



# Regenerative Medicine Minnesota

## Internal Controls and Compliance Audit July 2014 through February 2019

January 2020

**Financial Audit Division**

**OFFICE OF THE LEGISLATIVE AUDITOR**

STATE OF MINNESOTA

## Financial Audit Division

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January 2020

Members  
Legislative Audit Commission

Members  
Regenerative Medicine Minnesota Board

Members  
University of Minnesota Board of Regents

This report presents the results of our internal controls and compliance audit of Regenerative Medicine Minnesota for the period July 2014 through February 2019. The objectives of this audit were to determine if Regenerative Medicine Minnesota had adequate internal controls over selected financial activities and complied with significant finance-related legal requirements.

Regenerative Medicine Minnesota does not agree with all findings as stated in their response on page 23. We have considered all additional information presented by Regenerative Medicine Minnesota and the University of Minnesota and believe the evidence we obtained and the testing we performed during the course of the audit supports our conclusions.

This audit was conducted by Lori Leysen (Audit Director), Heather Rodriguez (Audit Coordinator), Tracia Polden (Senior Auditor), and Paul Rehschuh (Senior Auditor).

Regenerative Medicine Minnesota is a partnership between the University of Minnesota and the Mayo Clinic. We received the full cooperation of the partnership entities while performing this audit.

Sincerely,

A handwritten signature in black ink that reads "Lori Leysen".

Lori Leysen, CPA  
Audit Director



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# Report Summary

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Regenerative medicine assists the body’s own ability to heal. Cell and developmental biology, regenerative pharmacology and immunology, medicine and surgery, biotechnology, bioengineering, and other relevant fields, are brought together to develop ways to replace, restore, or regenerate damaged or malfunctioning cells, tissues, and organs to help people return to better health.

The 2014 Legislature provided funding to the University of Minnesota to bring Minnesota to the forefront of regenerative medicine. The Legislature provided \$4.5 million in Fiscal Year 2015 and \$4.35 million in subsequent fiscal years to establish a “collaborative partnership between the University of Minnesota and the Mayo Clinic for regenerative medicine research, clinical translation, and commercialization.”<sup>1</sup> This partnership is now referred to as Regenerative Medicine Minnesota (RMM).

RMM partners created an advisory board to help oversee the program. This five-person board includes two individuals that are not affiliated with the University of Minnesota or the Mayo Clinic. Representatives from the University of Minnesota and the Mayo Clinic serve as co-chairs of the board.

RMM partners use their funding primarily to issue grants. The partners awarded 125 grants, totaling \$17.44 million, from the inception of the program through the end of our audit scope, February 2019.

The Office of the Legislative Auditor (OLA) conducted this audit in response to allegations of mismanagement within the RMM partnership. OLA scoped its work to determine whether RMM had adequate internal controls and complied with finance-related legal requirements. The period under examination went from July 2014 through February 2019.

## Conclusions

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### Internal Controls

OLA found that internal controls over the areas in our audit scope were generally not adequate to safeguard assets and ensure compliance with applicable legal requirements.

#### Internal Controls



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<sup>1</sup> *Laws of Minnesota* 2014, chapter 312, art. 1, sec. 4, subd. 2.

Specifically, this audit identified internal control weaknesses related to proposal evaluations, project awards, and grant project oversight.

- Finding 2. One proposal evaluator had a conflict of interest. (p. 10)
- Finding 3. Grant proposals did not always receive an equal level of scrutiny. (p. 11)
- Finding 4. Administrative errors resulted in inappropriate grant funding decisions. (p. 12)
- Finding 5. Some grant contracts had inconsistent terms. (p. 13)
- Finding 6. Grant reimbursement requests lacked sufficient documentation to justify costs and, in one case, included unallowable costs. (p. 15)
- Finding 7. The Regenerative Medicine Minnesota Board does not review all project deliverable reports. (p. 17)

## Legal Compliance

The RMM partners generally did not comply with finance-related legal requirements.

### Legal Compliance



OLA found that RMM provided accurate information in its biennial reports to the Legislature. However, RMM awarded 58 grants that were not authorized in state law. We also found one instance where grant evaluators did not comply with RMM's conflict of interest policies. Finally, our audit found instances where grant proposals received unequal scrutiny due to noncompliance with RMM's proposal scoring methodology.

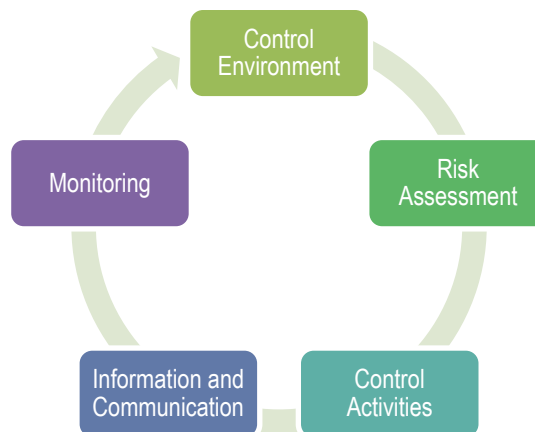
- Finding 1. RMM spent some of its state appropriation on grants the state appropriation law did not authorize. (p. 9)
- Finding 2. One proposal evaluator had a conflict of interest. (p. 10)
- Finding 3. Grant proposals did not always receive an equal level of scrutiny. (p. 11)



# Audit Overview

This report presents the results of an internal controls and compliance audit of selected activities of Regenerative Medicine Minnesota (RMM), a partnership between the University of Minnesota and the Mayo Clinic. Management is responsible for establishing internal controls to safeguard assets and ensure compliance with applicable laws, regulations, and policies.

A strong system of internal controls begins with management's philosophy, operating style, and commitment to ethical values. It also includes processes to continuously assess risks and implement control activities to mitigate risks. A successful internal controls system includes iterative processes to monitor and communicate the effectiveness of control activities.



## Regenerative Medicine Minnesota Overview

Regenerative Medicine Minnesota is a partnership between the University of Minnesota and the Mayo Clinic. The 2014 Legislature mandated that this partnership also include “representatives of private industry and others with expertise in regenerative medicine research, clinical translation, commercialization, and medical venture financing.”<sup>2</sup> The Legislature stipulated that these additional representatives cannot be affiliated with either the University of Minnesota or the Mayo Clinic.

RMM created an oversight board in response to the legislative governance mandate. The dean of the University of Minnesota’s Medical School and the director of the Mayo Clinic’s Center for Regenerative Medicine serve as co-chairs of the board. The partnership also includes three other oversight board members, as depicted in Exhibit 1.

<sup>2</sup> *Laws of Minnesota* 2014, chapter 312, art. 1, sec. 4, subd. 2.

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## Exhibit 1: Regenerative Medicine Minnesota Board



**Dr. Jakub Tolar**  
University of Minnesota  
(Co-Chair)



**Dr. Andre Terzic**  
Mayo Clinic  
(Co-Chair)



**Margaret Anderson  
Kelliher**  
Department of  
Transportation



**Roberta King**  
Be the Match



**Ven Manda**  
Medtronic

SOURCE: Regenerative Medicine Minnesota website (November 2019).

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The 2014 Legislature provided ongoing base funding for the RMM partnership from the state's General Fund for three purposes:

1. Regenerative medicine research
2. Clinical translation
3. Commercialization<sup>3</sup>



Funding for the Regenerative Medicine Minnesota partnership comes from the General Fund, with base funding set at \$4.35 million annually. Funding for the partnership does not have any sunset provision in law.

The legislation prohibits the University of Minnesota from using any funds appropriated to RMM for administrative or monitoring expenses. RMM uses its funding primarily to make grants. Exhibit 2 illustrates the grants that were awarded by the partnership from the inception of the program through March 2019. The University recorded project expenditures under the fiscal year the board funded the project.

University staff help carry out grant administration and oversight functions, and the University absorbs these costs. The University also pays for grant proposal evaluators and biennial audits, which are required by the 2014 legislation. Finally, the University and the Mayo Clinic alternate hosting and paying for an annual celebration (a gathering of current and former awardees and interested legislators). Outside of grant activity, the only expense paid with the partnership's base funding is the development and maintenance of the RMM website, which totaled \$155,466 from July 2014 through March 2019.

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<sup>3</sup> *Laws of Minnesota* 2014, chapter 312, art.1, sec. 4, subd. 2. A copy of the law is in the Appendix.

## Exhibit 2: Regenerative Medicine Minnesota Grant Activity, July 2014 through March 2019 (in thousands)

	Fiscal Year			
	2015	2016	2017	2018
Grants Awarded	\$4,421	\$3,746	\$4,469	\$4,801
Grant Expenditures by Category				
Research	\$2,963	\$2,259	\$2,190	\$1,175
Biobusiness Development	695	446	881	328
Education	700	714	482	226
Clinical Care	3	0	0	0
Total Expenditures	\$4,361	\$3,419	\$3,553	\$1,729
Unspent Awards <sup>a</sup>	\$ 60	\$ 327	\$ 916	\$3,072

NOTES: This exhibit includes expenditure information through March 2019; however, the scope of the audit went through February 2019. RMM made additional research grant awards in January and April 2019, which OLA did not include because the grant periods started after the end of the audit scope.

<sup>a</sup> Unused funding from each year is available to be awarded in future years.

SOURCE: Office of the Legislative Auditor, summary of University of Minnesota data.

Legislation requires the partnership to obtain a biennial financial audit. The results of the audit, as well as the names of award recipients and any affiliation with the University or the Mayo Clinic, must be submitted to the legislative committees overseeing higher education and economic development. The University submitted both the audit and accompanying affiliation reports in January 2017 and January 2019.

OLA compared the information submitted to the Legislature in the mandated reports to the partnership's award records and concluded that the reports were materially accurate.

## Audit Scope, Objectives, Methodology, and Criteria

### Grant Proposal Evaluation and Awarding

This part of the audit focused on the processes for evaluating grant proposals and selecting projects to fund. OLA designed its work to address the following questions:

- Did RMM develop adequate controls to objectively evaluate proposals and award grants?
- Did RMM evaluate proposals against its established criteria and fund the top scoring projects?

To answer these questions, OLA held discussions with the partnership co-chairs and staff from the University to gain an understanding of controls over grant project selection and awards. OLA randomly selected two of the five years in the audit scope and tested project selection and award controls during those periods.

## Grant Award Oversight

This part of the audit assessed the partnership's monitoring of grant projects. OLA designed its work to address the following questions:

- Did RMM develop adequate controls to ensure that funded projects met deliverables and expected outcomes?
- Did the RMM partnership only reimburse allowable project costs?

To answer these questions, OLA held discussions with the partnership co-chairs and staff from the University to gain an understanding of project monitoring controls. We randomly selected 16 of 124 awards for detailed testing, which included 6 University of Minnesota awards, 4 Mayo Clinic awards, and 6 awards to other institutions.<sup>4</sup> Our testing methodology included a review of grant recipient reporting, payroll expenditures, nonpayroll expenditures, and indirect costs.

We conducted this performance audit in accordance with generally accepted government auditing standards.<sup>5</sup> Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

We assessed internal controls against the most recent edition of the internal control standards, published by the U.S. Government Accountability Office.<sup>6</sup> While the University follows the internal control standards published by the Committee of Sponsoring Organizations (COSO), both frameworks describe internal controls through a relatively identical hierarchical structure of five components and seventeen principles.<sup>7</sup>

To identify legal compliance criteria, we examined RMM's enabling legislation. OLA also reviewed internal policies and standards, promulgated by the University of Minnesota, and grant issuance guidelines approved by the board. Finally, we reviewed certain grant policies from the National Institutes of Health.

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<sup>4</sup> There were 125 awards in the audit scope; however, we excluded a clinical care award because it was the only award made in that category.

<sup>5</sup> Comptroller General of the United States, Government Accountability Office, *Government Auditing Standards* (Washington, DC, December 2011).

<sup>6</sup> Comptroller General of the United States, Government Accountability Office, *Standards for Internal Control in the Federal Government* (Washington, DC, September 2014).

<sup>7</sup> University of Minnesota Board of Regents Administrative Policy, *Internal Control*.

# Grant Proposal Evaluation and Awarding

The Regenerative Medicine Minnesota (RMM) partners are responsible for establishing controls to solicit, review, and approve grants. Some of the most important controls that OLA identified include:

- Detailed instructions for grantees, with specific grant categories.
- Grant evaluator conflict of interest guidelines.
- Adoption of the National Institutes of Health’s nine-point scoring system for proposal evaluations.<sup>8</sup>

We reviewed the proposal evaluation and awarding process for two of the five fiscal years in our audit scope to assess the effectiveness of internal controls.

## Grant Award Categories

Legislation requires RMM to use its funds for “regenerative medicine research, clinical translation, and commercialization.”<sup>9</sup> Since the law did not define these terms, we used guidance from the National Institutes of Health, the framework used by the partnership, to arrive at more granular definitions, depicted in Exhibit 3.

### Exhibit 3: National Institutes of Health Definitions

Research	Translation	Commercialization
Systematic study directed toward fuller scientific knowledge or understanding of the subject studied	Applying discoveries generated during research in the laboratory and in preclinical studies to the development of trials and studies in humans  Research aimed at enhancing the adoption of best practices in the community  Cost-effectiveness of prevention and treatment strategies	Developing products, processes, technologies, or services  Production and delivery of the products, processes, technologies, or services for sale to use by...commercial markets

SOURCE: National Institutes of Health, glossary of terms.

<sup>8</sup> National Institutes of Health, *Scoring System and Procedure* (March 2015), [https://grants.nih.gov/grants/peer/guidelines\\_general/scoring\\_system\\_and\\_procedure.pdf](https://grants.nih.gov/grants/peer/guidelines_general/scoring_system_and_procedure.pdf), accessed October 22, 2019.

<sup>9</sup> *Laws of Minnesota* 2014, chapter 312, art. 1, sec. 4, subd. 2.

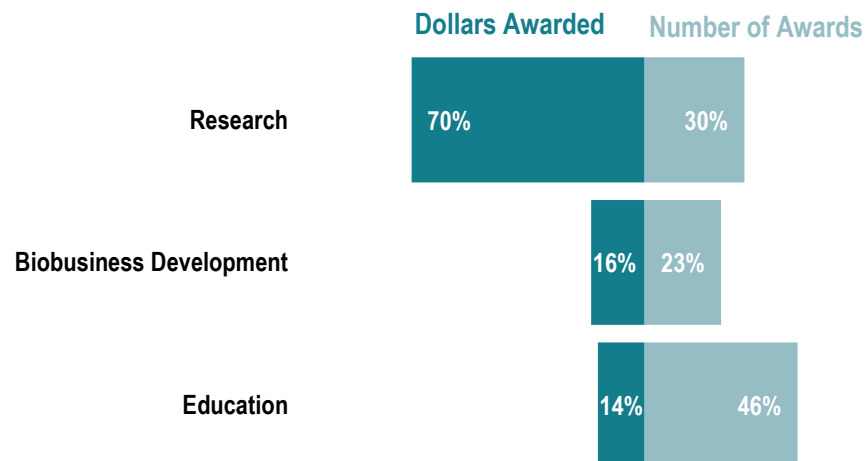
The RMM partnership established four categories for grant awards and defined them as follows:

- **Research.** Covers discovery science, translational research, and clinical trials.
- **Education.** Includes grants to improve knowledge, develop interest, and train and retain students from kindergarten through post-doctoral programs.
- **Biobusiness development.** Includes grants to develop Minnesota businesses and technologies that deliver products, devices, and services.
- **Clinical care.** Includes grants to create and update access to regenerative medicine for patients.

Exhibit 4 shows the distribution of RMM grants in three of these categories.

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#### Exhibit 4: Percentage of RMM Grants by Category



NOTE: The data excludes one clinical care award, which represented 1 percent of total dollars awarded.

SOURCE: Regenerative Medicine Minnesota award records.

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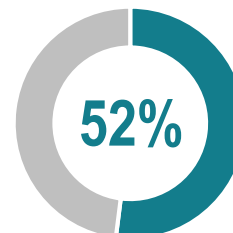
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**FINDING 1**
**RMM spent some of its state appropriation on grants the state appropriation law did not authorize.**


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The 2014 law that created an annual appropriation to the University established clear, unambiguous language for how RMM may use the money. The law says:

This appropriation is from the general fund for the direct and indirect expenses of the collaborative partnership between the University of Minnesota and the Mayo Clinic *for regenerative medicine research, clinical translation, and commercialization*.<sup>10</sup> [Emphasis added.]



of education awards were for grades K-12

In determining RMM’s compliance with this language, we followed the guidance of *Minnesota Statutes* 2019, 645.16, which says, “When the words of a law in their application to an existing situation are clear and free from all ambiguity, the letter of the law shall not be disregarded under the pretext of pursuing the spirit.”

In applying this guidance, we concluded that RMM did not comply with the law when it awarded 58 educational grants during the period covered by our audit, totaling \$2.46 million. We do not question the value of RMM’s education grants; we question RMM’s authority to use money the Legislature has annually appropriated to RMM for a purpose not stated in the appropriation law.

We specifically question RMM’s decision to make 30 education grants—totaling \$441,000—to support programs and activities at the K-12 level of education.<sup>11</sup> These grants paid for programs and activities such as Scrubs Camps,<sup>12</sup> Let’s Explore STEM Camps,<sup>13</sup> and workbooks for grade school students. In making these grants, RMM diverted state money from the purposes the Legislature stated in the RMM appropriation law.

During our audit, RMM officials told us that the Legislature did not intend to limit RMM’s use of its state appropriation to the purposes listed in the appropriation law. Rather, they told us that the Legislature intended for the experts in regenerative

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<sup>10</sup> *Laws of Minnesota* 2014, chapter 312, art.1, sec. 4, subd. 2. A copy of the law is in the Appendix.

<sup>11</sup> The other 28 education grants funded student scholarships and supported various other activities in several higher education institutions, including the University of Minnesota. RMM could have categorized some of these grants as research, but we included all 28 grants in the 58 education grants because that is how RMM categorized them.

<sup>12</sup> Scrubs Camps provide K-12 students with information and experiences related to medical careers generally and not necessarily about careers in regenerative medicine.

<sup>13</sup> STEM is the acronym for a curriculum concept to blend together the teaching of science, technology, engineering and mathematics. According to RMM’s website, its involvement in supporting STEM is to build networks and connections among underrepresented populations of youth, university and college students, and industry members.

medicine at the University and Mayo Clinic to use their discretion and judgment in deciding how RMM should spend the state appropriation. The officials also said that in various conversations, several legislators have supported RMM's use of some of the state appropriation for education grants.

If RMM officials are correct, the appropriate action would be to ask the Legislature to amend the 2014 law to explicitly authorize RMM to make education grants and, specifically, education grants at the K-12 level of education.

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#### **RECOMMENDATIONS**

- **Regenerative Medicine Minnesota should only issue grants for activities authorized in law.**
  - **Regenerative Medicine Minnesota partners should seek a law change if they want to continue awarding educational grants.**
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## **Preventing Conflicts of Interest**

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RMM partners established practices to identify and address potential conflicts of interest with grant proposal evaluators. The partnership has a pool of approximately 120 individuals who serve as independent evaluators. These evaluators cannot work for the University or the Mayo Clinic, and they must have subject matter expertise in regenerative medicine. Evaluators also must reside outside Minnesota, since grant applicants must be based in the state.

RMM partners assess evaluator independence on a proposal by proposal basis. Before assigning proposals, the partners send potential evaluators a list of grant applicants and project personnel to identify potential conflicts.

Overall, OLA found that the RMM partnership's conflict of interest controls were operating effectively. However, we identified one conflict of interest issue during our detailed grant testing.

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#### **FINDING 2**

##### **One proposal evaluator had a conflict of interest.**

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Six evaluators scored a group of biobusiness development proposals in 2016. One of these individuals was also a staff member on a funded proposal from that same category in 2016. The evaluator disclosed the conflict, and the RMM partners did not assign her to evaluate the proposal where she had a personal interest. However, she was still permitted to serve in an evaluator role for competing proposals in that same category.

The objectivity of grant awards can be questioned if evaluators have any personal affiliation with current or former RMM projects. The individual cited above evaluated eight biobusiness proposals in 2016 and gave the lowest scores to five. Had this



conflict been known by unsuccessful applicants, they could have challenged the integrity of the entire pool of biobusiness grant awards in 2016.

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#### **RECOMMENDATION**

**Regenerative Medicine Minnesota partners should not let evaluators score proposals if they have an affiliation with other competing projects.**

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## **Equitable Proposal Evaluation**

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Having the same number of evaluations helps ensure that the partnership treats grant applicants fairly, minimizing the risk of individual rater bias.

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#### **FINDING 3**

**Grant proposals did not always receive an equal level of scrutiny.**

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During detailed testing of the evaluation process, OLA found that grant applications did not always receive the same number of evaluations. For example, in Fiscal Year 2018, 11 of the 34 discovery science research proposals had two evaluations while the remaining 23 proposals had three evaluations. It is difficult to assess the effect that a third reviewer may have had on the final score of each proposal. However, all six of the discovery science research proposals funded in 2018 were from the group that only had two evaluations. Given the unequal treatment, unsuccessful grantees could have challenged the awards due to the potential bias in the scoring.

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#### **RECOMMENDATION**

**Regenerative Medicine Minnesota partners should ensure that all grant proposals receive a consistent review.**

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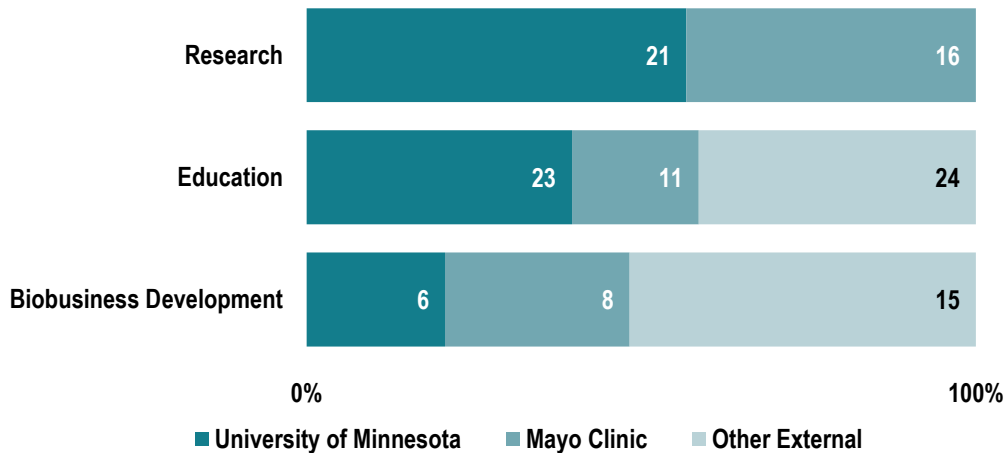
## **Awarding Projects**

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The RMM program administrator compiles all evaluator scores into a master list and works with the University co-chair to determine which projects to recommend for funding. The RMM Board establishes budgets for each award category, which the program administrator and University co-chair use to fund as many projects as possible, based on their relative scores. The RMM Board reviews the scores and recommendations before finalizing awards.

The University and the Mayo Clinic have received the majority of the research and education awards, as depicted in Exhibit 5. Evaluators often rate their proposals the highest, which we contribute, in part, to their existing infrastructure and resources.

**Exhibit 5: The University of Minnesota and Mayo Clinic received the majority of awards in two of three categories**



NOTE: This exhibit excludes one clinical care award received by the Mayo Clinic.

SOURCE: Regenerative Medicine Minnesota award records.

**FINDING 4**

**Administrative errors resulted in inappropriate grant funding decisions.**

Our audit found errors in the process used to aggregate evaluator scores and make grant funding decisions. Due to these errors, the RMM Board approved some grant projects that should not have been selected for funding. The RMM Board also disqualified some proposals that should have received funding.

For example, in 2016 the program administrator used an incorrect formula to calculate the final scores for the grant proposals. This error resulted in the Board erroneously funding a \$250,000 research proposal, thereby preventing funding of a competing proposal with higher evaluator scores. A similar situation occurred in 2018, leading the Board to reject a \$250,000 proposal that should have been funded.

OLA identified other scoring-related errors as well. These errors included incomplete evaluations, evaluator scores that did not follow the National Institutes of Health’s guidelines, errors in the transferring of scores from evaluation forms to compilation spreadsheets, and calculation errors within the compilation spreadsheets.

**RECOMMENDATION**

**Regenerative Medicine Minnesota partners should conduct a comprehensive review of the process used to compile grant proposal scores for decision making.**

The University of Minnesota prepares formal grant contracts for awards to all external entities.<sup>14</sup> These grant agreements are an important internal control because they outline all expectations and responsibilities related to the awards.

The award period in grant contracts is one year. However, research grant awards span two years. For research grants, half of the money is available in the first year. Second year funding is contingent on grantees making adequate progress in the first year of the award period. If approved by the RMM Board, University staff process an amendment to the initial research grant agreements, adding the second year of funding.

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## **FINDING 5**

### **Some grant contracts had inconsistent terms.**

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Grant contracts for Mayo Clinic awards differed from those of other institutions. Mayo Clinic grant contracts included terms from the National Institutes of Health's policy on prior approvals.<sup>15</sup> This language gave the Mayo Clinic the ability to charge costs to grants up to 90 days before the award began. This contract language also gave the Mayo Clinic the ability to make changes to approved grant budget categories, as long as there was no change to the overall project budget or scope. Contracts for other grantees did not include these provisions. To foster consistent grant administration practices, RMM partners should define a standard set of terms to include in all contracts.

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## **RECOMMENDATION**

**Regenerative Medicine Minnesota partners should standardize terms in grant contracts.**

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<sup>14</sup> Since the money for Regenerative Medicine Minnesota is appropriated to the University, the Board has determined that a grant agreement, or a document similar in nature, is not necessary for awards made to internal faculty.

<sup>15</sup> U.S. Department of Health and Human Services National Institutes of Health, *NIH Grants Policy Statement* (October 2018), <https://grants.nih.gov/policy/nihgps/index.htm>, accessed August 15, 2019.



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# Grant Award Oversight

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Regenerative Medicine Minnesota (RMM) partners are responsible for monitoring projects to ensure that grantees use state funds appropriately. This oversight includes the review of project deliverables, as well as the review of the costs charged to grants on an ongoing basis. Our audit included a detailed examination of how the RMM partners fulfilled these important responsibilities.

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## Monitoring Financial Activities

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Legislation prohibits the University from using any RMM funds for administrative or monitoring expenses. Therefore, University employees, paid through other funding sources, assist RMM Board members in performing grant monitoring duties.

RMM partners approve allowable cost categories in all grant agreements. When non-University grantees submit reimbursement requests, University staff and Co-chair Dr. Jakub Tolar review the requests to validate that they align with the allowable cost requirements. Specifically, they told us that they review each reimbursement request to ensure that costs were allowable, allocable, did not exceed the total award amount, were within the approved period, and included the correct indirect cost rate.

Grant agreements provide for quarterly reimbursement of costs. As part of reimbursement requests, grantees must submit current and cumulative project costs, along with a certification to the truth and accuracy of the information.

OLA examined nine grants that the RMM partners funded to organizations other than the University. Our testing confirmed that none of the grantees received reimbursements that exceeded their award amount, and that all grantees used the correct indirect cost rate. However, OLA could not validate the appropriateness of other costs charged to grants because the University did not require documentation, such as invoices.

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### FINDING 6

#### **Grant reimbursement requests lacked sufficient documentation to justify costs and, in one case, included unallowable costs.**

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RMM partners do not have prescriptive documentation requirements for reimbursement requests. As a result, documentation submitted with the requests that OLA examined varied significantly from grantee to grantee. One grantee provided invoices, several others broke out expenses into general categories, one included a system print-out of high-level accounting records, and one had a line item on their reimbursement request referencing their award.

Staff from the University told us that it would be administratively burdensome on the grantee to request more supporting documentation. They also said that there is minimal

risk of grantees seeking reimbursement for unallowable costs. And finally, they told us that they rely in part on a risk assessment done on institutions that receive individual awards exceeding \$25,000. OLA recognizes that reviewing supporting documentation will increase the workload of the University and grantees. However, without a more thorough review process, it will not be possible to verify that grantees appropriately use state money.

University staff told us that they reviewed reimbursement requests to ensure that costs were within the grant period. However, for one of the grants we tested, the University reimbursed \$6,454 in costs that the grantee incurred before the start of the award period. There was no provision in the grant contract that allowed for this type of reimbursement.

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## RECOMMENDATIONS

- **Regenerative Medicine Minnesota partners should outline documentation requirements that will support the ability to validate the allowability of costs.**
  - **Regenerative Medicine Minnesota partners should seek recovery of the \$6,454 in costs that were inappropriately paid to one grantee.**
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OLA also examined six grants that the RMM partners awarded to the University of Minnesota and found much stronger internal controls. For example, we found that the University had well-defined controls over payroll costs charged to grants. In our testing of 60 nonpayroll transactions, OLA also found no instances where the University did not comply with its internal policies or terms of the grant awards. The only exception that we found related to compliance with grant award limits. Three projects had expenditures that slightly exceeded their grant awards. Two of these projects exceeded their grant awards by less than \$500, and the final by \$4,532, due to a miscommunication with program administrators.

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## Monitoring Project Deliverables

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RMM partners rely on grantee reports to validate that projects are achieving the desired outcomes. Grantees must submit a final report at the conclusion of their project that describes the work done and the results. For two-year research grants, grantees also must submit an interim progress report at the end of the first year.

OLA was told that the RMM Board reviews interim progress reports for two-year research projects and takes follow-up action if necessary. Co-chair Dr. Jakub Tolar reviews the final progress reports for all projects.

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**FINDING 7****The Regenerative Medicine Minnesota Board does not review all project deliverable reports.**

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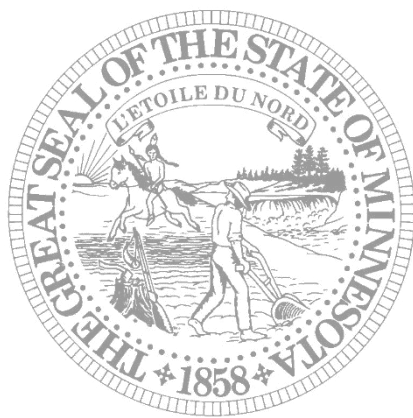
Co-chair Dr. Jakub Tolar said that he reviews every final project report. However, other members of the RMM Board do not consistently review or discuss final project deliverables. RMM Board members also do not review or discuss all interim progress reports for two-year research projects, which account for about 70 percent of the total dollars. We were told that when time permits, the RMM Board discusses interim reports to assess whether projects are making adequate progress. However, if time does not permit, Dr. Tolar presents an overview of each project's activities and accomplishments. Grantees submitted about 30 interim reports during the scope of our audit. However, OLA found evidence of only 11 interim project discussions in the board minutes.

Project reports are an important tool to assess whether grant money was well spent. They also can help the RMM partners identify grantees that may not merit future funding. RMM partners can strengthen grant oversight controls by spending more time at board meetings discussing interim and final project results.

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**RECOMMENDATION****The Regenerative Medicine Minnesota Board should review all interim and final progress reports.**

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# List of Recommendations

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- Regenerative Medicine Minnesota should only issue grants for activities authorized in law. (p. 10)
- Regenerative Medicine Minnesota partners should seek a law change if they want to continue awarding educational grants. (p. 10)
- Regenerative Medicine Minnesota partners should not let evaluators score proposals if they have an affiliation with other competing projects. (p. 11)
- Regenerative Medicine Minnesota partners should ensure that all grant proposals receive a consistent review. (p. 11)
- Regenerative Medicine Minnesota partners should conduct a comprehensive review of the process used to compile grant proposal scores for decision making. (p. 12)
- Regenerative Medicine Minnesota partners should standardize terms in grant contracts. (p. 13)
- Regenerative Medicine Minnesota partners should outline documentation requirements that will support the ability to validate the allowability of costs. (p. 16)
- Regenerative Medicine Minnesota partners should seek recovery of the \$6,454 in costs that were inappropriately paid to one grantee. (p. 16)
- Regenerative Medicine Minnesota Board should review all interim and final progress reports. (p. 17)



# Appendix: 2014 Appropriation Law

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***Laws of Minnesota 2014, chapter 312, art.1, sec. 4, subd. 2.***

(a) This appropriation is from the general fund for the direct and indirect expenses of the collaborative partnership between the Univerity [*sic*] of Minnesota and the Mayo Clinic for regenerative medicine research, clinical translation, and commercialization. In addition to representatives from the University of Minnesota and the Mayo Clinic, the collaborative partnership must include representatives of private industry and others with expertise in regenerative medicine research, clinical translation, commercialization, and medical venture financing who are not affiliated with either the University of Minnesota or the Mayo Clinic.

(b) By January 15 of each odd-numbered year beginning in 2017, the partnership must submit an independent financial audit to the chairs and ranking minority members of the committees of the house of representatives and senate having jurisdiction over higher education and economic development. The audit must include the names of all recipients of grants awarded by the partnership and their affiliation, if any, with the University of Minnesota or the Mayo Clinic.

(c) The full amount of this appropriation is for the partnership and may not be used by the University of Minnesota for administrative or monitoring expenses.

(d) For fiscal year 2016 and thereafter, the base for this program is \$4,350,000.





**Board**  
**Jakub Tolar, MD, PhD**  
*University of Minnesota Co-Chair*

**Andre Terzic, MD, PhD, FAHA**  
*Mayo Clinic Co-Chair*

**Margaret Anderson Kelliher, BA, MPA**

**Roberta King, MPH**

**Ven Manda, BS, MS**

January 8, 2020

James R. Nobles  
Legislative Auditor  
Office of the Legislative Auditor  
State of Minnesota  
Room 140, Centennial Building  
658 Cedar Street  
Saint Paul, Minnesota 55155-1603

Dear Mr. Nobles:

This letter is submitted in response to the audit report issued by the Office of Legislative Auditor (“OLA”) of the Regenerative Medicine Minnesota (“RMM”) program. As you know, RMM is a partnership between the University of Minnesota and the Mayo Clinic created in collaboration with the legislature. We believe the conclusions reached by OLA carry judgments that reach beyond the governing legislation, and thereby do a disservice to the diligence and good faith of those advancing the mission of the RMM partnership.

In 2014, the legislature set forth a three-part mission for the RMM partnership of research, clinical translation, and commercialization. In order to advance those goals, the RMM partnership, in good faith, developed a grant program that, in a variety of ways, furthers its mission. Over 160 projects have been funded that advance regenerative medicine – an evolving field where much education and work is required to position Minnesota as a leader.

For six years, the RMM partnership has had its eye on the three long-term goals prescribed by the legislature. As a good public servant should, RMM has dutifully and transparently reported to the legislature – and to OLA in 2017 – about the education and other grants awarded by the RMM partnership to further its mission. After a six-year history of collaboration and good faith, we believe it is unfair for OLA to now substitute its judgment for how our education institutions should partner together to carry out RMM’s mission. We respect that in your judgment the RMM partnership could better explain why we believe each grant furthers one or more of our three aims; we object to your 2019 audit conclusion that the RMM partnership may not include education in how it chooses to further its mission. For us, education is integral to all three aspects of our mission. Developing a patient base for research trials and clinical work, and building a future workforce, is essential to the future of regenerative medicine.

James R. Nobles  
Page 1

We respectfully disagree with your reading of the RMM partnership law that leads you to conclude that education grants – the value of which you state you do not question – are inconsistent with what the legislature and its Higher Education Committee expects of our two education institutions. Your conclusions hinge upon your interpretation of how to read the language of the legislation funding the RMM partnership created in close collaboration with the legislature in 2014. The RMM partnership is committed to the mission framed by the legislature for the RMM partnership of regenerative medicine research, clinical translation and commercialization. It is with that same humility with which we have approached that important work that we must now emphasize that the legislature called upon the RMM partnership to use its best education and scientific judgment to decide how to accomplish that three-part mission. See paragraph (c) of the law: “The full amount of this appropriation is for the partnership.” That paragraph (c) language informs whether the three-part mission in the statute is to be achieved using the scientific and educational judgment of the University of Minnesota and the Mayo Clinic, as opposed to it being an enumeration of the only type of grants authorized. Your report does a disservice to our dutiful partnership by isolating the three-part mission phrase from the rest of the law and then substituting your judgment as to how to accomplish those purposes in a manner that is contrary to the evidence of the legislature’s intent and a proper reading the law. The unfairness of your conclusions to the partnership’s work is evidenced by the efforts you take to import third party definitions and manipulate wording to support your interpretation of a law that you say is unambiguous, and then your later acknowledgement that many of the education grants fit the law if they are re-labeled to fit the way you read the law.

While we disagree with your reading of the law regarding education grants, we do not want our future work clouded by a disagreement. For that reason, the RMM partnership will takes steps to expressly tie future education grants to one of the three-parts of the RMM partnership mission spelled out in the authorizing legislation, and will continue to dutifully advise the legislature and OLA of its activities as the law requires. Furthermore, despite our disagreement with your conclusion on the strength of the RMM partnership’s internal controls which you detail in your report, we have taken or will take steps to implement certain recommendations from your report as described in this response.

### **Background**

Regenerative medicine has the potential to unlock new cures and treatments for some of the most devastating health conditions facing our population, such as dementia, diabetes, and cardiovascular disease by boosting the body’s natural ability to heal itself, using healthy cells, tissues, or organs from a living or deceased donor to replace damaged ones, or delivering specific types of cells or cell products to restore function in diseased tissues and organs. The field of regenerative medicine is complicated, challenging, and often misunderstood.

In recognition of the value of ensuring Minnesota is a leader in this complex, transformative field of health care, the 2014 legislature passed an appropriation law<sup>1</sup> as part of its omnibus supplemental budget bill. This appropriation law came about as the result of a joint advocacy effort by the University of Minnesota and the Mayo Clinic, two educational institutions in the state, to educate legislators on the importance of advancing this emerging area of science. While a different, and earlier bill would have appropriated funds for regenerative medicine activities to the Department of Employment and Economic Development, that bill was abandoned in favor of the appropriation being made “for the *direct and indirect* (emphasis added) expenses of the collaborative partnership between the University of Minnesota and Mayo Clinic.” This collaborative partnership is what is known today as the RMM partnership.

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<sup>1</sup> Laws of Minnesota 2014, Chapter 312, Art. 1, Sec. 4, Subd. 2.

## Legal Compliance

### Finding 1

RMM disagrees with OLA's Finding 1 that the RMM partnership spent some of its state appropriation on grants the state appropriation law did not authorize.

#### The RMM Partnership's Interpretation of the Law.

Paragraph (a) of the law reads: "This appropriation is from the general fund for the direct and indirect expenses of the collaborative partnership between the University [sic] of Minnesota and the Mayo Clinic for regenerative medicine research, clinical translation, and commercialization. In addition to representatives from the University of Minnesota and the Mayo Clinic, the collaborative partnership must include representatives of private industry and others with expertise in regenerative medicine research, clinical translation, commercialization, and medical venture financing who are not affiliated with either the University of Minnesota or the Mayo Clinic."

The RMM partnership has, in good faith, interpreted paragraph (a) of the law as describing the RMM partnership and its three-part mission of regenerative medicine research, clinical translation and commercialization. The law does not dictate how the RMM partnership must use funds to advance that three-part mission. Rather, that judgment was left to the partnership. The RMM partnership has exercised that judgment using the science, business and education background, knowledge and expertise of members of its board. This understanding of the law comes from reading the whole law, and not just separating out and focusing solely on the phrase "regenerative medicine research, clinical translation and commercialization" in isolation. For example, the second sentence of paragraph (a) of the law builds on the first sentence's description of the collaborative partnership by adding how the collaborative partnership must be constituted - "In addition to representatives from the University of Minnesota and the Mayo Clinic, the collaborative partnership must include representatives of private industry and others with expertise in regenerative medicine research, clinical translation, commercialization, and medical venture financing who are not affiliated with either the University of Minnesota or the Mayo Clinic." Paragraph (c) of the law then states that the full amount of the appropriation is "for the partnership." The only express limitation the law places on use of the state appropriation is in the second part of paragraph (c) which states that the appropriation may not be used "by the University of Minnesota for administrative or monitoring expenses".<sup>2</sup> It is with good faith and without any reason to believe that its interpretation would now be put into doubt that the RMM partnership has been dutifully exercising its judgment to fulfill its three-part mission by, among other things, awarding education grants.

#### Rules of Grammar; Legislative History; Legislative and Administrative Acquiescence.

Minnesota law expressly states that the object of all interpretation and construction of laws is to ascertain and effectuate the intention of the legislature, and that every law shall be construed, if possible, to give effect to all its provisions. Minn. Stat. § 645.16. For the past six years, the RMM partnership has fully believed that its reading of the law, giving effect to the entirety of paragraph (a) along with paragraph (c) of the law, was effectuating the will of the legislature and acting consistently with its direction. Nonetheless, in light of OLA now raising a question on how to read the law, it is appropriate to understand the plain meaning of the law by utilizing rules of grammar (*Barnhart v. Thomas*, 540 U.S. 20 (2003), *Woodhall v. State*, 738 N.W.2d 357 (2007) and Minn. Stat. § 645.08(1)), or if the law is

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<sup>2</sup> As noted in the OLA report, the University of Minnesota has not used any of the monies for administrative or monitoring activities performed by the University of Minnesota.

ambiguous to ascertain the intention of the legislature through mechanisms such as legislative history and legislative and administrative interpretations of the law (Minn. Stat. § 645.16).

Under the grammatical rule of the last antecedent, a clause or phrase should be read to modify only the noun or phrase that it immediately follows. Applying this rule, the clause “for regenerative medicine research, clinical translation and commercialization” in paragraph (a) must modify the phrase “the collaborative partnership between the University of Minnesota and the Mayo Clinic,” supporting the RMM partnership’s good faith understanding that such clause is an expression of the three-part mission of the partnership and not a limitation on use of funds. See *Barnhart, Woodhall*, and *State v. Pakhnyuk*, 926 N.W.2d 914 (Minn. 2019).

Furthermore, legislative history along with legislator and state administration endorsement of the RMM partnership’s interpretation of the law for the past six years serves as confirmation of the partnership’s interpretation, see Minn. Stat. § 645.16, and it would be inappropriate at this late date to retroactively impose a different interpretation as a standard for assessing and concluding on the partnership’s financial compliance with the law.

That reading of paragraph (a) is the reading that gives effect to that law’s other provisions, as Minn. Stat. § 645.16 counsels. While you read the three-part mission as an enumeration of grant authorizations, the law authorizes the *direct* expenditures you approve of and the *indirect*, longer-term education expenditures the RMM partnership employs. Indeed, only administration and monitoring expenses are excluded in paragraph (c), the provision that emphasizes that the state funds the partnership, not simply direct funding of three narrowly-read types of grants.

The law came out of the Higher Education and Workforce Development Committee. In testimony before the Higher Education and Workforce Development Committee, the University of Minnesota and Mayo Clinic stated clearly that this investment is needed to advance the field of regenerative medicine, showing that the occasion for the law was to position Minnesota as a leader in the field of regenerative medicine, now and into the future. By necessity, this must include educating people of all ages in all aspects of this emerging area. The fact that the University of Minnesota and the Mayo Clinic, two educational institutions, were selected to form the partnership and administer the program, rather the legislature providing funding to other, capable non-academic bio-business entities in the state to administer it, is telling of the importance of education in this effort. The RMM partnership co-chairs recall that during the legislative process that House and Senate leaders on this bill made it clear that they expected an education and job creation component to the program.

In addition to the legislative history, the fact that education grants have been awarded by the RMM partnership has been completely transparent to the legislature, administrative agencies, the public and OLA, as evidenced by the following:

- In November 2014, Senators and Representatives received an email from the RMM partnership attaching the announcement of Minnesota Regenerative Medicine (now RMM), which stated the goal of the RMM partnership as “bringing the benefits of regenerative medicine to Minnesotans through research, education, outreach, healthcare, and technology development” and listing “Education” as a category for which funding was available. Responses to that email included “This is fantastic news! So glad we were able to accomplish this.”

- Legislators have been invited to and have attended all annual meetings of RMM at which the education program grants and projects have been prominently and extensively featured. At every



interaction, representatives have been supportive of the inclusion of the education grants, recognizing how those grants advance the program's goals.

- As noted in OLA's report, the RMM partnership provided a full report and audit, with an agreed upon procedures report from the public accounting firm of Deloitte LLP, to the legislature in 2017 and in 2019, covering all grants issued by the RMM partnership. Those reports clearly identified that education grants had been awarded, both in the cover letters addressed to the Chairs and Ranking Minority Members of Senate and House Committees having jurisdiction over Higher Education and Economic Development, and by line items labeled "education programs" in the audited statements. The legislature accepted the reports without raising questions or concerns about those education grants.
- The state's own website (Minnesota Department of Administration Grants Management web page - <https://mn.gov/grants/?id=1093-289594>) and Minnesota State Register volumes beginning with December 1, 2014 clearly identify education grants as one type of grant available through RMM.

The fact that the legislature and the Minnesota Department of Administration Grants Management have acquiesced in the RMM partnership's interpretation that education grants are allowed by law must be given considerable weight in the proper interpretation of the law. *Anderson-Cherne v. Hatfield*, 279 Minn. 478 (1968) and Minn. Stat. § 645.16(8).

In fact, in May 2017, OLA sent a letter to the RMM partnership stating that OLA was reviewing RMM and requested information from RMM for that review. The information requested included information about education grants. The RMM partnership provided all the requested materials. OLA did not raise any objections to the education grants or any other practices of the RMM partnership in that 2017 review. OLA's decision to now call into question the interpretation of a law that has been consistently, transparently and in good faith applied since its inception is a disservice to an important program.

#### OLA's Interpretation.

It is difficult to understand how OLA, six years after the passage of the law, fails to recognize the RMM partnership's good faith interpretation and application of the law, as supported by legislative history and legislator and administration acquiescence, and instead chooses to believe that the law does not authorize education grants.

In reaching its conclusion, OLA asserts that the law established clear, unambiguous language for how RMM may use the money. To reach this conclusion, OLA has found it necessary to rearrange the text of, add new words to, and selectively quote and highlight sections of, paragraph (a).<sup>3</sup> Furthermore, recognizing that the law does not provide any definitions, OLA chooses to look to federal National Institute of Health ("NIH") definitions to define words in a state law. How are these exercises not an acknowledgment by OLA that the law is not free from all ambiguity? Furthermore, OLA's presentation of three NIH definitions extracted from a glossary of definitions in the form of a three-column color chart could easily mislead a reader into thinking that the NIH has a similar law for regenerative medicine research, translation and commercialization. This is not the case. Rather, OLA is merely carrying over three definitions from a list of hundreds of words in the NIH Glossary and Acronym List to define a state law that should need no importing of third party terms if, as OLA asserts, the law is unambiguous. If OLA feels it is necessary to go through these efforts to achieve, in OLA's opinion, an unambiguous

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<sup>3</sup> See pages 5, 8 and 10 of the OLA report.

reading of the law, it would be fair for OLA to also acknowledge that the law does not expressly prohibit education grants.

Against this backdrop, we do not believe there is a sound basis for the audit report to conclude that education grants are “not authorized in state law.” Again, we respect an auditor’s quest for clarity. If it is your judgment that the legislature should have excluded education grants as part of the administrative-and-monitoring exclusion in paragraph (c), then your report should explain that education grants are not *specifically* authorized and that OLA accordingly questions those grants. Instead, you declare that education grants are “unauthorized” – creating an impression that they lack good faith, when in fact, education has an important role in advancing the RMM mission as you implicitly acknowledge for many of the education grants.

Significantly, OLA recognizes that many of the grants labeled as “education grants” would have been deemed allowable if they had carried a different label of research, clinical translation or commercialization. While we acknowledge that the RMM partnership can do a better job in the future to expressly tie future education grants to one of the three-parts of the RMM partnership mission, we struggle to find the fairness in OLA’s insertion of its own judgment for the will of the legislature. If OLA seeks more clarity in the law, a more judicious approach is for OLA to recommend that clarity from the legislature rather than fault the University of Minnesota and the Mayo Clinic for using their judgment in good faith to implement the legislature’s directive.

### Findings 2 and 3

We do not see how Findings 2 and 3 are applicable to the question of whether the RMM partnership complied with finance-related requirements. Our specific comments to those two findings are expressed below under “Internal Controls.”

### Internal Controls

We believe that OLA has unfairly and arbitrarily characterized RMM’s internal controls as generally not adequate without providing any objective basis on which it has reached its conclusion, and in fact acknowledges that the law does not set forth grant administration requirements or standards for the RMM partnership to follow. No finding in the report by itself or in combination with others is sufficient to support OLA’s conclusion that the RMM partnership’s internal controls were generally not adequate. While it may be appropriate for OLA to share with the RMM partnership suggestions opportunities for improvement, to insert OLA’s judgment in the absence of prescribed grant administration requirements to conclude that the RMM partnership does not have adequate internal controls is misplaced and misleading, and does a disservice to the work of the public servants who carefully administer the RMM program within grant administration boundaries routinely found acceptable by the federal government and other granting entities. In fact, it is important to note that the OLA report identifies, and therefore acknowledges, the specific internal controls that the RMM partnership has in place and is applying in its grant administration. While it may be fair to say that the RMM partnership did not execute on its internal controls flawlessly, it is misleading and inconsistent with other OLA statements in its report to say that the RMM partnership does not have generally adequate internal controls.

The particulars of our reactions and responses to OLA’s internal controls findings are as follows.

## Finding 2

We disagree with this finding. While we have changed our practice to not permit evaluators to score any proposals if they have an affiliation with other competing projects to avoid the perception of a conflict, we disagree with your finding because the conflict that arose with one evaluator in 2016 was appropriately managed.

## Finding 3

We disagree with this finding because neither the law nor any written policy of the RMM partnership establishes requirements on how many evaluators are to review proposals. The RMM partnership has ensured that all proposals are reviewed by multiple evaluators, with a goal of using three evaluators. OLA's statement that two, instead of three, evaluators used in some proposals may have created bias in scoring results is, as OLA acknowledges, speculative.<sup>4</sup>

## Finding 4

We agree that administrative errors are not acceptable. A comprehensive review of the process used to compile grant proposal scores will be undertaken to ensure errors are avoided.

## Finding 5

We disagree with this finding. Federal regulations require pass-through entities, such as the University of Minnesota, to evaluate each subrecipient's risk of noncompliance with statutes, regulations, and the terms and conditions of the subaward to determine the appropriate type of subrecipient monitoring and the appropriate award conditions (45 CFR § 75.352(b) and 45 CFR § 75.207). The University of Minnesota employs this risk analysis for all potential subrecipients, whether funding is provided by a federal agency or another entity, such as the state of Minnesota.

The terms included in each RMM partnership grant contract are based on this comprehensive risk analysis of the subrecipient. Accepting OLA's recommendation would weaken the RMM partnership's ability to include stronger terms in certain subrecipient grant contracts, where the risk assessment finds that stronger terms are warranted to safeguard how state funds are used. In order to maintain this strong internal control, we disagree that there should be standardized terms for all RMM partnership grant recipients. Nonetheless, the RMM partnership will review the grant template to identify opportunities to balance the existing important risk assessment considerations with OLA's recommendation to achieve more uniformity in contract provisions.

## Finding 6

We disagree that grant reimbursement requests lacked sufficient documentation to justify costs. As explained, the documentation required to justify costs submitted for reimbursement by a subrecipient is based upon the above mentioned risk assessment process. This process for documentation support is consistent with federal agency and other grant making entity requirements, as evidenced by a recent, routine audit by the Department of Health & Human Services Office of Inspector General. We agree with the part of the finding that in one case a grant reimbursement request included an unallowable cost. The University will refund the RMM partnership the amount the OLA identified was incorrectly paid to one grantee.

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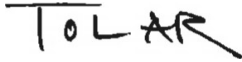
<sup>4</sup> See page 13: "It is difficult to assess the effect that a third reviewer may have had on the final score of each proposal."

Finding 7

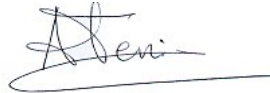
We agree with this finding. All interim and final reports will be made available for review by the RMM board going forward.

As always, we welcome the opportunity to discuss our perspective with you and respectfully request that you reassess the conclusions you are reaching. We believe in this program and want it to be successful for the people of Minnesota.

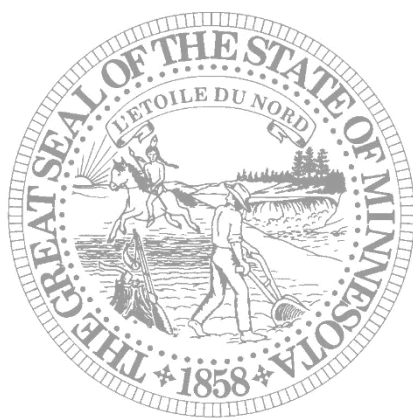
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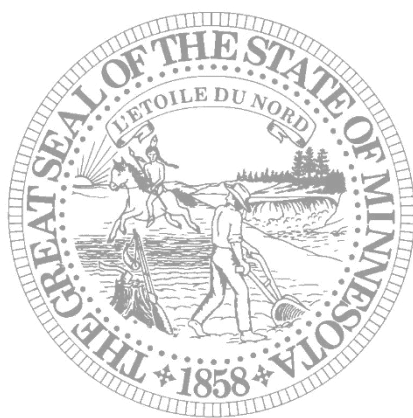
Handwritten signature of Jakub Tolar in black ink, consisting of the letters 'TOLAR' in a stylized, slightly slanted font.

Jakub Tolar, M.D., Ph.D.  
Vice President for Clinical Affairs  
Co-Chair, Regenerative Medicine Minnesota  
Board

Handwritten signature of Andre Terzic in black ink, featuring a stylized 'A' and 'T' followed by 'Terzic' in a cursive script, with a long horizontal line underneath.

Andre Terzic, M.D., Ph.D.  
Mayo Clinic Center for Regenerative Medicine  
Co-Chair, Regenerative Medicine Minnesota  
Board





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