

**TRAUMATIC BRAIN INJURY**

**Translational Science at the Neural Injury Center:  
Expanding Clinical Services, Establishing Diagnostic  
Testing, and Developing Novel Therapeutic Interventions for  
Traumatic Brain Injury Survivors**

**Principal Investigators:**

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- Thomas Rau · College of Biomedical and Pharmaceutical Sciences · UM
- Alex Santos · Motor Control Laboratory · UM

**Funding Amount:** \$2,234,834

**Brief:**

Traumatic brain injury (TBI) affects 13% of Montana's adult population and costs Montana an estimated \$1.4 billion per year. One of the primary issues affecting TBI survivors is proper diagnosis and accurate assessment of injury severity. This project expands scientific research and technology to develop rapid, accurate diagnosis of brain injury. The four objectives focus on blood-based biomarkers for hospital lab testing, molecular techniques to develop new therapeutic inhibitors, a computer-based cognitive training system for TBI subjects that suffer from permanent brain damage, and a deep-learning computer analysis program to analyze brain waves and detect epilepsy before it develops in TBI subjects.

**Objectives and Progress:**

1. Expand clinical services for TBI survivors and veterans at the UM Neural Injury Center:
  - A. The NIC has screened and provided follow-up services for 119 TBI survivors, 40 of whom are veterans, and has provided neuropsychological testing to those individuals with lasting brain damage that affects academic performance.
  - B. Data collection is underway to determine barriers to concussion screening and define best interventions to encourage early screening and treatment in two at-risk Montana populations (student veterans and CSKT).
2. Develop a comprehensive panel of tests to diagnose mild TBI:
  - A. TBI survivors and non-injured controls (166 subjects total) have been assessed using the following newly developed technologies: Synergy Applied Medical Research BalanceLab, cognitive fatigue testing, VAST divergent thinking assessment, FYR diagnostics blood based biomarker testing, and Neurokinetics I-portal assessments. Combined together, they provide a comprehensive overview of brain damage after TBI.
  - B. 3 new IP disclosures and patents from research have been filed.
3. Develop micro RNA inhibitors to reduce nerve damage after TBI:
  - A. microRNA inhibitors have been developed and are being validated in laboratory testing prior to use in the animal model.



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- B. A neuroprotective drug, owned by UM and discovered by Dr. Rau, has been tested and has significant therapeutic potential for victims of TBI.
  - C. FYR Diagnostics LLC, a start-up biotechnology company has been formed to develop novel microRNA biomarkers for the diagnosis of chronic traumatic encephalopathy (CTE), a neurodegenerative disease caused by repeated head trauma.
4. Develop a computer-based cognitive training system for TBI subjects:
    - A. VAST has completed testing individuals with the divergent thinking technology and has followed up with the development of a novel virtual reality platform. Feasibility of VR head mounted display has been completed, 3 new original VR cognitive tests have been developed and incorporation of eye-tracking technology is underway
  5. Complete development and testing of post-traumatic epilepsy diagnostic analysis program:
    - A. N-SITE has incorporated all of the TBI electroencephalogram (EEG) data from Massachusetts General Hospital. The data is currently being processed through the deep-thinking program to extract variables of interest that can be assessed as biomarkers of epilepsy. First potential EEG biomarkers of epilepsy have been identified and are currently being validated.

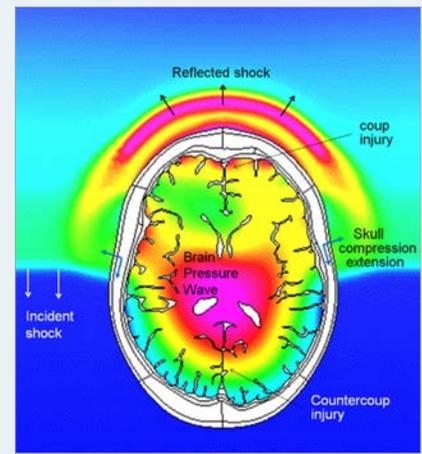
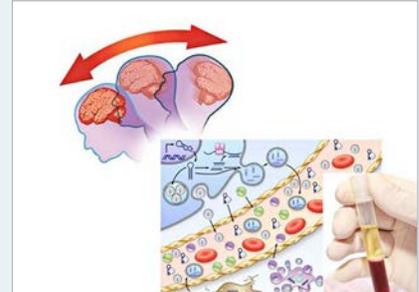
### Return on Investment:

#### • Jobs

- Clinical trials coordinator—Neural Injury Center
- Research specialist
- Post-doctoral fellow
- Computer programmers (2)—VAST & N-Site
- Research technicians (2)
- Biostatistician
- Molecular Biologist
- Neuropsychologist-Neural Injury Center

#### • Connections – Private sector partnerships:

- **VAST-Missoula:** Mobile virtual reality testing goggles and rehabilitation program developed for rapid assessment of TBI.
- **N-SITE-Missoula:** Deep learning program developed to assess EEG brain wave activity and decipher patterns indicative of epilepsy before seizures occur.
- **Glia Diagnostics:** PIs have facilitated a licensing agreement with Glia Diagnostics, an Australian biotechnology company. This agreement transfers intellectual property developed at the University of Montana under the MREDI program for TBI diagnosis using micro RNA biomarkers. UM will retain all ownership, and will receive royalty monies from this agreement.
- A recent partnership with Dr. Stephanie McCalla of MSU formed to develop new technology for rapid molecular detection of blood-based biomarkers to assess severity of injury and recovery duration.
- **Synergy Applied Medical and Research:** A partnership with EMG Systems of Brazil is being established to conduct development of instrumented technologies developed under the MREDI award and clinical trials here in Montana. This technology company is now on the track to attract capital and revenue to the Missoula area.



- **Leverage—Additional grant funds received:**

- GE/NFL grant: \$500,000
- Match funding from N-SITE: \$350,000
- Match funding from VAST: \$65,500
- CTR-IN grant: \$65,000
- BARDA grant submission pending
- AI/AN CTR grant-planning grant received initial approval for Tribal project related to mTBI testing.

- **Output**

- The following MREDI funded technology expanded into private spinoff companies in Missoula, Montana:
  - **FYR Diagnostics:** Formed in August 2016, FYR is licensing the technology from UM to take small molecule microRNA into a commercial platform for rapid diagnosis of TBI. They are currently in discussion with an angel group for seed funding of \$500,000–\$1M.
  - **Synergy Applied Medical Research:** Synergy was formed in July 2016 and is currently licensing the BalanceLab technology from UM. A fully viable product is ready for commercialization and further computer technology development is ongoing.
  - **C.A. LAUKES, LLC Clinical and Health Research Consulting Services:** a woman-owned clinical and health research consulting and services company, created to provide professional expertise and hands-on support to health, biotech, and medical research companies, health professionals, and research investigators.

