



FOR US POSTAL SERVICE DELIVERY:

Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
National Institutes of Health (MSC 7507)
Rockville, Maryland 20892-7507

FOR HAND DELIVERY OR EXPRESS MAIL:

Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
Rockville, Maryland 20852

Telephone: 301-435-0668

FAX: 301-402-2071

E-mail: mceillp@od.nih.gov

March 29, 2001

David M. Goldenberg, Sc.D., M.D.
President
Garden State Cancer Center
520 Belleville Avenue
Belleville, New Jersey 07109-0023

**RE: Human Research Subject Protections Under Multiple Project Assurance
(MPA) M-1490**

Dear Dr. Goldenberg:

The Office for Human Research Protections (OHRP) has reviewed the Garden State Cancer Center's (GSCC) report dated March 2, 2001 responding to OHRP's letter of January 24, 2001. Based on the documents provided with your report, OHRP acknowledges the following corrective actions taken by the GSCC:

- (1) The GSCC has conducted a review of all ongoing research not exempt under Department of Health and Human Services (HHS) regulations at 45 CFR 46.101(b) and determined that there has not been any research projects approved at an IRB meeting where a quorum was not achieved.
- (2) The GSCC has developed a satisfactory corrective action plan to ensure the protection of human subjects which includes:
 - (a) Development of a data safety and monitoring plan.
 - (b) Development of revised IRB investigator guidelines for research involving human subjects.
 - (c) Establishment of a training program for clinical investigators and related staff.

(d) Establishment of an Office of Regulatory Affairs to perform audits of clinical sites and report findings to GSCC management and the IRB.

(3) The GSCC has revised its written IRB policies and procedures to address the requirements under HHS regulations at 45 CFR 46.103(b)(4) and (5).

OHRP notes that the revised GSCC IRB policies and procedures failed to include written procedures for ensuring prompt reporting to appropriate institutional officials, Federal Department or Agency heads, and OHRP of any unanticipated problems involving risks to subjects or others or continuing non-compliance as required under 45 CFR 46.103(a) and (b)(5). GSCC should incorporate a mechanism for proper reporting of unanticipated problems involving risks to subject or others or continuing non-compliance into its written IRB policies and procedures.

(4) Where the GSCC IRB has reviewed a protocol and has requested revisions by the principal investigator, the IRB will limit the use of expedited review of such research protocols to instances where the convened IRB stipulates specific revisions requiring simple concurrence of the investigator.

(5) The GSCC has clarified the definition of a quorum to include a non-scientist in its IRB policies and procedures.

OHRP recommends that members and alternates be identified, as such, in the minutes of IRB meetings, so as to avoid confusion when determining a quorum. Additionally, OHRP requests that GSCC provide an updated IRB roster to our office.

As a result of the above corrective actions, and on the condition that GSCC IRB policies and procedures are further revised in accordance with paragraph 3, above, 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.

Please note that OHRP anticipates conducting a compliance oversight site visit at GSCC within the next 12 - 24 months.

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,



Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

Page 3 of 3

The Garden State Cancer Center - Dr. David M. Goldenberg

March 29, 2001

cc: Dr. R.H. Menard, Vice President of Administration, GSCC
Dr. Rhona Stein, Chair, IRB, GSCC
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA
Dr. Steven Masiello, FDA
Ms. Lyn Bacon, NCI
Ms. Joan Mauer, NCI
Dr. Greg. Koski, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael A. Carome, OHRP
Ms. Freda Yoder, OHRP
Mr. Barry Bowman