

To: Prof. Connie Weaver

From: Prof. Jeannie DiClementi, Chair, Social Sciences Institutional Review Board (alternate for/Prof. Manuel Cleinest

Stephen Elliott, Chair, Biomedical Institutional Review Board, due to recusal)

Re: Appeal of IRB Determinations regarding Camp DASH (reference 1511016781)

Date: November 22, 2017

The Purdue Biomedical Institutional Review Board convened a meeting on November 20, 2017 to review materials submitted for Dr. Weaver's request for appeal, dated November 10, 2017 ("Appeal"). Extenuating circumstances prevented the Purdue Biomedical IRB from reviewing the Appeal at its meeting on November 14, 2017.

The Board reviewed all materials, including the original Report by the Vice President for Ethics & Compliance and Dr. Weaver's submissions to the University and the IRB. Based on its review of all materials, the IRB makes the following determinations:

- 1. The current study (reference 1511016781) referred to in the document and Report as "Camp DASH" will be immediately terminated.
- 2. In addition, Purdue IRB will not review any new protocol submissions filed by or on behalf of Dr. Weaver until IRB is satisfied that appropriate controls are in place to ensure compliance with applicable regulations and policies regarding the safety of human subjects. To that end, Dr. Weaver must submit a comprehensive remediation plan to the IRB, and have the plan approved before any new applications will be considered.

To be acceptable to the Board, the remediation plan must include discernable, auditable milestones to document completion at regularly scheduled points as well as a strong mentor from outside Dr. Weaver's department to oversee Dr. Weaver's remediation and research program. Remediation must incorporate onsite training (i.e., not solely online/virtual training).

The Board suggests seeking advice or training services from professional Human Subjects Research organizations, bioethics committees, or clinical research compliance societies. Dr. Weaver must affirm that neither she nor her research staff possess a financial and/or professional relationship with the providers of the remediation plan that would compromise the integrity of the plan, or give the appearance of conflict of interest.

Submission of the remediation plan may be sent to irb@purdue.edu for consideration of the full board.

Prof. Christopher Agnew, Associate Vice President for Research, Regulatory Affairs CC: Suresh Garimella, Executive Vice President for Research and Partnerships Jay Akridge, Provost and Executive Vice President for Academic Affairs and Diversity Stephen Elliott, Chair, Biomedical IRB Trenten D. Klingerman, Esq. Assistant Legal Counsel and Chief Privacy Officer