MARYWOOD UNIVERSITY
INSTITUTIONAL REVIEW BOARD
O'Neill Center for Healthy Families, 2300 Adams Avenue, Scranton, PA 18509

DATE:	August 19, 2014
TO:	Ellen Payne
FROM:	Marywood University Institutional Review Board
STUDY TITLE:	[619059-2] *Investigation of a Concussion Education Program Using Concussion Goggles(TM) with High School Athletic Teams: A Pilot Study*
MUIRB #:	2014-021
SUBMISSION TYPE:	Amendment/Modification
ACTION:	APPROVED
APPROVAL DATE:	August 19, 2014
EXPIRATION DATE:	August 19, 2015
REVIEW TYPE:	Expedited Review
EXPEDITED REVIEW TYPE:	45 CFR 46.110 (b)(1)(5 and 7)

PLEASE READ THIS LETTER CAREFULLY IN ITS ENTIRETY.
IT CONTAINS IMPORTANT INFORMATION ABOUT YOUR RESEARCH PROPOSAL AND YOUR RESPONSIBILITIES AS AN INVESTIGATOR. THE IRB IS REQUIRED BY FEDERAL LAW TO REPORT ALL SERIOUS OR CONTINUING NONCOMPLIANCE WITH THESE REQUIREMENTS TO FEDERAL AGENCIES.

Thank you for your submission of Amendment/Modification materials for this research study. Marywood University's Institutional Review Board has **APPROVED** your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulations.

Please remember that informed consent is a process beginning with a description of the study and assurance of participant understanding, followed by a signed consent and/or assent form (unless a waiver was requested and granted). Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant to receive a copy of the signed consent document (unless waived).

The IRB's approval stamp must appear on versions of the flyer and consent/assent forms which will be used with participants.

Please be aware that all research records must be retained by the researcher for a minimum of three years after IRB closure of the project.

Please also note that:

- Any revision to previously approved materials, however minor, must be submitted to, and approved by, the IRB prior to initiation.
- All UNANTICIPATED PROBLEMS and SERIOUS ADVERSE EVENTS must be reported to this office. All FDA and sponsor reporting requirements must also be followed.
- All NON-COMPLIANCE issues, DEVIATIONS or VIOLATIONS from the approved protocol, or COMPLAINTS regarding this study must be reported to this office.
- **Researchers must submit a status report 6 months from the date of approval. Your first status report is due on or before February 19, 2015. A final status report is due prior to August 19, 2015, unless you are applying for renewal/continuing review.**
- Federal regulations require research to be reviewed no less than annually; therefore, research activities may not continue beyond the expiration date until a renewal application is submitted to, reviewed and approved by the IRB. Renewal applications should be submitted at least 60 days prior to your study's expiration date. Failure to obtain approval for the renewal of your study prior to the expiration date will require discontinuance of all research activities, including recruitment of participants, enrollment of new participants, data collection and data analysis. To renew, please submit a Continuing Review application along with all required materials via IRBNet.

The appropriate forms for any of the reports mentioned above may be found at http://www.marywood.edu/irb/ or in the Forms and Reference Library on IRBNet.

If you have any questions, please contact the IRB Office at 570-348-6211, x.2233 or irbhelp@marywood.edu.

Please include your study title and IRBNet ID number in all correspondence with this office.

Thank you and good luck with your research!