

MEMORANDUM OF COOPERATION

Between the

The Canadian Institutes of Health Research  
Institute of Neurosciences, Mental Health and Addiction  
Canada

and the

DG Research and Innovation  
European Union

and the

National Institute of Neurological Disorders and Stroke  
National Institutes of Health  
Department of Health and Human Services  
The United States of America

Regarding

The International Initiative for Traumatic Brain Injury Research (InTBIR)

The undersigned founding Participant Organizations to this Memorandum of Cooperation seek to establish an International Initiative for Traumatic Brain Injury Research (InTBIR) to accelerate scientific and clinical progress in traumatic brain injury (TBI) research through enhanced communication, coordination and collaboration. A description of the science and background of InTBIR is included as an annex hereto.

## **I. Objectives and Key Aspects**

InTBIR's goal is to improve clinical outcomes and lessen the global burden of TBI by 2020 through the discovery of causal relationships between treatments and clinically meaningful outcomes. InTBIR seeks to encourage well-designed, hypothesis-driven studies that include the collection of high quality data followed by rigorous statistical analysis. The core idea is to take advantage of the widespread variability in how otherwise identical patients are treated in order to tease out causal relationships, associated with either benefit or harm.

To that end, InTBIR intends to pursue four main objectives:

- Create an international TBI research network by establishing an infrastructure and guidelines for data sharing and collaboration;
- Further establish and promote the use of the TBI Common Data Elements as harmonised, international standards for TBI clinical data collection;
- Organize and convene, when feasible, project review meetings to discuss opportunities and challenges, and develop reports that meet the needs of the Participant Organizations; and
- Develop and apply sophisticated analytical tools to enable CER for TBI treatments, as well as for diagnostic tools and outcome measures.

InTBIR hopes that its efforts towards standardized data collection, sharing and meta-analysis will facilitate the:

- Development and validation of surrogate markers of injury and therapeutic success;
- Development and validation of a patho-anatomical and biomarker-based TBI classification system to enable early diagnosis, patient stratification and targeted treatment therapies; and
- Prediction of outcome - including unanticipated consequences for mental health - and its modulation by patient, injury, and the quality of general and specific management across the continuum of care.

To promote these goals and to coordinate InTBIR activities, Participant Organizations may assemble, as feasible, international scientific committees and other working groups.

## **II. Operations**

InTBIR is intended to be a pragmatic collaboration with less emphasis on its own structure and administration and more on enabling the exchange of information and data from coordinated international TBI clinical studies. Nonetheless, some structure is desired to guide and optimize the collaborative research efforts.

### **A. Leadership**

InTBIR should have a leadership committee composed of equal number of representatives from each of the Participant Organizations. The leadership committee should:

- Establish the overall vision for InTBIR in support of international communication, coordination and collaboration on TBI research;
- Oversee general administrative and strategic operations of InTBIR;
- Convene scientific committees and working groups in support of InTBIR goals; and
- Review and approve applications for new Participant Organizations.

B. Meetings

Meetings among Participant Organizations should be held annually, with additional teleconferences as necessary to promote effective cooperation. Participant Organizations should communicate and discuss TBI research priorities and seek ways to assist each other on expediting progress in these areas.

C. Involvement in InTBIR by Non-Participant Organization Entities

Organizations that are invested in TBI research and seek full membership in InTBIR as a Participant Organization may do so upon application to InTBIR, unanimous consent of the then existing Participant Organizations, and execution and adoption of this Memorandum of Cooperation through a letter of intent.

Organizations that are invested in TBI research and seek limited involvement with InTBIR (e.g., observing meetings, sharing information) may do so when feasible upon application to InTBIR and unanimous consent of the Participant Organizations.

D. Representatives

The Participant Organizations intend for the responsible Directors of the Participant Organizations, or their authorized designees at the institutions that are signatory to this Memorandum of Cooperation, to serve as the organizational representatives on the InTBIR and represent their signing institutions in all activities related to InTBIR.

E. Information, Specific Plans and Participant Organizations' Understanding

Any exchange of information or other activities of this Memorandum of Cooperation are to be performed in accordance with each Participant Organization's applicable laws and regulations. The intent is to ensure that each participant's laws will be followed, but **not** to cause one participant's laws to apply to everyone else. As the need arises with regard to goals and objectives described herein, the Participant Organizations may, when feasible, develop specific plans of cooperation which may be incorporated in written arrangements and procedures.

Participant Organizations understand that this Memorandum of Cooperation does not establish legally binding obligations on the part of any of the Participant Organizations. All cooperative activities undertaken by the Participant Organizations are subject to the availability of appropriated funds, personnel and other resources. The Participant Organizations are signing this Memorandum of Cooperation with the express understanding that the Memorandum of Cooperation itself does not give rise to a claim for compensation for services against any of the respective participants.