DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Public Health and Science

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August 17, 2001

James P. Karr, Ph.D.
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Daniel Green, M.D.
Medical Director, RPCI Protocol Office
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RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1037

Research Conducted by Dr. Steven Greenberg Using Staff Blood

Dear Drs. Green and Karr:

The Office for Human Research Protections (OHRP) has reviewed the Roswell Park Cancer Institute's (RPCI's) July 30, 2001 report regarding the above referenced matter.

Based upon its review, OHRP makes the following determinations:

(1) OHRP finds that the RPCI IRB had reviewed only minimal information regarding additional safeguards to protect the rights and welfare of subjects who are likely to be vulnerable, in contravention of HHS regulations at 46.111(b). OHRP also finds that the IRB had not been receiving sufficient information to make the determinations at 45 CFR 46.111(a)(3).

Corrective Action: OHRP acknowledges that the IRB has updated the New Protocol Submission Form to solicit information regarding subject recruitment and vulnerable subjects. This corrective action adequately addresses the above finding.

(2) OHRP finds that the RPCI Institutional Review Board's (IRB's) plan for contacting all subjects who participated in the above referenced research and informing them of their previous participation in the research, the risks associated with the research, and the nature of the noncompliance by RPCI with the requirements of Department of Health and Human Services (HHS) regulations at 45 CFR Part 46 is adequate.

(3) OHRP finds that RPCI's audit and identification of all on-going research projects involving human subjects that were not exempt under HHS regulations at 45 CFR 46.101(b) and confirmation that all such research has been reviewed and approved by one of the RPCI IRBs is adequate. OHRP acknowledges that RPCI suspended immediately any nonexempt research involving human subjects that had not been reviewed and approved by the RPCI IRB.

(4) OHRP finds that RPCI's plan to ensure that all IRB members, all IRB staff, and all research investigators are appropriately educated, on an ongoing basis, about the regulatory requirements for the protection of human subjects, including the definitions as stipulated by HHS regulations at 45 CFR 46.102 appears adequate. OHRP recommends that IRB staff and members be encouraged to attend additional training, such as workshops sponsored by OHRP and meetings sponsored by Public Responsibility in Research and Medicine (PRIM&R).

(5) OHRP finds that the RPCI IRB meeting minutes are prepared and maintained in sufficient detail as required at 45 CFR 46.115(a)(2).

(6) OHRP finds that the institution now has written IRB policies and procedures that adequately describe the activities required by HHS regulations at 45 CFR103(b)(4) and (5).

(7) OHRP acknowledges that the RPCI IRB has formed an additional IRB for continuing review of research. OHRP's review of the minutes for meeting of this IRB indicate that continuing review is now substantive and meaningful.

Based upon its review of the documents provided with your report, OHRP finds that the corrective actions taken by RPCI adequately address OHRP's findings and concerns regarding the above referenced research project and are appropriate under the RPCI Multiple Project Assurance. As a result, OHRP is closing this case and 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:

OHRP notes that no prisoner may be enrolled in an HHS-supported research protocol unless RPCI has certified to the Secretary of HHS that the IRB has approved the research under 45 CFR 46.305. This applies not only to "prisoner-specific protocols" but to any protocol in which a prisoner may be enrolled. OHRP also notes that research involving children that is not otherwise approvable cannot be conducted until the Secretary of HHS, after consultation with a panel of experts in pertinent disciplines and following opportunity

for public review makes the determinations required at 45 CFR 46.407(b)(2). OHRP recommends that the RPCI revise its forms and policies and procedures to indicate these requirements.

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

Sincerely,

Kristina C. Borror, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc Dr. David C. Hohn, RPCI
Dr. Barbara Bambach, RPCI
Dr. Steven Greenberg, RPCI
Dr. Joaquin Silva, RPCI
Dr. Greg Koski, OHRP
Dr. Melody Lin, OHRP
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Mr. Barry Bowman, OHRP
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA