



FOR US POSTAL SERVICE DELIVERY:

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August 29, 2001

Jan Malcolm
Commissioner
Minnesota Department of Health
P.O. Box 64882
St. Paul, MN 55164-0882

Richard Wexler
Assistant Commissioner
Minnesota Department of Health
85 East Seventh Place
St. Paul, MN 55101

**RE: Human Research Subject Protections Under Single Project Assurances (SPA) S-7133
and Federalwide Assurance (FWA) 000072**

Research Activity: Blue Cross/Blue Shield tobacco survey

Dear Dr. Malcolm and Dr. Wexler:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks (OPRR), has reviewed the Minnesota Department of Health's (MDH's) January 31, 2000 report responding to allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46) that were presented in OPRR's October 20, 1999 letter. OHRP apologizes for the delay in responding to your report.

OHRP acknowledges your report that the above-referenced research (i) was not supported by the Department of Health and Human Services, and (ii) was conducted solely by Minnesota Blue Cross/Blue Shield.

As a result, OHRP has determined that it does not have jurisdiction over this research and is closing its compliance oversight investigation of 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 regarding the categories of

human subject research that are exempt under HHS regulations at 45 CFR 46.101(b).

(1) OHRP notes that the HHS-supported research project entitled “Evaluation of the Effect of Enhanced Social Support in the Fitness Fever Program on Elementary Student’s Fruit and Vegetable Intake” (HHS award number H75 CCH514928-01) was determined to be exempt under HHS regulations at 45 CFR 46.101(b)(1) and (2).

Please note that the exemption at 45 CFR 46.101(b)(2) does not apply to research involving children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed (see 45 CFR 46.401(b)). Therefore, the above referenced project would not be exempt under HHS regulations at 45 CFR 46.101(b)(2) because it involves administering questionnaires to children.

(2) OHRP notes that the HHS-supported project entitled “Community Partners for Health Farming - Surveillance of Agriculture-Related Child and Adolescent Injuries” (HHS award number U06 CCU512939) was determined to be exempt under HHS regulations at 45 CFR 46.101(b) (the exact category for exemption is unclear).

Based upon OHRP’s review of the research protocol, the research does not appear to satisfy the criteria for any exemption under the HHS regulations at 45 CFR 46.101(b).

(3) OHRP notes that the HHS-supported project entitled “Enhancing Agriculture Safety and Health Through Education” (HHS award number R01 CCR514360) was determined to be exempt under HHS regulations at 45 CFR 46.101(b)(5).

Based upon OHRP’s review of the research protocol, the research does not appear to satisfy the criteria for exemption under the HHS regulations at 45 CFR 46.101(b)(5). Furthermore, there appears to be insufficient information to make a determination with respect to the other categories of exempt research under the HHS regulations at 45 CFR 46.101(b).

(4) OHRP notes that the HHS-supported project entitled “Occupational Cancer Surveillance through Record Linkage” (HHS award number K01 OH00161) was determined to be exempt under HHS regulations at 45 CFR 46.101(b)(5).

Based upon OHRP’s review of the research protocol, the research does not appear to satisfy the criteria for exemption under the HHS regulations at 45 CFR 46.101(b)(5). Furthermore, the research does not appear to satisfy the criteria for any other exemption under HHS regulations at 45 CFR 46.101(b).

MDH should review all active human subject research protocols being conducted under the

MDH FWA that have been determined to be exempt under HHS regulations at 45 CFR 46.101(b) and confirm the appropriateness of this determination. Any nonexempt federally supported human subject research that was determined to be exempt and was not reviewed and approved by an IRB designated under the MDH FWA (or SPA) should be suspended until such review and approval occurs. OHRP notes that any research referenced above that does not satisfy the criteria for exemption under HHS regulations at 45 CFR 46.101(b) may be eligible for an expedited review procedure by the IRB. Please feel free to consult with OHRP's Ms. Roslyn Edson (301-402-7565) or me if you need further guidance regarding the exemptions under HHS regulations at 45 CFR 46.101(b).

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,

Michael A. Carome, M.D.
Director, Division of Compliance Oversight

cc: Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Dixie Snider, CDC
Dr. John Livengood, CDC
Dr. Greg Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Jeffrey Cohen, OHRP
Mr. George Gasparis, OHRP
Mr. Barry Bowman, OHRP