RESOURCE SHARING PLAN – PROJECT 2 - PRECLINICAL MODEL FOR ANTIEPILEPTOGENIC THERAPY SCREENING IN POST-TRAUMATIC EPILEPSY

We will adhere to the NIH Grant Policy on Sharing of Unique Research Resources including the Sharing of Biomedical Research Resources Principles and Guidelines for Recipients of NIH Grants and Contracts issued in December, 1999 http://www.ott.nih.gov/policy/rt_guide_final.html. "Model organisms" created by this project will be made available to the research and academic community, as soon as possible after publication of the results. If we assume responsibility for distributing them, we will fill requests in a timely fashion and will provide protocols relevant to these organisms, as needed. For academic and non-profit entities, material transfers will be made with no more restrictive terms than in the Simple Letter Agreement (SLA) or the Uniform Biological Materials Transfer Agreement (UBMTA) and without "reach-through" requirements. In the case of for-profit entities requesting materials, a Materials Transfer agreement will be negotiated with terms which will vary according to the proposed use(s) of the materials by the company. Typically, the for-profit entity will be charged an annual fee for this license. All MTA requests will be handled by the Office of Biotechnology, which is the technology transfer and industrial liaison center. This office also will also manage the filing of patent applications, if any, corresponding to inventions involving the materials in compliance with Bayh-Dole Act. During any pursuit of intellectual property rights and/or technology licensing activities, we will ensure that the technology (materials and data) remains widely available to the research community in accordance with the NIH Principles and Guidelines document.

What data will be shared: The data from EpiBioS4Rx-Project 2 includes data on methodologies (induction of the LFPI model, MRI studies and data analyses, video-EEG monitoring and analysis, drug pharmacokinetic data, model phenotype, data on biomarkers and treatment effects, data on target relevance and validation, study design for preclinical AEG trial). Data will be deposited at the Informatics and Analytics Core (IAC) Database and will be included in the publications stemming from our consortium. NIH data sharing policies will be applicable.

Who will have access to the data: All investigators involved in the EpiBioS4Rx consortium will have access to the data deposited at the IAC. Investigators interested in accessing the data of the IAC database (LONI) will have access to the data, based on the terms agreed by the Administrative Core and IAC Core. Utllization of data for meta-analyses or publications will be possible for (a) the investigators of EpiBioS4Rx, following discussions and agreements with the EpiBioS4Rx investigators, (b) investigators not included in the original EpiBioS4Rx consortium, provided that specific agreements of collaboration are done with the EpiBioS4Rx, in accordance to the policies of the EpiBioS4Rx consortium. Following publication of our data, the data will be made publically available, 12 months following publication, according to NIH standards for public access.

Where the data will be available: All data will be deposited at the IAC database (LONI) for analysis. Access to the data will be restricted to the EpiBioS4Rx investigators until finalization and up to 12 months following publication of the data, after which timepoint, they will be made publically available. If a patent is submitted based on these data, the data will be made available at the earliest after public disclosure of the patent.

When the data will be shared: All data will be deposited at the IAC database (LONI) for analysis. Access to the data will be restricted to the EpiBioS4Rx investigators until finalization and up to 12 months following publication of the data, after which timepoint, they will be made publically available. If a patent is submitted based on these data, the data will be made available at the earliest after public disclosure of the patent.

How researchers will locate and access the data: The data will be deposited at the IAC database (LONI) and access will be made possible through registration at this database and acceptance or the conditions governing it. The investigators involved will be identifiable so that interested individuals can approach them for further information of collaboration. The location of the data will be included in our publications and presentations so that interested researchers can be directed to their source.

INTELLECTUAL PROPERTY STRATEGY

IP Landscape: The research project involves screening of six different compounds in a rat model for anti-epileptic effects. Four of the compounds are commercially available with no patent restrictions. One of the compounds (Z944) is protected by three composition-of-matter patents currently owned by Sun Pharmaceuticals (Taro Pharmaceuticals). Dr. Terrance Snutch (University of British Columbia) was instrumental in studies involving the Z944 preclinical development, epilepsy proof-of-concept and phase 1 trials and the structure, synthetic scheme and other preclinical data concerning Z944 have been placed into the

public domain. As such, Z944 is available for the collaboration with Einstein, University of Melbourne, UCLA, University of Eastern Finland, and University of Minnesota in screening this drug for the goals and objectives of this project.

Distribution of results: Einstein, University of Melbourne, UCLA, University of Eastern Finland, University of Minnesota, and University of British Columbia and their collaborators in this project are committed to the timely and unfettered distribution of the results of the research project. To facilitate distribution of any material generated in the research project, this collaborative team team will distribute such materials under material transfer agreements, consistent with NIH guidelines. For distribution within the United States, Einstein, University of Minnesota, and UCLA will utilize the Uniform Biological Material Transfer Agreement (UBMTA). The NIH encourages use of material transfer agreements with simple terms and provisions, such as the UBMTA, for documenting the distribution of materials to other academic, non-profit institutions. Since hundreds of academic institutions are signatories to the UBMTA, there will be a rapid distribution of materials, without the need for extended contract negotiations. For distribution outside of the US, material transfer agreements with provisions similar to the UBMTA will be used.

How technologies are commercialized: The Offices of Biotechnology and Business Development (OBBD) at each involved Institution (Einstein, University of Melbourne, UCLA, University of Eastern Finland, University of Minnesota, and University of British Columbia) is responsible for establishing and maintaining relationships with commercial partners. When a novel finding occurs in a research lab, the investigator submits an invention disclosure to OBBD. The disclosure is reviewed by the Patent Committee, which is comprised of researchers within the Institution from the different academic departments. After evaluating the technology for its commercial merits, the committee decides whether or not patent protection is warranted. When the committee decides to pursue patent protection, then a patent application is filed. OBBD then produces short marketing pieces describing the technology. Through a targeted marketing campaign, OBBD contacts a variety of companies, venture capital firms, and entrepreneurs who may be interested in licensing and further developing the technology. Once a potential partner has indicated an interest in the technology, OBBD executes a confidentiality agreement with the entity so as to allow more detailed discussions regarding the technology. If the entity is interested in pursuing a license, OBBD promptly initiates negotiations for the financial terms. It is the Institutions' prerogative that the technology be developed in a timely manner. As such, Einstein, University of Melbourne, UCLA, University of Eastern Finland, University of Minnesota, and University of British Columbia require firm diligence requirements such that if a company does not meet the requirements in a timely manner, they can terminate the license to seek a different commercial partner.

Sharing and filing of jointly developed IP: Prior to initiation of the research project, Einstein, University of Melbourne, UCLA, University of Eastern Finland, University of Minnesota, and University of British Columbia will execute a collaboration agreement. The collaboration agreement will require that the results of the project be published in a timely and effective manner. Inventorship of any inventions will be determined in accordance with applicable patent laws, with ownership to follow inventorship. The most likely scenario is that the results of the project are jointly invented, and therefore jointly owned. The investigators will determine percent relative contribution in development of the innovation. An invention disclosure will be provided to one of the technology transfer offices and the technology will be evaluated through the normal channels of the institution. The institutions will decide amongst themselves which office will take the lead in negotiations with commercial partners. Irrespective of which office takes the lead, certain provisions will be maintained in any executed license agreement. The most important provisions to be included are the institutions' retained rights to practice the invention for academic, non-profit purposes, to distribute the invention to other academic, non-profit institutions, the unfettered right to publish the results of any research project that involves use of the results of the research project, and the right to terminate the license agreement if firm diligence requirements are not met.