

MEMORANDUM

DATE: February 2, 2018

TO: Stefan M Duma, Steven Rowson Jr, Per Gunnar Brolinson, Arthur Maerlender, Eamon Thomas Campoletano, **Ryan Aaron Gellner**, Ty Morris, Michael L Madigan

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires January 29, 2021)

PROTOCOL TITLE: Biomechanical Basis of Pediatric mTBI Due to Sports Related Concussion

IRB NUMBER: **15-517**

Effective January 25, 2018, the Virginia Tech Institution Review Board (IRB) approved the Amendment request for the above-mentioned research protocol.

This approval provides permission to begin the human subject activities outlined in the IRB-approved protocol and supporting documents.

Plans to deviate from the approved protocol and/or supporting documents must be submitted to the IRB as an amendment request and approved by the IRB prior to the implementation of any changes, regardless of how minor, except where necessary to eliminate apparent immediate hazards to the subjects. Report within 5 business days to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

All investigators (listed above) are required to comply with the researcher requirements outlined at:

<http://www.irb.vt.edu/pages/responsibilities.htm>

(Please review responsibilities before the commencement of your research.)

PROTOCOL INFORMATION:

Approved As: **Expedited, under 45 CFR 46.110 category(ies) 4,6,7**

Protocol Approval Date: **May 5, 2017**

Protocol Expiration Date: **May 4, 2018**

Continuing Review Due Date*: **April 20, 2018**

*Date a Continuing Review application is due to the IRB office if human subject activities covered under this protocol, including data analysis, are to continue beyond the Protocol Expiration Date.

FEDERALLY FUNDED RESEARCH REQUIREMENTS:

Per federal regulations, 45 CFR 46.103(f), the IRB is required to compare all federally funded grant proposals/work statements to the IRB protocol(s) which cover the human research activities included in the proposal / work statement before funds are released. Note that this requirement does not apply to Exempt and Interim IRB protocols, or grants for which VT is not the primary awardee.

The table on the following page indicates whether grant proposals are related to this IRB protocol, and which of the listed proposals, if any, have been compared to this IRB protocol, if required.

Invent the Future

Date*	OSP Number	Sponsor	Grant Comparison Conducted?
12/28/2017	PWID567B	National Operating Committee on Standards for Athletic Equip (Title: Research Initiatives to Inform the Development of Youth Football Helmet Standard)	Not required (Not federally funded)
05/05/2015	14257705	US Department of Health & Human Services (Title: Biomechanical Basis of Pediatric mTBI Due to Sports Related Concussion)	Compared on 05/05/2015

* Date this proposal number was compared, assessed as not requiring comparison, or comparison information was revised.

If this IRB protocol is to cover any other grant proposals, please contact the IRB office (irbadmin@vt.edu) immediately.