

Memorandum

Office of the Vice Principal (Research and Innovation)

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TO: Board of Governors
FROM: Dr. Rosie Goldstein, Vice-Principal (Research and Innovation)
SUBJECT: International Progressive Multiple Sclerosis Alliance Grant Agreement
DATE: February 2, 2017
DOCUMENT #: GD16-33

ACTION REQUIRED: INFORMATION APPROVAL/DECISION

ISSUE & EXPECTED OUTCOME Approval is sought to execute a grant agreement valued at €3.8 million (\$5.4 million CAD) with the International Progressive Multiple Sclerosis Alliance (IPMSA). The project is entitled “An MRI biomarker for disability progression for use in clinical trials” led by Dr. Douglas Arnold from the Department of Neurology and Neurosurgery, Faculty of Medicine.

BACKGROUND & RATIONALE **The International Progressive Multiple Sclerosis Alliance (IPMSA):** IPMSA was established in 2012 by six founding members, including the Multiple Sclerosis (MS) Society of Canada, as a joint commitment to accelerate the development of treatment for progressive MS by removing scientific and technology barriers. Pursuant to a Memorandum of Understanding between members of IPMSA, the National MS Society in the United States serves as the lead entity for issuing and managing any awards and funding provided by the Alliance.

About the Proposal: Dr. Arnold’s proposal is under the umbrella of one of three Collaborative Network Awards granted by IPMSA worldwide. The project aims to develop new MRI outcome measures that could result in more efficient preliminary assessment of drug efficacy, potentially resulting in smaller, shorter, and less costly clinical trials. In addition to several co-investigators at McGill which include Drs. Sridar Narayanan, Louis Collins, Tal Arbel and Doina Precup, the team is composed of investigators from collaborating institutions, which include Brigham and Women’s Hospital affiliated with Harvard University, University of Genoa, University College London, University of Alabama at Birmingham, University Hospital of Basel; VU University Medical Center, University of California at San Francisco, University of Texas Health Center at Houston, and Oregon Health and Science University.

The four-year grant agreement is valued at €3.8 million, which will be issued to McGill in its entirety. Whereas €2.2 million will support research at McGill, the University will transfer the remaining €1.6 million after the

finalization of formal sub-award agreements with each respective collaborating institution.

ALIGNMENT WITH MISSION AND STRATEGIC PRIORITIES	The project covered by the grant agreement is in line with the Office of the Vice-Principal (Research and Innovation)'s mission to increase research intensity and revenues at McGill. It is also aligned with McGill's strategic priority in the field of Neuroscience.
COMPLIANCE WITH UNIVERSITY POLICY	The grant agreement is in compliance with the <i>Policy on Intellectual Property</i> and the <i>Regulation on the Conduct of Research</i> . In accordance with the <i>Regulations Relating to the Approval of Contracts and Signing Authority</i> , the grant agreement is being presented to the Board of Governors for approval. Consultations are in progress to align the agreement with the Montreal Neurological Institute (MNI)'s Open-Science Initiative which favors the release of data and results to the scientific community and precludes the filing of patent applications for the commercialization of any new discoveries.
COMPLIANCE WITH LEGISLATION/ EXTERNAL REGULATIONS	The submission process to the Research Ethics Board of the MNI, required due to the use of data collected from human participants, has been completed and approval is anticipated shortly. The Office of Sponsored Research and Legal Services have reviewed and approved the agreement.
RISK FACTORS	<p>As McGill will be issuing a certain number of sub-award agreements to various institutions in Europe and the United States, it will require a high level of coordination to ensure the achievement of project milestones in a timely fashion. There is a minor risk that IPMSA will terminate the agreement in advance of completion if certain milestones are not accomplished. All relevant terms and conditions, including termination clauses, will be disseminated to collaborators through formal sub-award agreements, which will be reviewed by Legal Services.</p> <p>An additional risk factor is related to the value of different currencies (Euro, CAD and USD) and the losses that may be incurred due to currency exchanges. While the grant has been awarded in Euros, the funds will be issued to McGill partly in CAD and partly in USD. McGill's accounting systems require that all the funds be handled in CAD. Given that a number of sub-awards to other institutions in the US and Europe will need to be issued, there is an inherent risk related to fluctuations in the value of currency. In order to mitigate the University's risk, sub-award agreements will include clauses that allow for re-adjustments in budget to compensate for any large fluctuations.</p>
SUSTAINABILITY CONSIDERATIONS	The nature of the project is such that it is an example in the field of sustainability. The project centers on the secondary use of previously collected magnetic resonance imaging and other clinical data from phase 2 and 3 studies run by various pharmaceutical companies over the last 10 years. These previously collected data will be used to generate new tools (MRI-based biomarkers) to be used in future phase 2 multiple sclerosis clinical trials that aim to look at the effect of clinical candidates on the progression of disease.
IMPACT OF DECISION AND NEXT STEPS	The execution of the grant agreement will allow the funds to be released and the project to officially start as the proposed start date was January 1, 2017.

**MOTION OR
RESOLUTION
FOR APPROVAL**

Be it resolved that the Board of Governors, on the recommendation of the Vice-Principal (Research and Innovation), approve the Grant Agreement between The Royal Institution for the Advancement of Learning/McGill University and the National Multiple Sclerosis Society, on behalf of the International Progressive Multiple Sclerosis Alliance, and authorize the Vice-Principal (Research and Innovation) to sign the Grant Agreement and any related documents, provided that where necessary, they are reviewed by Legal Services.

APPENDICES

IPMSA Grant Agreement is available from the Secretariat upon request.
