



Office for Human Research Protections
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August 20, 2002

Bruce S. Anderson, Ph.D., M.P.H.
Director of Health
Hawaii Department of Health
P.O. Box 3378
Honolulu, Hawaii 96801-3378

RE: Human Research Subject Protections Under Federalwide Assurance (FWA) FWA-0118

Research Project: Outcome Evaluation of a Multi-Systemic Therapy (MST)-Based Continuum of Care

Dear Dr. Anderson:

The Office for Human Research Protections (OHRP) has reviewed the State of Hawaii Department of Health's, (DOH) September 12, 2001 report that was submitted in response to OHRP's August 16, 2001 letter regarding the above-referenced research.

OHRP acknowledges DOH's statement in its September 12, 2001 letter that, under the terms of its Federalwide Assurance, DOH assures compliance with the terms of assurance only for Federally-sponsored research. Because the above-referenced research was funded by a grant from a private foundation and Hawaii state funds, OHRP does not have jurisdiction over this research.

As a result, OHRP anticipates no further involvement in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

In OHRP's August 16, 2000 letter to DOH, OHRP asked for a copy of any written IRB policies and procedures. Based upon the information received, OHRP provides the following additional guidance:

Written IRB policies and procedures should provide a step-by-step description with key operational details for each of the procedures required by HHS regulations at 45 CFR 46.103(b)(4) and (5) (see OHRP's July 11, 2002 guidance at URL <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/irb71102.pdf> (pdf version))

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/irbgd702.htm> (html version))

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

Sincerely,

Leslie K. Ball, M.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Virginia Pressler, Chair, DOH IRB
Commissioner, FDA
Dr David Lepay, FDA
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
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