DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
The Tower Building
1100 Wootton Parkway, Suite 200
Rockville, Maryland 20852

Telephone: 301-402-3006
FAX: 301-402-2071
E-mail: rmeyer@osophs.dhhs.gov

October 6, 2003

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research
National Institutes of Health
Building 1, Room 114
Bethesda, Maryland 20892

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1000**

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|---|---|
| **Research Project:** | Pathophysiology of Voice Disorders |
| **Intramural Institute:** | National Institute on Deafness and Other Communication Disorders (NIDCD) |
| **Principal Investigator:** | C.L. Ludlow, M.D. |
| **Protocol Number:** | 92-DC-0093 |
| **Research Project:** | Efficacy and Pathophysiology of Botulinum Toxin for Treatment of Involuntary Movement Disorders |
| **Principal Investigator:** | Mark Hallett, M.D. |
| **Protocol Number:** | 85-N-195 |

Dear Dr. Gottesman:

The Office for Human Research Protections (OHRP) has reviewed NIH's (NIH) September 12, 2003 report that was submitted in response to OHRP's August 21, 2003 letter to NIH regarding the determinations of noncompliance with the Department of Health and Human Services (HHS) regulations for the protection of human subjects (45 CFR Part 46) involving the above-referenced research. OHRP has determined that the corrective actions summarized below

adequately address the findings presented in OHRP's letter of August 21, 2003 and are appropriate under the NIH's MPA.

(1) The current practice at the NIH is to require a description of the expected length of research participation as well as any follow-up activities in both the protocol and the informed consent document. NIH plans to remind the NIH Institutional Review Boards (IRBs) that this practice must be followed.

(2) NIH requires that all current NIH informed consent documents include the following sentences:

> "The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or other authorized people."

NIH advises that the NIH investigators may include and the NIH IRBs may approve additional language dealing with confidentiality issues in a particular protocol, so long as it is not inconsistent with the sentences above. In particular, informed consent documents may not include statements offering total confidentiality of research data.

As a result of the above determination, 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.

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

Sincerely,

Robert J. Meyer
Compliance Oversight Coordinator
Division of Compliance Oversight

**cc:** Dr. Elias Zerhouni, NIH
Dr. James F. Battey, NIDCD
Dr. Thomas R. Insel, NIMH
Dr. Alan L. Sandler, OHSR, NIH
Dr. Christy L. Ludlow, NIDCD
Dr. David R. Rubinow, NIMH
Commissioner, FDA
Dr. David A. Lepay, FDA
Dr. Bernard A. Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael A. Carome, OHRP
Dr. Kristina Borror, OHRP
Ms. Shirley Hicks, OHRP
Ms. Yvonne Higgins, OHRP
Dr. Harold Blatt, OHRP
Ms. Melinda Hill, OHRP
Ms. Patricia El-Hinnawy, OHRP