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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.

Two distinct U of M disclosures and related patent applications have been filed for: 1) the use and development of specific small molecule drugs labeled with radioactive atoms that serve as brain imaging biomarkers for the central nervous system target protein known as the serotonin transporter, and 2) the use and development of specific small molecule drugs labeled with radioactive atoms that serve as brain imaging biomarkers for the central nervous system target protein known as the norepinephrine transporter, in addition to their cognate non-radioactive forms that possess potential as disease modifying therapeutic agents affecting the central noradrenergic system. These new chemical compositions and their uses were discovered at U of M in the course of related research funded by the National Institutes of Health.

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

Dr. John M. Gerdes

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

Rio Pharmaceuticals, a California limited liability company

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.
4. How will approval of this relationship contribute to the objectives of the university's technology transfer and intellectual property development programs?

By allowing this University-private sector relationship to be established, intellectual property established and developed by the University faculty can be used to grow a faculty spin-off company, it will set an example for other entrepreneurs from the University looking for opportunities for commercialization of their innovations and creations, and it will generate revenue and goodwill for the University and its employees, in addition to the Montana private biomedical research domain and related regional business development sectors.

The benefits to U of M and the State of Montana arising from current and proposed research activities of Rio Pharmaceuticals, LLC are:

Dr. Gerdes has filed invention disclosures with the University of Montana Technology Transfer Office from technology developed under grants from National Institutes of Health (NIH). Both technologies have been protected with patent applications, and both technologies are currently licensed to GT Neuropharma, Inc. (a Montana-based faculty spin-off company, 100% owned by Dr. Gerdes and previously approved by the Board of Regents on May 31, 2007). Since the development and advancement of new drug entities demand a variety of specific preclinical and clinical measures, GT Neuropharma, Inc., has sought the necessary experts and technological laboratory resources to effect and interpret those determinations. The unique unmet needs are realized with Rio Pharmaceuticals, LLC.

Rio Pharmaceuticals, LLC has the resources and expertise to advance these technologies. It is currently seeking specific private domain investment capital, establishing strategic partnerships with global pharmaceutical houses, and making applications for additional grant funding to promote the development of these technologies. When funded, Rio Pharmaceuticals, LLC will advance the technologies with specific pre-clinical and clinical testing followed with development into the marketplace. A portion of the pre-clinical studies may be as subcontract research with U of M. From this relationship, Rio Pharmaceuticals, LLC presents the potential opportunity to further patent and license a number of drug products and processes within the biomedical diagnostic and therapeutic sectors, especially as clinical research tools and novel pharmaceutical entities, which may be important regionally, nationally, and globally. Agreements on specific technologies between Rio Pharmaceuticals, LLC and UM are contemplated in detail.

Although the potentials of these technologies are deemed high, at this time specific revenue streams per technology have not been fully projected. The relationship with Rio Pharmaceuticals, LLC brings a new and prospectively highly productive regional collaboration to U of M. It will allow for advancing and developing the established inventions and patents. It may afford pre-clinical research support for 2-3 people and

equipment at U of M. This is a unique opportunity to broaden the research landscape at U of M and the region, to prospectively realize technology transfer revenue streams, and to provide potential for desired local and regional economic development.