will propose a mutually decided funding scenario to their respective Boards of Directors. Applicants will be informed of the decision on September 21, 2015 and funding will start on October 1, 2015. Should there be more meritorious applications than available funds, applications will be funded in descending order of merit. Partial projects may be funded, but only in situations where teams remain intact.

All applicants at both LOI and full application stages will receive anonymized reviewers' comments and a summary of major discussion points from the Director of Research, but applications considered uncompetitive by all reviewers may not be discussed in detail at the meeting of the Peer Review Panel.

VII) CONDITIONS OF THE AWARD

1) Release of funds will be subject to receipt of relevant ethics approvals from the lead PI's institutional review committees, where necessary (for use of human subjects, research animals, or hazardous materials). Note, the lead PI will be responsible for ensuring that relevant ethics approvals have been obtained at each participating institution. Continued funding will be contingent upon receipt year-end progress reports, acceptable achievement of milestones and continued feasibility of the project (as reviewed by ALS Canada and Brain Canada), as well as continued availability of funds at ALS Canada and Brain Canada. Carryover of unspent funds is permissible. No-cost extensions are possible, pending approval by the Boards of ALS Canada and Brain Canada. Significant changes in research aims or budget allocation requires *a priori* permission of ALS Canada and Brain Canada.

2) Funds will be sent as quarterly instalments, to the lead PI's institution (Institution paid) which is responsible for financial agreements and distribution of funds to co-PIs' institutions. The last instalment will be released upon receipt of the final progress report.

3) An annual statement of expenditures is required from the PI's institution and must be submitted within eight weeks of each year-end to ALS Canada.

4) Progress Reports: Year-end progress reports must be submitted within four weeks to ALS Canada. The final progress report is due within four weeks of termination of the grant. A template for reports will be provided by ALS Canada upon acceptance of the award.

5) Funding is contingent upon compliance with the policies of ALS Society of Canada and Brain Canada.

6) An investigator may be a member of more than one team, but can be lead PI on only one application in a given competition. An individual who is PI of an active Translational Team Grant is eligible to apply in subsequent competitions.

7) Budgetary overlap for the project with other funding provided by ALS Canada, Brain Canada, or another agency must be disclosed.

8) The intent of this grant is to fund research that will be in the open domain. All manuscripts, presentations, abstracts, etc. must acknowledge funding by ALS Canada and Brain Canada. Grantees should make every effort to publish all findings related to the project and to acknowledge ALS Canada and Brain Canada in media events discussing research funded by ALS Canada and Brain Canada. Manuscripts or other presentations in press must be sent to the Director of Research of ALS Canada upon acceptance for publication. ALS Canada should also be notified as soon as possible of media events related to the project.

9) Grantees are required to inform the Director of Research of significant difficulties, availability of resources, additional funding sources, or changes to the experimental plan throughout the term of the grant.

10) For the purposes of advocating the mission of ALS Canada, researchers may be asked to provide a short lay summary for use in printed or verbal communications by ALS Canada. With this mission in mind, it is expected that ALS Canada funded researchers will actively engage with, or on behalf of, ALS Canada when requested.

11) To encourage collaboration and increase visibility of ALS researchers, ALS Canada is establishing an official national research network. Participation and registration in this network is required in order to receive funding from ALS Canada.

12) A representative of the team will be obliged to present the project at the annual ALS Canada Research Forum.

VIII) QUESTIONS AND ADDITIONAL INFORMATION

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IMPORTANT DATES:

- Call announced February 13, 2015
- Letter of Intent due March 23, 2015
- Invitation for full proposal April 24, 2015
- Full proposal due July 13, 2015
- Announcement of award September 21, 2015
- Earliest funding start date October 1, 2015