



## Unraveling Traumatic Brain Injuries

University of Pittsburgh researchers—including McGowan Institute for Regenerative Medicine affiliated faculty members [Stephen Wisniewski, PhD](#), senior associate dean and co-director of the Epidemiology Data Center at the University of Pittsburgh Graduate School of Public Health, and [David Okonkwo, MD, PhD](#), associate professor of neurological surgery and clinical director of the Brain Trauma Research Center at Pitt’s School of Medicine—are key players in a national “dream team” that seeks to identify the best biological and imaging markers of traumatic brain injury (TBI) to improve the ability of clinical trials to find effective treatments for the condition, which annually affects 2.5 million people in the U.S., including athletes and soldiers.



The \$17 million initiative, called the TBI Endpoints Development (TED) Award, is funded by the U.S. Department of Defense (DOD) and includes many universities, the U.S. Food and Drug Administration (FDA), companies, and philanthropies. It is overseen by the University of California, San Francisco (UCSF).

“This project is going to redefine how we measure the outcomes for traumatic brain injury studies,” said TED investigator Dr. Wisniewski. “We need a more robust, detailed way to determine what challenges a person faces when he suffers a traumatic brain injury, and that is what we’re setting out to accomplish with this ambitious study.”

Under Dr. Wisniewski's leadership, Pitt Public Health will run the data analysis for the project, meaning the school will compile data from previous studies and analyze it to see what existing methods for measuring traumatic brain injuries prove most promising. That information will be used as a launch point for clinical evaluation in real-life situations.

Dr. Okonkwo is co-leading the second branch of the project to test those findings through the previously announced \$18.8 million National Institutes of Health (NIH) project called Transforming Research and Clinical Knowledge in TBI, or TRACK-TBI.

“In the clinical component of the TED project, we will take the insights Dr. Wisniewski and his team gather from their systematic review of previous research and apply that to real-world TBI cases,” said Dr. Okonkwo. “If we can more accurately identify and quantify these injuries, we will be better able to select appropriate patients for clinical trials and to evaluate the success or failure of our therapies.”



TED will examine data from thousands of patients to identify effective measures of brain injury and recovery, using biomarkers from blood, new imaging equipment and software, and other tools. The research collaborators will be collecting a broad range of long-term data from existing studies and databases, and integrating these into a dataset that can be interrogated for TBI associations and causes in a way that has never before been possible.

The project is specifically designed to overcome the difficulty in demonstrating the effectiveness of TBI drugs and medical devices by actively involving the FDA in clinical-trial design from the outset. It also fosters collaboration between the DOD, the NIH, foundation-funded research networks, industry co-sponsors such as General Electric, and patient advocacy groups to try to develop procedures, outcomes measures, and standards for interpreting clinical data.

Each year, more than 2.5 million people in the U.S. seek medical care for traumatic brain injuries that arise when blows to the body or nearby explosions cause the brain to collide with the inside of the skull. According to the U.S. Centers for Disease Control and Prevention, an estimated 2 percent of the U.S. population now lives with TBI-caused disabilities, at an annual cost of about \$77 billion. No TBI treatment has proven to be effective.

“TBI is really a multifaceted condition, not a single event,” said UCSF neurosurgeon Geoffrey T. Manley, MD, PhD, principal investigator for the new award and chief of neurosurgery at San Francisco General Hospital and Trauma Center, a UCSF partner hospital. “TBI lags 40 to 50 years behind heart disease and cancer in terms of progress and understanding of the actual disease process and its potential aftermath. More than 30 clinical trials of potential TBI treatments have failed, and not a single drug has been approved.”

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