



Office for Human Research Protections
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February 18, 2005

Douglas S. Diekema, M.D., M.P.H.
Chair, Institutional Review Board
Children's Hospital & Regional Medical Center
Office of Research Support Services
Metropolitan Park West, M/S MPW5-1
1100 Olive Way, Suite 500
Seattle, Washington 98101

Subject: Secretary's Determination under Department of Health and Human Services Regulations at 45 CFR 46.407 on the Research Protocol Entitled "Precursors to Diabetes in Japanese-American Youth" (1 R01 DK59234-01); Principal Investigator Edward Boyko, M.D.

Dear Dr. Diekema:

Thank you for your letter of January 24, 2005. On behalf of the Assistant Secretary for Health, Department of Health and Human Services (HHS), the Office for Human Research Protections (OHRP) finds that all of the stipulations outlined in OHRP's letter of July 11, 2003, have been met.

As a result, OHRP finds that the research conforms with the requirements of HHS regulations at 45 CFR part 46, subpart A, and at 45 CFR 46.407 and 46.408, and now may proceed with the HHS support provided by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH) under grant number 1 R01 DK59234-01.

Please do not hesitate to contact us with any questions. Thank you for your continuing commitment to the protection of human subjects.

Sincerely,

/s/ Bernard A. Schwetz

Bernard A. Schwetz, D.V.M., Ph.D.
Director
Office for Human Research Protections

cc: Dr. Edward Boyko, University of Washington
Dr. Lana Skirboll, NIH
Dr. Allen M. Spiegel, NIDDK, NIH
Dr. Barbara Linder, NIDDK, NIH
Dr. Melody Lin, OHRP
Dr. Michael Carome, OHRP
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