DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

FOR US POSTAL SERVICE DELIVERY:
Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
Institutes of Health (MSC 7507)
Rockville, Maryland 20892-7507

FOR HAND DELIVERY OR EXPRESS MAIL:
Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01 National
Rockville, Maryland 20852

Telephone: 301-435-8072
FAX: 301-402-2071
E-mail: borrork@od.nih.gov

August 17, 2001

Alvin L. Kwiram, Ph.D.
Vice-Provost for Research
University of Washington
Office of Research, Box 351237
Seattle, WA 98195

Helen McGough
Manager
University of Washington
Human Subjects Division, Box 355752
Seattle, WA 98105-6613

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1183

Research Project: Improved CPR via Telephone– A Randomized Trial
Principal Investigator: Alfred P. Hallstrom, Ph.D.
Protocol Number: R18 HS05280

Research Project: Computer-Aided Dispatching for Emergency Medical Services and a Randomized Trail of Two CPR Messages
Principal Investigator: Alfred P. Hallstrom, Ph.D.
Protocol Number: R01 HS06125

Research Project: Assessing the Technology of CPR Strategies: A Randomized Trial
Principal Investigator: Alfred P. Hallstrom, Ph.D.
Protocol Number: R01 HS08197

Dear Dr. Kwiram and Ms. McGough:

The Office for Human Research Protections (OHRP) has reviewed your report of July 11, 2001 regarding the above referenced research conducted at the University of Washington (UW).

Based upon its review, OHRP previously made the following determinations regarding the

above-referenced research:

(1) OHRP found that the IRB failed to satisfy the requirements for waiver of informed consent for collapse victims, 911 callers, and dispatchers in the above-referenced research, as found in Department of Health and Human Services (HHS) regulations at 45 CFR 46.116(d). OHRP also found that the IRB failed to make the required findings when approving a waiver to obtain a signed consent form from all subjects for the follow-up interviews of 911 callers, as required by HHS regulations at 45 CFR 46.117(c).

UW's corrective action plan acknowledged that the IRB failed to document the findings for waiver of informed consent and waiver to obtain a signed consent form. OHRP acknowledges that members and staff have been counseled to include specific reference to the grounds for allowing waiver of consent and obtaining a signed consent form in the minutes of the IRB meetings. This corrective action, along with the development of guidelines for writing minutes, adequately addresses the finding of failure to document the requirements for waiver of informed consent.

OHRP remains concerned, however, that the research appeared to be greater than minimal risk and therefore may not have satisfied the criteria for waiver of the informed consent requirements.

(2) OHRP found that the informed consent documents reviewed and approved by the IRB for this research for dispatchers and follow-up interviews of 911 callers failed to include several elements required by HHS regulations at 45 CFR 46.116(a).

UW acknowledged that the IRB failed to document waiver of some elements of informed consent. OHRP acknowledges that members and staff have been counseled to document their determinations to waive certain elements of informed consent in the minutes of the IRB meetings, and to request justification from the researcher for withholding information about the purpose of the research. This corrective action adequately addresses the finding regarding failure to document waiver or alteration of some elements of informed consent.

However, OHRP is concerned that the research may not have been eligible for waiver or alteration of some elements of informed consent, since the IRB could have found that the research could have been practicably been carried out without the waiver or alteration, and that it would have been appropriate to provide subjects with additional pertinent information after participation.

Recommended Action: OHRP recommends that UW IRB members and staff receive additional education regarding the appropriate conditions for waiver of informed consent and waiver or alteration of some elements of informed consent.

OHRP finds that UW's corrective actions adequately address these and other findings of

OHRP in its April 20, 2001 letter and are appropriate under the UW Multiple Project Assurance. As a result there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination. Please note that OHRP plans to conduct a compliance oversight site visit at UW sometime within the next 12 months.

OHRP appreciates your institution's continued commitment to the protection of human research subjects. Do not hesitate to contact me if you have any questions regarding this matter.

Sincerely,

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

cc: Dr. Zane Brown, Chair, Biomedical IRB, UW
Dr. Alfred P. Hallstrom, UW
Dr. John Mather, VA
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael A. Carome, OHRP
Mr. George Gasparis, OHRP
Dr. Jeffrey M. Cohen, OHRP
Dr. Kamal Mittal, OHRP
Mr. Barry Bowman, OHRP