



Office for Human Research Protections
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May 5, 2006

Robert E. Burke
Managing Director
Research Foundation for Mental Hygiene, Inc.
New York Psychiatric Institute Division
44 Holland Avenue
Albany, NY 12229

RE: Human Research Subject Protections Under Federalwide Assurance FWA 6105

<u>Research Project:</u>	Brain Imaging and Treatment of Persistent Lyme Encephalopathy
<u>Principal Investigator:</u>	Brian Fallon, M.D.
<u>Protocol Number:</u>	3613

Dear Mr. Burke:

The Office for Human Research Protections (OHRP) has reviewed the Research Foundation for Mental Hygiene, Inc.'s (RFMH) April 25, 2006 report submitted in response to OHRP's April 11, 2006 letter regarding the above-referenced research.

Based on the review of your report, OHRP notes that only 58 subjects were enrolled in Protocol #3613. This included 38 subjects with Lyme disease and 20 healthy controls. OHRP further notes that this did not exceed the IRB-approved enrollment of 65 subjects (45 Lyme subjects and 20 healthy controls).

OHRP finds that RFMH has adequately addressed the additional concern raised in its April 11, 2006 letter. As a result of this determination, OHRP anticipates no further involvement in this matter.

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,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Abel Lajtha, President, RFMH
Ms. Susan J. Delano, Deputy Managing Director, RFMH
Mr. Frank Mucha, Deputy Director of Administration, RFMH
Dr. David Strauss, Chair, IRB #1, NYSPI
Commissioner, FDA
Dr. Lana Skirboll, NIH
Dr. Bernard Schwetz, OHRP
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Ms. Janet Fant, OHRP