

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.**

“High Throughput and High Sensitivity Detection of Disease Biomarkers and Pathogens”. This technology is a point-of-care microfluidic device that accelerates and bypasses traditional RT-qPCR diagnostics for significantly faster and easier testing. The device will employ a nucleic-acid based test that operates at a temperature of 60-65°C called reverse transcriptase LAMP (RT-LAMP). The microfluidic system reduces the time to assay to under 15 minutes, while retaining the sensitivity and specificity required to make the diagnostic test both safe and effective. Diagnostic readout is provided on a self-contained cartridge that is very cheap to manufacture and does not require trained users to administer.

Funding for the research that resulted in this invention was supported by DOD-DARPA. In addition, collaborators at Harvard have made intellectual contributions, which has resulted in intellectual property generating a joint MSU-Harvard IP filing.

Private funding, ULTSafety, Inc., currently is under negotiation, and will sponsor research at MSU. Future inventions at MSU could potentially be licensed by ULTSafety, Inc.

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

- Dr. Connie Chang
  - Lead Inventor of intellectual property
  - Assistant Professor, Chemical & Biological Engineering, MSU

The MSU Office of Research Compliance is working with Dr. Chang to develop a Conflict of Interest Management Plan. The purpose of the plan is to accurately describe the potential conflicts in writing, create explicit agreements to protect against actual conflicts, and to facilitate oversight. A Plan Manager will be assigned to review the case annually and whenever major changes in circumstance occur. Once Dr. Chang begins actively participating as an employee, officer, board member, or equity holder, and she reaches the Significant Financial Interest threshold, one of the safeguards of the Management Plan will include Dr. Chang's agreement not to participate in any capacity on the MSU side on any sponsored research or contracted work between MSU and ULTSafety, Inc., all pending this BOR 407 approval.

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

ULTSafety, Inc., a new technology startup in Houston, TX.

**2. 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.

3.

**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).**

ULTSafety, Inc., wishes to license the intellectual property referenced above that is owned by MSU or MSU/Harvard. Negotiations are currently underway between ULTSafety, Inc., and the MSU Technology Transfer Office ("TTO"). TTO expects to execute a license agreement sometime in the next year.

**b. The proposed duration of the agreement or arrangement.**

The duration of the license is not yet known. This will be covered in the language of the agreement.

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

MSU will use the following standard agreement termination conditions:

1. If ULTSafety, Inc., 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 ULTSafety, Inc., 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 ULTSafety, Inc..
3. If an examination by MSU's accountant shows an underreporting or underpayment of ULTSafety, Inc., in excess of twenty percent for any twelve month period.
4. If ULTSafety, Inc., fails to satisfy the performance milestones.
5. Without the obligation to provide notice, if ULTSafety, Inc., 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 ULTSafety, Inc., a third party on behalf of the ULTSafety, Inc., or a third party at the written urging of the ULTSafety, Inc..

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.

**4. 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 provides MSU with annual maintenance and sublicensing fee income and royalties will generate revenue upon successful commercial development of the technologies
- b. Technical advances in the field with public and private contribution provides both academic and economic development
- c. Collaborative research opportunities for Montana State University and its students

**5. 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 will be reimbursed by ULTSafety, Inc., per the upcoming license agreement. 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. Chang will assist in the preparation and completion of the patent filings.

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

The license agreement will set performance milestones for sales of the licensed technology, as well as annually due sales and marketing reports. There is no way to determine anticipated revenue at this early stage.

**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. Chang is currently a co-founder of ULTSafety, Inc.