

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](#).

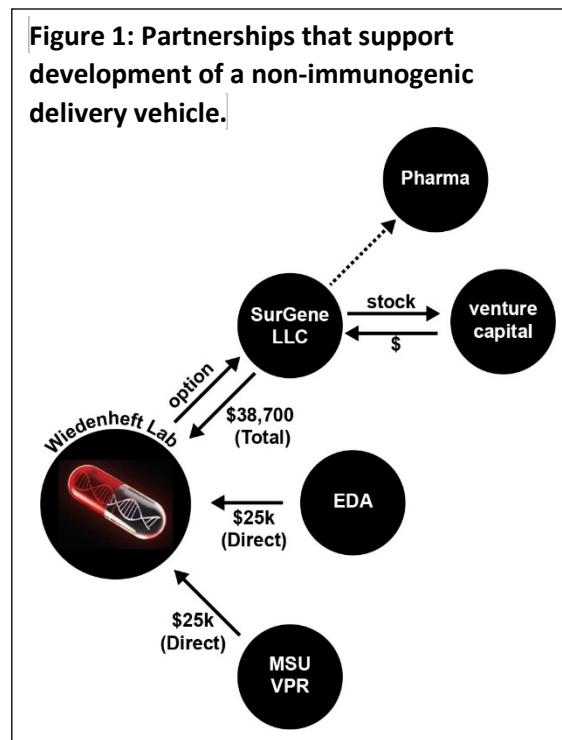
When the submission concerns matters of trade secrets or confidential business information, or any other matter entitled to privacy under state or federal law (e.g., the federal statute known as Bayh/Dole) the submitting campus may request consideration of the submission, in whole or in part, in executive 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 that was developed by the employee seeking approval. Indicate the sources of funding for the research that resulted in this invention.**

This application seeks BOR 407 approval for a Sponsored Research Agreement (“SRA”) with Montana State University (“MSU”) and SurGene, LLC. The intellectual property (“IP”) involved refers to future inventions created at MSU that could be licensed by SurGene. The SRA work covers research entitled, “Repurposing Arc-Capsids for delivery of designer RNA cargos for treating monogenic diseases. This research aims to develop a non-immunogenic delivery system for treating monogenic diseases.

Notably, Arc proteins are ancient retroelements and Arc has recently been shown to assemble into virus-like capsids that encapsulate and traffic RNA across synaptic boutons (Ashley et al., 2018; Pastuzyn et al., 2018). Thus, we aim to hijack the natural function of this endogenous human protein to encapsulate therapeutic RNAs for *in vivo* delivery. We appreciate the substantial regulatory challenges, associated costs and the expertise, necessary to bring this product to market. We have no intention of doing this ourselves, but we do anticipate that the work in this proposal, supported by a joint effort between SurGene LLC, EDA and MSU VPR (Figure 1), will provide a clear demonstration that human Arc can be repurposed for programmable encapsulation of designer cargos and that this will add significant value to our provisional patent.



2.

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

- Dr. Blake Wiedenheft
 - 1.0 FTE Associate Professor in the Department of Microbiology & Immunology at Montana State University
 - Past and potential inventor of MSU IP
 - Founder and Owner of start-up company, SurGene, LLC

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

SurGene, LLC, based in Bozeman, MT. SurGene registered as a Limited Liability Company on December 8, 2016 and has “Active Good Standing” status with the Montana Secretary of State.

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 from the business entity.
- d. Other. Please explain.

4.

a. 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).

SurGene is a business entity specifically formed and wholly owned by Wiedenheft to sponsor research at MSU and to option and license IP from MSU for the purpose of commercial development of technologies. SurGene has entered into a SRA with MSU. This SRA is considered a precursor to an “Option to License” intellectual property that might come from the agreement.

The standard MSU SRA contains definitive parameters for ownership of future IP. SurGene shall own all rights and title to inventions and improvements created solely by SurGene and without use of MSU resources. MSU shall own all rights and title to inventions and improvements created solely by MSU employees. MSU and SurGene shall jointly own all rights and title to inventions and improvements made jointly by MSU and SurGene.

As to all licenses which may be granted by MSU to SurGene, MSU retains for itself and other not-for-profit institutions a perpetual royalty-free non-exclusive right to practice the licensed patents and to use the licensed information for research, testing, and educational purposes of MSU.

b. The proposed duration of the agreement or arrangement.

The current SRA goes from December 1, 2019 to December 1, 2020. The SRA can be extended or renewed with a written agreement from both MSU and SurGene. The Option to License shall be exercisable by SurGene for a period of six (6) months after disclosure of any inventions and improvements, unless said option is otherwise declined by SurGene in writing.

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

The agreement may be terminated at any time upon the written mutual consent of the parties, by either party for failure of the other party to cure a breach of the SRA within ten (10) days after having received written notice of the breach, or by MSU for any reason upon thirty (30) days prior written notice to SurGene.

Or, the SRA will be superseded by a formal license agreement should SurGene choose to exercise the option.

All SRAs and possible future licenses as provided for by Option Agreements issued by the MSU Office of Technology Licensing are contingent upon this BOR 407 approval.

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

- a. The proposed SRA provides the opportunity for new IP to be developed that will be wholly or jointly owned by MSU, leading to a full license that could be negotiated with annual fees and royalties that would generate significant revenue upon successful commercial development of the technology.
- b. This field of technology is playing an important role in gene-editing, placing Montana business and Montana research at the cutting edge of applications.
- c. The SRA provides a base of collaboration that may lead to future funding opportunities that benefit MSU.
- d. This SRA will support MSU undergraduate students, graduate students, postdoctoral fellows, and career scientists.

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

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

The University may front additional accrued patent filing costs for new MSU technologies at its discretion, which would be paid back by the company following the schedule set forth in a future Option to License Agreement.

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

As an employee of MSU, Wiedenheft will contribute to the preparation and completion of MSU patent filings. As a business owner, Wiedenheft plans to sponsor significant research at MSU for the mutual benefit of all parties.

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

A License Agreement is yet to be negotiated so projected revenue is difficult to anticipate at this time.

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

MSU's standard SRA considers SurGene's support of the research. Upon reimbursement for all reasonable costs associated with the filing and maintenance of patent protection for any applicable MSU inventions and improvements, MSU will agree to grant SurGene an option to negotiate a

royalty-bearing license to practice such MSU inventions and improvements developed pursuant to the SRA (or for jointly owned inventions and improvements, a royalty-bearing license to cover MSU's interest therein).

The SRA is an early stage agreement and has no provision for royalties. Only a full licensee is permitted to conduct commercial sales of products or services containing the MSU optioned technology. Future royalty revenue and expense rates (including standard development fee to MSU and collection of any unreimbursed patent costs) will be determined in a future License Agreement.

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

Wiedenheft holds 100% equity in SurGene.