DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

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August 5, 2002

Alan H. Teramura, Ph.D.
Senior Vice President for Research
University of Hawaii
Office of Research Services
Bachman, Room 204
Honolulu, Hawaii 96822

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1217

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

Principal Investigator: Stephen Haynes, Ph.D.

Dear Dr. Teramura:

The Office for Human Research Protections (OHRP) has reviewed the University of Hawaii's (UH) September 7, 2001 report that was submitted in response to OHRP's August 16, 2001 letter regarding the above-referenced research.

Based upon its review, OHRP makes the following determinations:

(1) Department of Health and Human Services (HHS) regulations at 45 CFR 46.101(b) delineate six specific categories of exempt activities.

The following criteria must be satisfied to invoke the exemption for research and demonstration projects examining "public benefit or service programs" as specified under HHS regulations at 45 CFR 46.101(b)(5): (a) the program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act); (b) the research or demonstration project must be conducted pursuant to specific Federal statutory authority; (c) there must be no

statutory requirement that the project be reviewed by an Institutional Review Board (IRB); and (d) the project should not involve significant physical invasions or intrusions upon the privacy of participants (see 12/97 OPRR Guidance at URL http://ohrp.osophs.dhhs.gov/humansubjects/guidance/exmpt-pb.htm). This exemption is for projects conducted by or subject to approval of Federal agencies, and is most appropriately invoked with authorization or concurrence by the funding agency. Of note, institutions retain the option under their Assurances not to claim the exemptions provided in the regulations, choosing instead to require IRB review of all research involving human intervention/interaction or identifiable private information.

According to UH's letter to OHRP dated September 7, 2001, "[t]he application [for the above referenced research] was approved [by the UH IRB] June 28, 2000 as an exempt project under Section 101(b)(5)." OHRP finds that UH inappropriately applied exempt status under 45 CFR 46.101(b)(5) to the above-referenced research. Specifically, OHRP notes that the above referenced research was not conducted under a Federal statutory authority. Further, OHRP notes that according to the protocol, the UH principal investigator was contracted by the Hawaii State Department of Health to evaluate "the effect of the MST-based continuum on youth mental health functioning, criminal activity, and alcohol and drug use, as well as family functioning and school attendance..." and, as such, had the potential for intrusions upon the privacy of participants.

OHRP acknowledges UH's statement in its September 7, 2001 letter to OHRP that "the project was officially closed and the approval to conduct research was terminated [by the UH IRB] as of January 31, 2001" after the UH principal investigator notified the IRB that he was no longer going to be principal investigator of the project. OHRP reminds UH that research determined to be "exempt" under HHS regulations at 45 CFR 46.101(b) cannot, by definition, be "approved" or "terminated" by the IRB.

OHRP acknowledges UH's statement in its September 7, 2001 letter that UH initiated a comprehensive restructuring of its human subjects research review and oversight system that has included additional training for UH IRB members and investigators, recruiting and hiring additional professional and support staff for the UH IRB, and the creation of a second IRB panel focusing on social science and behavioral protocols. Further, OHRP acknowledges UH's statement that "[w]e do not believe that the MST project and [the State of Hawaii Department of Health] consent form would be approved as it had been last year, without full committee review and more attention to the detail of the consent process under the current climate of greater scrutiny at our institution."

OHRP finds that these corrective actions adequately address the above finding and are appropriate under the UH MPA.

(2) Regarding the allegation that the UH IRB failed to ensure that risks to subjects are minimized as required by HHS regulations at 45 CFR 46.111(a)(1), OHRP finds there is no evidence to substantiate this allegation.

As a result of the above determinations, 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.

At this time, OHRP provides the following additional guidance:

(3) The UH IRB policies and procedures should be expanded to include 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 04/02 OHRP Guidance at URL http://ohrp.osophs.dhhs.gov/humansubjects/guidance/wirbproc.pdf).

OHRP appreciates the commitment of UH 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. Stephen Haynes, UH
Dr. Peter Garrod, UH IRB #1 Chair
Dr. Patricia Steinhoff, UH IRB #2 Chair
Commissioner, FDA
Dr. David Lepay, FDA
Dr. Greg Koski, OHRP
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