

MULTIPLE PI LEADERSHIP PLAN - PROJECT 2 – PRECLINICAL MODEL FOR ANTIEPILEPTOGENIC THERAPY SCREENING IN POST-TRAUMATIC EPILEPSY

Project 2 of EPIBioS4Rx will have a PI and co-PLs. Aristeia Galanopoulou (Albert Einstein College of Medicine, Bronx NY) will be the PL and contact PI, Dr. Terence O'Brien (University of Melbourne) and Dr. Asla Pitkänen (University of Eastern Finland) will be co-PLs in this project. These three PLs will be responsible for coordinating the workflow across the following participating sites:

1. Albert Einstein College of Medicine, Bronx, NY, USA (site leadership by Aristeia S. Galanopoulou MD PhD (PL, contact PI))
2. University of Melbourne, Melbourne, Australia (site leadership Terence O'Brien, MD (co-PL))
3. University of California, Los Angeles, CA, USA (site leadership Rick Staba, PhD (co-I))
4. University of Eastern Finland (UEF), Kuopio, Finland (site leadership Asla Pitkänen, MD, PhD (co-PL))
5. University of Minnesota, Minneapolis, Minnesota, USA (site leadership James Cloyd III PharmD (co-I))
6. University of British Columbia (UBC), (site leadership Terrance Snutch, PhD (co-I))

In addition, they will be coordinating the workflow with the Agoston lab for the analysis of the plasma protein biomarkers and the other Informatics and Analytics Core (IAC) investigators for the analysis required for the imaging and EEG data, will be in contact with the Data Safety Monitoring Board (DSMB), Public Engagement and Administration Cores and the Project 2 consultants. Specific responsibilities of each PI include the following.

Aristeia S. Galanopoulou MD PhD (PL, contact PI for Project 2): Dr. Galanopoulou will be responsible for the communications among the Project 2 PIs and co-Is and the rest of the EpiBioS4Rx collaborators (DSMB, Public Engagement and Administration Cores, IAC, and the Project 2 consultants), for matters that pertain to the goals and experiments done through Project 2, and for maintaining the procedures for blinding, randomization, and harmonized methods of testing across institutions. This will include organization of teleconferences or webconferences, planning of annual meeting schedules to discuss the Project 2 progress, email or phone conversations, preparation of minutes and progress reports from these events. Dr. Galanopoulou with Drs. O'Brien and Pitkänen will be planning the Project 2 investigator meetings for the harmonization of procedures and data analyses, calling and organizing the data presentation for the DSMB / Public Engagement Core meetings to discuss the progress of Project 2 and next steps. Dr. Galanopoulou will be the contact PI to communicate with NINDS staff and prepare the progress reports to NINDS, if funded. The two PIs of Project 2, Drs. Galanopoulou with Drs. O'Brien and Pitkänen will be organizing the workflow of experiments across sites so that milestones and timelines are met, will be supervising the manuscript preparation for Project 2 and decisions on authorship, and will be chairing the meetings of Project 2 that will decide on GO /NO GO decisions and selection of lead compound for testing in the preclinical antiepileptogenesis trial. Such meetings will include the Project 2 investigators, the DSMB, Public Engagement representative, IAC representatives, the consultants of Project 2 and the Steering committee of EpiBioS4Rx. Dr. Galanopoulou will also be responsible for the maintenance and cataloguing of the biospecimens of the BioBank and their inclusion in the centralized database of the IAC and will be the contact person to investigators who are interested in collaborating by performing specific analyses on these biospecimens.

Terence O'Brien MD (University of Melbourne) (co-PL for Project 2): Dr. O'Brien will be responsible for matters that relate on study design of experiments that test some of the compounds that have been tried in his lab (sodium selenate, deferiprone, Z944) and their optimal testing of such compounds in the LFPI model. He will alternate with Drs. Galanopoulou and Pitkänen in the communications needed among Project 2 investigators and the other EpiBioS4Rx, if scheduling conflicts arise. Dr. O'Brien with Drs. Galanopoulou and Pitkänen will be planning the Project 2 investigator meetings for the harmonization of procedures and data analyses, calling and organizing the data presentation for the DSMB/Public Engagement Core meetings to discuss the progress of Project 2 and next steps. The three co-PLs of Project 2, Drs. Galanopoulou, O'Brien, and Pitkänen will be organizing the workflow of experiments across sites so that milestones and timelines are met, will be supervising the manuscript preparation for Project 2 and decisions on authorship, and will be chairing the meetings of Project 2 that will decide on GO/NO GO decisions and selection of lead compound for testing in the preclinical antiepileptogenesis trial. Such meetings will include the Project 2 investigators, the DSMB, Public Engagement representative, IAC representatives, the consultants of Project 2, and the Steering committee of EpiBioS4Rx.

Asla Pitkänen MD PhD (UEF) (co-PL for project 2): Dr. Pitkänen will be responsible for the utilization and analysis of biomarkers in Project 2, to align them with the findings in project 1, where she is the PL. Dr.

Pitkänen will alternate with Dr. Galanopoulou and O'Brien in the communications needed among Project 2 investigators and the other EpiBioS4Rx, if scheduling conflicts arise. Drs. O'Brien, Galanopoulou and Pitkänen will be planning the Project 2 investigator meetings for the harmonization of procedures and data analyses, calling and organizing the data presentation for the DSMB/Public Engagement Core meetings to discuss the progress of Project 2 and next steps. The three co-PLs of Project 2 will be organizing the workflow of experiments across sites so that milestones and timelines are met, will be supervising the manuscript preparation for Project 2 and decisions on authorship, and will be chairing the meetings of Project 2 that will decide on GO/NO GO decisions and selection of lead compound for testing in the preclinical antiepileptogenesis trial. Such meetings will include the Project 2 investigators, the DSMB, Public Engagement representative, IAC representatives, the consultants of Project 2 and the Steering committee of EpiBioS4Rx.