DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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May 13, 2008

Christopher Heller, MD
Acting Chief Medical Officer
Carondelet Health Network
1601 W. St. Mary's Road
c/o Quality Management Office
Tucson, AZ 85745

RE: Human Research Protections Under Federalwide Assurance FWA-5710

Research Project: Post Partum Depression Studies
Principal Investigator: Carole P. Sheehan, M.A., R.N.C.
Protocol Number: #163 and #198

Dear Dr. Heller:

Thank you for your March 27, 2008 report regarding determinations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46) involving the above-referenced research.

In our December 19, 2007 letter, we made the following determination regarding Carondelet Health Network's (CHN) written institutional review board (IRB) procedures:

> OHRP determined that CHN does not have written IRB procedures that adequately describe the following activities, as required by HHS regulations at 45 CFR 46.103(a) and 46.103(b)(4) and (5):
>
> (1) The procedures which the IRB will follow for reporting its findings and actions to investigators and the institution.
>
> (2) The procedures which the IRB will follow for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given,

may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(3) The procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any Department or Agency head, and OHRP of: (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval.

Corrective Action: We acknowledge that CHN has developed written IRB procedures to address the above activities. We determine that this corrective action adequately addresses the above determination. As a result, we anticipate no further involvement in this matter.

OHRP offers the following additional guidance:

We note that the draft CHN policy on expedited review states "The IRB may review studies through an expedited review process if the study involves no more than minimal risk as defined by 45 CFR 46.102(i)." Please note that in order to be eligible for an expedited review process for initial or continuing review, the study must also involve only procedures listed in one or more of the categories published in the *Federal Register* at 63 FR 60364--60367 (see http://www.dhhs.gov/ohrp/humansubjects/guidance/expedited98.htm). We recommend that you revise this procedure to clarify this additional requirement for a study to qualify for expedited review.

We appreciate 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. Borror Ph.D.
Director
Division of Compliance Oversight

cc: Dr. Chris Arslanian, IRB Coordinator, CHN
Dr. Lawrence Marsteller, IRB Chair, CHN IRB
Ms. Carole P. Sheehan, CHN