



Office for Human Research Protections
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March 27, 2002

Daniel R. Masys, M.D.
Institutional Official for Human Subjects
University of California, San Diego
9500 Gilman Drive
La Jolla, CA 92093-0052

RE: Human Research Protections Under Multiple Project Assurance (MPA) M-1274

**Research Project: Safety and Tolerability of Rapidly Titrated Risperidone
Related Publication: Safety and Tolerability of Rapidly Escalating Dose-Loading
Regimen for Risperidone, Feifel, D., et al, Journal of Clinical Psychiatry 2000; 61: 909-
911.
Principal Investigator: David Feifel, M.D.
Protocol Number: 000827X**

Dear Dr. Masys:

The Office for Human Research Protections (OHRP) has reviewed your March 21, 2002 report regarding the above referenced research conducted at the University of California, San Diego (UCSD) that was submitted in response to OHRP's February 11, 2002 letter.

Based upon its review, OHRP finds that UCSD has adequately addressed the findings made by OHRP in its January 8, 2002 letter.

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.

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,

Kristina C. Borrer, Ph.D.
Compliance Oversight Coordinator
Division of Human Subject Protections

cc: Ms. Lucille Pearson, UCSD
Mr. Gary Rossio, San Diego VA Medical Center
Dr. J. Allen McCutchan, UCSD IRB Chair
Dr. Richard Kornbluth, UCSD IRB Chair
Dr. John Mather, ORCA, Dept of Veterans Affairs
Dr. Greg Koski, OHRP
Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
Dr. Jeff Cohen, OHRP
Mr. George Gasparis, OHRP
Dr. Kamal Mittal, OHRP
Mr. Barry Bowman, OHRP