HSP-CTR Virtual Scientist Engagement Fellowship Program for Ukrainian Life Scientists

Proposal Narrative

Project Title: Establishing a Cryobank of blood plasma samples for the search for novel TBI diagnostics (Cryo-TBI)

Project Point of Contact (POC):

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Summary: We aim to establish in the frame of this proposal **Cryo-TBI** at the Institute of Cell Biology NAS of Ukraine a bank of blood samples from patients with traumatic brain injury (TBI) events in their medical history. This cryobank will be further used for collaborative multidisciplinary biomedical civilian research aimed at identifying new diagnostic and prognostic biomarkers for such patients and construction of corresponding diagnostic kits (as ELISA or Lateral flow tests).

Justification: Currently, TBI is one of the common causes of mortality and disability among civilians worldwide (car accidents, sports injuries, falls, etc.). Unfortunately, only a few blood biomarkers have been exploited up to now in clinical practice, with narrow applications primarily for early TBI diagnostics. Many questions associated with TBI progression, response to the treatment, and prognosis, particularly long-term, remain unanswered. Thus, there is a strong need for novel biomarkers that would allow physicians to make optimal treatment decisions to improve patient's quality of life.

The development of a cryobank of blood plasma samples obtained from patients with TBI of various etiologies should allow the search for new protein biomarkers on representative cohorts of patients and promote further cooperation with other research groups both in Ukraine and abroad.

The project is planned for six months with an estimated budget of 11,994.02 USD that will cover personnel costs, two items of specialized small equipment, and consumables. The project team possesses all the skills and other basic equipment needed for project realization. The project will be conducted according to all currently applying ethical regulations concerning blood sample collection, processing and disposal, patients' anonymization, data protection and Good Laboratory Practices rules.

Scope of Work:

1. In cooperation with our domestic partners from clinics, we plan to establish at the Institute of Cell Biology, NAS of Ukraine (ICB NASU) a cryobank of blood samples from patients

with confirmed TBI of different etiology and severity (old, recent, repeated, etc.), We also plan to collect blood samples from patients with confirmed complications after TBI (including TBI-associated PTSD, post-concussion syndrome, neurodegenerative disorders, chronic traumatic encephalopathy, etc.).

2. It is expected that there will be a possibility of collecting blood samples from specific cohorts of patients repeatedly for monitoring levels of blood protein biomarkers in dynamics during different phases of treatment and for studying the long-term effects of TBI. It is also expected that the established cryobank could be steadily enlarged in terms of the number and specifications of the samples to support unforeseen research activities. The cryobank will also include a limited number of samples from healthy donors.
3. The uniform protocols will be set up, describing the collection of blood samples, plasma preparation and storage, as well as forms of informed consent, which shall be approved by the Institute Ethics Committee and collaborating medical institutions beforehand.
4. Blood samples will be collected in partner facilities by qualified medical personnel after informed consent is obtained from a patient. Plasma samples will be prepared from each blood sample using standard laboratory procedures, divided into several small aliquots, and stored at -70°C at ICB NASU. All biological wastes will be processed and disposed according to national legislation and ICB NASU protocols to exclude any harm to the environment.
5. All samples and other relevant data will be stored anonymized and marked with personal codes. Descriptions and numerical data will be stored in a separate Database and processed without the possibility of unauthorized external connections to eliminate the risks of data corruption or leakage. The data and samples collected will be available to partner institutions on request according to the terms of corresponding bilateral research agreements.
6. The number of samples collected till the project completion may vary but is expected to cover several patients' cohorts with TBI of various etiology and periods after the traumatic event.
7. The pilot research activity planned in the frame of the project will include monitoring levels of specific known protein biomarkers in the collected samples using commercially available ELISA test kits or previously developed by us monoclonal antibodies to prove the reliability of the applied procedures for sample collection and storage. Depending on the associated diagnoses for the collected samples, they will include (but will not be limited to):

- markers of inflammation/neuroinflammation (e.g., IL-1b, IL-6, C-reactive protein).
- markers of blood-brain barrier integrity (e.g., S100B, GFAP).
- markers of neurodegeneration (e.g., total tau, amyloid-beta, and their variants).

Deliverables:

1. Establishment of Cryobank with a collection of plasma samples from TBI patients and healthy volunteers.
2. Development of an anonymized database with all relevant numerical and text data.
3. Submission of a review article on TBI biomarkers to a peer-reviewed scientific journal.
4. Dissemination of the information about the newly created **Cryo-TBI** bank to potential research partners in Ukraine and abroad.

HEALTH SECURITY PARTNERS

Activities and Timelines:

No.	Activity	Timeline (Month/s)
1	Development and approval of the study and sample collection protocols by the Local Ethics Committee	May 2024
2	Collection of blood samples from patients with confirmed TBI, plasma preparation, cryopreservation of samples	June – September 2024
3	Development of an anonymized accompanying database for the Cryobank	July – September 2024
4	Pilot study of selected protein biomarkers in the samples	July – September 2024
5	Writing and submitting a review article on TBI biomarkers	May - July 2024
6	Final report preparation	October 2024

Budget: The project duration is planned for six months (May-October, 2024) with an estimated budget of $11,994.02. Detailed budget is provided in a separate file.