

SUBMISSION FORM
University System/Employee Intellectual Property Joint Participation
MUSP 407

This form is to be submitted with any Board of Regents item whereby a campus seeks the approval of an agreement with or arrangement regarding an employee pursuant to 20-25-109 MCA and Regents Policy 407.

When the submission concerns matter of trade secrets or confidential business information, or any other matter entitled to privacy under state or federal law (e.g., the federal statute known as Bayh/Dole) the submitting campus may request consideration of the submission, in whole or in part, in executive session.

The submitting campus should also provide the Commissioner a copy of the contract(s) that form the basis for the cooperative arrangement for which approval is sought. Submission of the contract does not indicate a conclusion that all or part of the contract is a public document and the question of whether it is in whole or in part protected from public disclosure will be evaluated on a case-by-case basis.

1. Summarize the nature of the intellectual property (IP) that was developed by the employee seeking approval. Indicate the sources of funding for the research that resulted in this invention.

Neurofluidic Diagnostics is an entrepreneurial idea which may lead into a spin off from the Kunze Neuroengineering Lab at Montana State University (MSU) in the upcoming years. This spin-off idea was developed by the graduate student Zeynep Malkoc (Chemical Engineering) and me with support from the MSU Launch Pad.

The idea involves commercializing a microfluidic-based technology which allows us to refine diagnostics for neurodegenerative diseases. The IP covers a microfluidic device, its design and fabrication which was made in-house and is called NeuroCOMEXI. The IP also covers applications of this technology in exosome-based and calcium signal assessment in relation to neurodegeneration. Preliminary results of the application have been presented at two peer-reviewed conferences (MicroTAS) in 2020, and 2021, from which two provisional patents were filed, initially in September 2020, and refiled in October 2021 through the MSU Technology Transfer Office (TTO).

Source of funding at the initial state has been MSU VPREDGE sponsored faculty start-up for the PI Dr. Kunze (August 2016 – December 2020). Further technology enhancement of this project has been entirely sponsored by MSU intern research funds (TEER award, January 2019 – May 2020), and MSU Gap Catalyst grant in Fall 2021. The project is based on a collaboration between the Kunze (Electrical Engineering) and the McCalla Lab (Chemistry) at MSU.

Zeynep Malkoc also participated and presented the commercialization idea at the MSU Idea Challenge in Fall 2021, where she won 1st place in the life science category.

2.

a. Name(s) of the university employee(s) involved.

- Dr. Anja Kunze
 - Lead Inventor of the intellectual property
 - Assistant Professor, Electrical and Computer Engineering, MSU
- Dr. Stephanie E. McCalla
 - Co-Inventor of the intellectual property
 - Associate Professor, Chemical and Biological Engineering, MSU
- Zeynep Malkoc
 - Co-Inventor of the intellectual property, Project collaborator
 - Graduate Student, Chemical Engineering Program, MSU
 - Supervised/Mentored by Dr. Kunze
- Esther Stopps
 - Project collaborator, Technology development/improvement
 - Graduate Student, Chemical Engineering Program, MSU
 - Supervised/Mentored by Dr. McCalla

b. Name(s) of business entity(ies) involved.

Neurofluidic Diagnostics, a new technology startup / spin-off in Bozeman, MT (not yet filled / incorporated).

3. The university and employee(s) are seeking approval for (check as many as appropriate):

- a. The employee to be awarded equity interest in the business entity
- b. The employee to serve as a member of the board of directors or other governing board of the business entity
- c. The employee to accept employment (consulting activity) from the business entity
- d. Other. Please explain.

4. Summarize the nature of the relationship between the university and the business entity (e.g., the entity is licensing the intellectual property from the university, the entity is co-owning the intellectual property with the university).

Neurofluidic Diagnostics is currently negotiating terms and condition for the technology transfer with the MSU Technology Transfer Office (“TTO”). Currently TTO has filed all the intellectual property through a provisional patent application which will remain valid until October 2022. If Neurofluidic Diagnostics becomes a successful entity, it will aim to obtain at least an exclusive know-how license ship with possible co-ownership. The duration of the license is not yet known. This will be covered in the language of the agreement.

a. The conditions under which the agreement may be terminated or dissolved.

MSU will use the following standard agreement termination conditions:

1. If Neurofluidic Diagnostics does not make a payment due and fails to cure such nonpayment within forty-five days after the date of notice in writing of such nonpayment by MSU.
2. If Neurofluidic Diagnostics shall become insolvent, shall make an assignment for the benefit of creditors, or shall have a petition in bankruptcy filed for or against it. Such termination shall be effective immediately upon MSU giving written notice to Neurofluidic Diagnostics.
3. If an examination by MSU's accountant shows an underreporting or underpayment of Neurofluidic Diagnostics in excess of twenty percent for any twelve-month period.
4. If Neurofluidic Diagnostics fails to satisfy the performance milestones.
5. Without the obligation to provide notice, if Neurofluidic Diagnostics files a claim, including in any way the assertion that any portion of the patent rights is invalid or unenforceable where the filing is by the Neurofluidic Diagnostics, a third party on behalf of Neurofluidic Diagnostics, or a third party at the written urging of Neurofluidic Diagnostics.

All License Agreements (and possible future licenses as provided for by Option Agreements) issued by the MSU Technology Transfer Office in which the inventor seeks business participation are contingent upon this BOR 407 approval. This is stated in the License Agreement.

5. Explain specifically how the University System or the State of Montana will likely benefit from the agreement or arrangement.

- a. The IP owned by MSU under the negotiated license agreement will provide MSU with annual maintenance, sublicensing fee income and royalties, or company options/equity, which will generate revenue upon successful commercialization of the technology, or upon a successful exit strategy of the company.
- b. Technical advances in the field with public and private contribution provides both academic and economic development and generates STEM-related workforce in Montana.
- c. Collaborative research opportunities for MSU and its students, specifically strengthening collaboration and building strong relations to the local entrepreneur ecosystem between MSU / The Kunze Lab and the local network of entrepreneurs in our community.
- d. Work-force development in the biotechnology sector will offer graduating students from MSU additional employment opportunities allowing to stay in Montana after graduation.

- e. The technology will allow in the future low-cost screening of neurodegenerative signals making it accessible closer to the people in Montana.

6. Summarize the financial terms of the agreement or arrangement. Include:

a. The value, nature and source of the University's contribution.

MSU will pay for patent costs and maintain ownership of the IP. Neurofluidic Diagnostics will pay the negotiated terms under the license agreement based on equity, or license fees. TTO will pursue patent prosecution and provide marketing services and personnel hours. MSU will own any patents and retains the right to use the technology and patents for academic research or other not-for-profit scholarly purposes.

b. The value and nature of the employee's contribution.

As an MSU inventor, Dr. Kunze will assist in the preparation and completion of the patent filings of the IP.

c. The anticipated revenue to be generated by the project and the timeline for generating such revenue.

There is currently no way to determine anticipated revenue at this early stage of this business idea. We will, however, work with experienced business advisors and mentors to generate a profitable business plan.

d. The manner in which revenue and expenses will be shared by the parties.

Royalty revenues will be shared by MSU and the inventors after payment of a development fee to MSU and collection of any unreimbursed patent costs. All expense information will be detailed in the confidential agreement language.

e. The nature of each party's equity interest in the project. If none, so indicate.

Dr. Kunze aims to obtain co-ownership (equity) in Neurofluidic Diagnostics, once a legal entity has been formed. Currently, the company has not yet been legally formed. Currently, further technology validation and market analysis is getting performed in the Kunze Neuroengineering Lab based on the MSU Gap Grant. In the future, Dr. Kunze aims to provide consulting hours to Neurofluidic Diagnostics.