



FOR US POSTAL SERVICE DELIVERY:

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December 15, 2000

Elayn G. Byron, CRA
Director
Office of Research Administration
Massachusetts Eye and Ear Infirmary
243 Charles Street
Boston, MA 02114

**RE: Human Research Subject Protections Under Multiple Project Assurance
(MPA) M-1354**

**Research Project: Postural Stability Following a Short Period of Adaptation to an
Unusual Gravitoinertial Force Environment**

Principal Investigator: Captain Angus Rupert, MC, USN

MEEI Collaborator: Conrad Wall, III, Ph.D.

Dear Ms. Byron:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks (OPRR), has reviewed your August 19, 1999 letter regarding the above referenced research project. OHRP apologizes for the delay in responding to your letter.

OHRP acknowledges your report that the above referenced research (i) was to be sponsored and conducted by the Naval Aerospace Medical Research Laboratory (NAMRL) in Pensacola, Florida; (ii) had been reviewed and approved by the NAMRL Institutional Review Board (IRB), but had not been initiated as of the date of your letter; and (iii) had not been reviewed by the Massachusetts Eye and Ear Infirmary (MEEI) IRB. Furthermore, OHRP acknowledges your report that Dr. Wall's involvement in the research project was suspended pending the outcome of OPRR's evaluation of this matter.

OHRP notes that the NAMRL does not hold an OHRP-approved Assurance. As such, research conducted and supported solely by NAMRL, as well as the activities of the NAMRL IRB in reviewing the above referenced research, are not subject to OHRP's jurisdiction.

As a result, OHRP makes no findings regarding the above referenced research and is closing its compliance oversight investigation into this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

At this time, OHRP would like to provide the following guidance to MEEI:

(1) OHRP notes that protocol for the above referenced research indicated that Dr. Wall's involvement in the proposed research included serving as an advisor on vestibular testing and bioengineering issues specific to vibrotactile sway cuing, assisting in the set-up and pilot testing of the vibrotactile cueing device, and collaboration on data analysis and write-up.

OHRP also notes that the MEEI MPA applies to all human subject research, regardless of sponsorship, that is conducted by or under the direction of any employee or agent of MEEI in connection with his or her institutional responsibilities.

Therefore, if Dr. Wall's involvement in the above referenced research is connected to his responsibilities as an employee or agent of MEEI **and** meets the criteria for "engagement" in human subject research (see the January 26, 1999 OPRR memorandum entitled Engagement of Institutions in Research at <http://ohrp.osophs.dhhs.gov/humansubjects/assurance/engage.htm>), the MEEI MPA requires that the MEEI IRB review and approve the research prior to Dr. Wall's involvement in the conduct of the research (i.e., under the current MEEI MPA, the NAMRL IRB may not review the research on behalf of MEEI). OHRP emphasizes that pilot testing of the research intervention may constitute human subject research.

(2) If MEEI determines that the above referenced research requires the review and approval of its IRB, it would be appropriate for the IRB to ensure that all research equipment used in subject interventions and interaction has been appropriately maintained and inspected for safety so that risks to subjects are minimized in accordance with the requirements of HHS regulations at 45 CFR 46.111(a)(1). Furthermore, it would also be appropriate for the MEEI IRB to consider whether the risk section of the informed consent document should be expanded to include a description of the possible injuries that could result if a subject falls in the CAP room.

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,



Michael A. Carome, M.D.

Director, Division of Compliance Oversight

December 15, 2000

cc: Dr. Kathryn Colby, Chair, IRB, MEEI
Dr. Conrad Wall, MEEI
Captain R. E. Hain, NAMRL
Commander Doug C. Forcino, USN
Commissioner, FDA
Dr. David Lepay, FDA
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