OFFICE OF HIGHER EDUCATION

David J. Tomassoni ALS Research Grant Program Annual Report

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About the Office of Higher Education

The Minnesota Office of Higher Education is a cabinet-level state agency providing students with financial aid programs and information to help them gain access to postsecondary education. The agency also serves as the state's clearinghouse for data, research and analysis on postsecondary enrollment, financial aid, finance and trends.

The Minnesota State Grant Program is the largest financial aid program administered by the Office of Higher Education, awarding more than $224 million annually in need-based grants to Minnesota residents attending eligible colleges, universities and career schools in Minnesota. The agency oversees other state scholarship programs, tuition reciprocity programs, student loan programs, Minnesota's 529 College Savings Plan, licensing and early college awareness programs for youth.

About This Report

This is a legislative-mandated report. As requested by Minnesota Statutes, section 3.197, this report cost approximately $735.29 to prepare, including staff time.

Contents

Executive Summary

The 2022 Minnesota Session Laws, Chapter 42, Section 2 ([David J. Tomassoni ALS Research Grant Program](#)[1]) provided a one-time $20,000,000 appropriation from the State's General Fund to the Commissioner of the Minnesota Office of Higher Education (OHE) for the purpose of accelerating Amyotrophic Lateral Sclerosis (ALS) research. These funds are available until June 30, 2026.

The David J. Tomassoni ALS Research Grant awards $19,600,000 to research institutions in Minnesota on a competitive basis to support clinical and translational research that leads to the prevention, functional improvement, and curative efforts for people ALS.

The Agency collaborated with the American Institute of Biological Sciences (AIBS) to conduct a thorough review of the 28 proposals received. After the review, five proposals were selected for awards for a total of $4,341,910 in grants.

Grant Program Development

The 2022 Minnesota Session Laws, Chapter 42, Section 2 provided a one-time $20,000,000 appropriation from the State's General Fund to the Commissioner of the Minnesota Office of Higher Education (OHE) for the purpose of accelerating Amyotrophic Lateral Sclerosis (ALS) research. These funds are available until June 30, 2026. The David J. Tomassoni ALS Research Grant awards $19,600,000 to research institutions in Minnesota on a competitive basis to support clinical and translational research related to ALS.

Round One Request for Proposals

Per the appropriation language, grants were to be awarded to support clinical and translational research related to ALS; "Research topics may include but are not limited to environmental factors, disease mechanisms, disease models, biomarkers, drug development, clinical studies, precision medicine, medical devices, assistive technology, and cognitive studies." [2]

Additionally, eligible applicants for the grants were research facilities, universities, and health systems located in Minnesota.

OHE collaborated with Minnesota Department of Health (MDH) as well as the national Amyotrophic Lateral Sclerosis Association (ALS Association) to develop the Request for Proposals (RFP). The ALS Association is the largest philanthropic funder of ALS research in the world. It has funded more than $120 million to worldwide

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[1] https://www.ohe.state.mn.us/mPg.cfm?pageID=2521
[2] https://www.revisor.mn.gov/laws/2022/0/Session+Law/Chapter/42/

research collaborations. The ALS Association currently funds close to 100 active research projects, selected through a peer review process involving top ALS scientists.

The proposals were assessed to evaluate the studies aim and objectives, innovation, approach, investigators team, environment, and the budget. Each criterion was weighted by a percentage, with Approach and Budget making up 50% of the scoring. The full criteria description can be found in Appendix A.

Timeline and Evaluation

The OHE grant cycle timeline was as follows:

September 1, 2022	Request for Proposals available to applicants
October 7, 2022	Letter of Intent to Submit (LOI) Deadline
December 16, 2022	Deadline for full proposals

There were 28 proposals submitted. Request for funding totaled $34,240,367.

Through the initial application intake, OHE experienced delays due to a lack of institutional and scientific knowledge on ALS research. Recognizing the importance of specialized industry insight, OHE enlisted the American Institute of Biological Sciences (AIBS) through the state bidding process. AIBS, with over five decades of experience, assembled a panel of 19 experts in medical research and scientific fields.

Reviewers included research scientists, professors in Neurology, and heads of neurological research institutes.

After conflict of interest vetting, the panel virtually reviewed proposals in late June, leading to the awarding of five proposals totaling $4,341,910 in July 2023. The 17% success rate aligns with industry standards, reminiscent of the NIH's 2022 research grant success rate of 20%. [3] AIBS and the panel emphasized that unsuccessful applications often lacked sufficient research specificity, deviating from program criteria.

AIBS and panel feedback shared that many of the applications not suitable for funding were scored as such because they were not as research-specific and therefore didn't closely enough align with the program criteria to be considered.

Fiscal Year 2024 Funded Program and Outcomes

Grantee Overview and Program Summary

Institution: **University of Minnesota**
Principle Investigator: **Dr. Pramod Pisharady**
Awarded: $1,437,644

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[3] https://nexus.od.nih.gov/all/2023/03/01/fy-2022-by-the-numbers-extramural-grant-investments-in-research/

Project: *Multimodal Longitudinal Imaging Of Brain And Cervical Cord As A Disease Biomarker Using Microstructure Statistics And Morphometry*

A multimodal analysis of MRI biomarkers (microstructure and morphology) from the brain and spine to improve the sensitivity to detect disease-related changes for durations as low as 3 to 6 months. Hypothesizing that the improved effect size from the multimodal analysis will reduce the required cohort size and duration of clinical trials in ALS, uncovering important correlations between (changes in) MRI biomarkers and plasma neurofilament light (Nfl).

Institution: Mayo Clinic
Principle Investigator: Dr. Nathan Staff
Awarded: $1,125,337
Project: *Predicting The Clinical Response To Mscs: Analysis Of Biomarkers From A Phase 2 Clinical Trial*

To perform serial CSF cytokine, growth factor, and neurofilament analysis in pALS receiving intrathecal adMSCs and to develop a predictive model for response to adMSC therapy utilizing contemporary AI/ML approaches.

Institution: Mayo Clinic
Principle Investigator: Dr. Divyanshu Dubey
Awarded: $793,008
Project: *Humoral Immunoprofiling And Proteomic Analysis Of Amyotrophic Lateral Sclerosis*

A deep analysis of the humoral immune response and cerebrospinal fluid exosomes in ALS will uncover a distinct biomarker signature that will reveal a new understanding of the disease pathogenesis and also enable better identification of ALS.

Institution: University of Minnesota
Principle Investigator: Dr. Marija Cvetanovic
Awarded: $495,000
Project: *Identification Of Protective Factors For Spinal Motor Neurons Using An Ipscs Model*

To create ALS and PLS human motor neurons from patient donated induced pluripotent stem cells (iPSCs), and study human motor neurons in culture as they provide several advantages; they model disease in the context of human genetic background and relevant disease-affected cell type.

Institution: University of Minnesota
Principle Investigator: Dr. David Walk
Awarded: $490,921
Project: *Biorepository To Support ALS Research In Minnesota*

Funding the resources needed to proactively provide sufficient staffing and protocols to meaningfully increase the ability to contribute to basic ALS research.

Future Recommendations and Conclusion

Following this initial awards process, OHE has been collaborating with the ALS Association and AIBS oh how to allocate the rest of the funding in alignment with the legislative intent.

Per AIBS and ALS Association recommendations, this may include revisions to broaden the types of projects these funds may support beyond only research; including but not limited to fellowships, professional development, ALS-adjacent scientific research and projects, etc.

OHE may also suggest directly partnering with the ALS Association or a similar organization to award the remaining funds as it did with AIBS; the ALS Association or similar organization would use these funds to award Minnesota-based projects they receive, and OHE would manage the post-award and monitoring processes.

Additionally, since research projects funded through this program have the potential of operating over 3 to 5 years in order to be meet their goals and objectives, the funding availability end date should be extended in order to have enough time available to hold future competitions and have projects fully completed.

Appendix A

Evaluation Criteria

1. Study Aims and Objectives; Significance; Innovation (25%)
   - Clearly state the specific study aims, objectives, and hypotheses.
   - The proposed project addresses an important problem or a critical barrier to progress in the field.
   - If the aims of the project are achieved, scientific knowledge, technical capacity, and/or clinical practice will be improved.
   - Successful completion of proposed project aims will change the concepts, methods, technologies, treatment, or rehabilitative services that drive this field.
2. Innovation (10%)
   - The proposal challenges and seeks to shift current research or clinical practice paradigms by using novel theoretical concepts, approaches or methodologies, instrumentation, or interventions.
   - A refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions is proposed.
3. Approach; Budget (50%)
   - The overall strategy, methodology, and analyses are well-reasoned, rigorous, and appropriate to accomplish the specific aims of the proposed project.
   - A refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions is proposed. Potential problems, alternative strategies, and benchmarks for successes are presented.
   - If the project is in the early stages of development, the proposed strategy will establish feasibility and manage particularly risky aspects of the proposed project.
   - If the project involves human subjects and/or NIH-defined clinical research, plans are in place for Protection of Human Subjects and inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children, justified in terms of the proposed scientific goals and research strategy.
   - Dissemination and data sharing
   - The budget is clear, concise, and justified by the narrative describing proposed costs.
   - The budget is cost effective and reflective of the RFP and program objectives.
4. Investigator Team; Environment (15%)
   - The PI, collaborators, and other researchers are well suited for the project.
   - Early Stage Investigators or New Investigators have appropriate experience and training.
   - Established Investigators have demonstrated an ongoing record of accomplishments that have advanced their field(s).
   - If the project is collaborative or multi-PI, the investigators have complementary and integrated expertise and their leadership approach, governance, and organizational structure are appropriate for the project.
   - The scientific environment in which the work will be done will contribute to the probability of success.
   - Institutional support, equipment and other physical resources available to the investigators are adequate for the proposed project.
   - The project will benefit from unique features of the scientific environment, subject populations, or collaborative arrangements.

Appendix B

The 2023 ALS competitive grant timeline was as follows:

Jan-April 2023	State RFP procurement to select AIBS
May 2023	Panel Reviewer Recruitment
June 2023	Panel Review and Scoring
July 2023	Finalize and shared outcomes with OHE
August 2023	Grantee Notification

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2024