DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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April 15, 2009

Jeffrey M. Cheek, Ph.D.
Associate Vice Provost for Research Compliance and Operations
University of Washington
Office of Research
G 80 Gerberding Hall Box 351202
Seattle, WA 98195-1202

**RE: Human Research Subject Protections Under Federalwide Assurance FWA-6878**

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| **Research Project:** | Hypertonic Saline Study |
| **Principal Investigator:** | Eileen Bulger, M.D. |
| **Research Project:** | Prehospital Resuscitation using an IMpedance valve and Early vs. Delayed analysis – ROC PRIMED |
| **Principal Investigator:** | Peter J. Kudenchuk, M.D. |

Dear Dr. Cheek:

Thank you for your October 1, 2008 report in response to our August 1, 2008 letter regarding research conducted under the above-referenced research projects.

Based on the information provided, we note the following:

Under Department of Health and Human Services (HHS) regulations at 45 CFR 45.116, no investigator may involve a human being as a subject in research covered by the regulations unless (a) the investigator has obtained the legally effective informed consent of the subjects or the subject's legally authorized representative; (b) the institutional review board (IRB) has waived the requirements to obtain informed consent in accordance with 45 CFR 46.116(c) or (d); or (c) the conditions for waiver of informed consent in certain research in emergency settings under the October 2, 1996 Secretarial waiver (see 61 FR 51531-51533 at http://www.hhs.gov/ohrp/documents/100296.pdf) have been satisfied.

In our August 1, 2008 letter, we expressed concern that the investigator initiated human subject research specific to the hypertonic blood draw ancillary study by collecting three post-intervention blood draws without obtaining (a) legally effective informed consent of

the subjects; or (2) IRB approval of a waiver of the requirements to obtain informed consent in accordance with 45 CFR 46.116 (c) or (d). In response, UW acknowledged the following:

(a) the principal investigator and the University of Washington (UW) IRB believed that the IRB-approved emergency exception to the requirement for informed consent under the Food and Drug Administration (FDA) regulations at 21 CFR 50.24 for the Hypertonic Saline Study also applied to the three post-intervention blood draws for the ancillary study as indicated by the inclusion of this activity in the initial IRB application, and the IRB-approved documents labeled "Information Statement" and "Consent for Continuing Participation;"

(b) the principal investigator acknowledged to FDA that the ancillary study activities were not described in the protocol or any protocol amendment submitted to FDA for the Hypertonic Saline Study; and

(c) it is not clear from the IRB file whether the UW IRB (i) considered the blood samples for inflammatory markers "necessary to determine the safety and effectiveness of particular interventions;" and (ii) approved the collection of the blood samples under a waiver of informed consent for emergency research.

Given the above, it is not clear at this point whether or not this ancillary blood study is being conducted under the waiver of informed consent for emergency research. As a result, our office is deferring this matter to FDA for appropriate follow up and action.

In light of the recent decision by the National Institutes of Health to permanently close the Hypertonic Saline Arm of the study noted above, we have determined that there should be no need for further involvement by our office in this matter. Moreover, please note that our office did not have any outstanding questions and concerns regarding the ROC PRIMED Study noted above. As a result, we have determined that there should be no need for further involvement by our office in this matter. Please notify us if you identify new information which might alter these determinations.

We appreciate your institution's continued commitment to the protection of human research subjects. Please contact me if you should have any questions regarding this matter.

Sincerely,

Lisa A. Rooney, J.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Karen E. Moe, Ph.D., Director, Human Subjects Division, UW
Dr. Zane A. Brown, Chair, IRB #1A, UW

Dr. Alan J. Wilensky, Chair, IRB #2B, UW
Dr. Patricia C. Kuszler, Chair, IRB #3C, UW
Dr. Margaret J. Neff, Chair, IRB #4D, UW
Dr. Carl Rimmele, Chair, IRB #5G, UW
Dr. Donald J. Sherrard, Chair, IRB #6V, UW
Dr. McCutchen E. Deborah, Chair, IRB #7J, UW
Dr. Eileen Bulger, UW
Dr. Peter J. Kudenchuk, UW
Ms. Sherry Mills, Office for Extramural Research, National Institutes of Health
Mr. Joe Ellis, Office for Extramural Research, National Institutes of Health
Acting Commissioner, FDA
Dr. Joanne R. Less, FDA
Dr. Laurence Landow, FDA