DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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January 21, 2004

Randy P. Juhl, Ph.D.
Vice Chancellor for Research Conduct and Compliance
University of Pittsburgh
132 Cathedral of Learning
Pittsburgh, PA 15260

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1259

Research Project: Helmet Type and Recovery From Concussion in High School Athletes
IRB Number: 020747
Principal Investigators: Mark Lovell, Ph.D., and Michael Collins, Ph.D.

Dear Dr. Juhl:

The Office for Human Research Protections (OHRP) has reviewed the University of Pittsburgh 's report dated December 12, 2002 responding to allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46) involving the above-referenced research.

In its October 29, 2002 letter, OHRP had raised the following concerns:

(1) The research, involving testing football helmets in high school athletes, involves children. OHRP expressed concern that the research may not comply with the provisions of HHS regulations at 45 CFR part 46, subpart D.

(2) Informed consent, parental permission, and subject assent may not have been sought under circumstances that minimize the possibility of coercion or undue influence, as required by HHS regulations at 45 CFR 46.116 and 45 CFR 46.408.

(3) Risks to subjects may not have been minimized, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and risks to subjects may not be reasonable in relation to anticipated benefits, as required by HHS regulations at 45 CFR 46.111(a)(1) and (2).

Based upon its review of your December 12, 2002 report, OHRP finds that these concerns cannot be substantiated. As a result, OHRP anticipates no further involvement in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

At this time, OHRP offers the following guidance and comments.

(1) OHRP notes that institutions whose employees or agents interact with living individuals for research purposes (e.g., obtaining informed consent) would be considered engaged in human subjects research and would need an Assurance of Compliance with OHRP. Therefore, if high school team medical staff obtain informed consent, then the high school would need to obtain an Assurance. Please see OHRP's memo on "Engagement of Institutions in Research" at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/engage.htm for guidance on when an institution becomes engaged.

(2) Under "What are the possible benefits from taking part in this study?" the IRB-approved informed consent document for this research states "You will also receive free follow-up evaluation on three occasions (within 72 hours, 4 days, and 7 days post-injury.)" OHRP notes that the protocol and the informed consent document state that these follow-up evaluations will occur regardless of whether or not the person is enrolled in the research. HHS regulations at 45 CFR 46.111(2) state, in part, that the IRB should consider only those benefits that may result from the research, as distinguished from benefits subjects would receive even if not participating in the research.

(3) Written IRB policies and procedures should provide a step-by-step description with key operational details for each of the procedures required by HHS regulations at 45 CFR 46.103(a) and 46.103(b)(4) and (5), including the following:

(a) A specific procedure for how the IRB determines which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review, including specific criteria used to make these determinations (e.g., such criteria could include some or all of the following: (i) randomly selected projects; (ii) complex projects involving unusual levels or types of risk to subjects; (iii) projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB; and (iv) projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources).

(b) A description of what steps are taken to ensure that investigators do not implement any protocol changes without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to subjects (e.g., this might be addressed through training programs and materials for investigators, specific directives included in approval

letters to investigators, and random audits of research records).

(c) A description of which office(s) or institutional official(s) is responsible for promptly reporting to the IRB, appropriate institutional officials, any supporting Agency or Department heads, and OHRP any suspension or termination of IRB approval.

(d) A description of the required time frame for accomplishing the reporting requirements in the preceding paragraph.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Kristina C. Borror, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Mr. Dennis Swanson, Director, IRB Office
Dr. Philip Troen, IRB Chair, Pitt
Dr. Mark Lovell, Pitt
Dr. Michael Collins, Pitt
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Ms. Janice Walden, OHRP
Ms. Shirley Hicks, OHRP
Ms. Melinda Hill, OHRP
Ms. Patricia El-Hinnawy, OHRP