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Agency No. 126

APPLICATION

FRED HUTCHINSON CANCER RESEARCH CENTER
INSTITUTIONAL ASSURANCE FOR THE
PROTECTION OF HUMAN SUBJECTS

DATE December 16, 1980

Please type, use supplemental sheets, as needed. Submit 11 copies, including a signature copy, the Human Subjects Review Committee, Room 118, 1124 Columbia St., Seattle, Washington 98104. Each copy should have all relevant materials, eg. research protocol, Consent Form(s), questionnaires, text of presentation for obtaining verbal consent, drug data sheets.

I. TITLE OF PROPOSAL OR ACTIVITY, ETC. ONCOLOGY PROTOCOL # 126

Prevention of Graft-Versus-Host Disease (GVHD) by Deletion in Vitro of Donor T Cells with Monoclonal Antibody and Complement

II. PRINCIPAL INVESTIGATOR:

Name	Affiliation	Telephone
J.A. Hansen, M.D.	Associate Member, Medical Oncology	292-

Associates: Drs. P.J. Martin, E.D. Thomas

REVIEW BOARD ACTION

The F.H.C.R.C. Human Subjects Review Committee at its meeting of 1/20/81 recommended the following:

☐ Approved for a 12 month period.

☒ Disapproved (Comments to Follow)

☐ Approved Subject to the following conditions See Transcript of discussion in the meeting minutes.

a) Investigator notified of conditions for approval on 1/26/81.

b) Investigator response received on N/A

Approval valid only as long as committee approved procedures are followed.

Signed Harold Slavkin Date 1/26/81

Doc Ref No. 012081

Approved From N/A To N/A

#126

UNIVERSITY OF WASHINGTON SCHOOL OF MEDICINE
DEPARTMENT OF MEDICINE, DIVISION OF ONCOLOGY
AND THE FRED HUTCHINSON CANCER RESEARCH CENTER

Consent Form for Use of Monoclonal T-cell Antibody (mcAb) for Removal of T-cells from Donor Marrow

Investigators: Drs. J.A. Hansen, P.J. Martin, E.D. Thomas, and Members of the Division of Oncology. Emergency Phone (24 hours): 292-2892.

Investigators' Statement

PURPOSE AND BENEFITS

Patients undergoing marrow transplantation are at risk to develop graft-versus-host disease (a reaction of the donor cells against recipient's tissues). This complication may vary from a mild skin rash to a severe form involving the skin, liver and/or gut and may be fatal. The immunological reaction that we identify as graft-versus-host disease is caused by certain cells called T-cells in the donor marrow that recognize the host as "foreign". This study is being carried out to determine whether removal of T-cells from the donor marrow will prevent graft-versus-host disease. This can be accomplished by using a relatively new form of very specific antibodies (monoclonal T-cell antibodies).

PROCEDURES

Bone marrow will be removed from the donor in the usual fashion. After processing to remove most of the red cells, the bone marrow will then be incubated with monoclonal T-cell antibody and with rabbit serum which provides factors necessary to kill T-cells coated with antibody. The monoclonal antibody and rabbit serum will be removed from the bone marrow before infusion.

RISKS, STRESS OR DISCOMFORT

The use of monoclonal antibody in human patients is still investigational and with any such product there may be unanticipated adverse effects. There is a possibility of an allergic reaction even though nearly all of the monoclonal antibody and the rabbit serum will have been removed. Other possible effects are fever, chills, temporary difficulty in breathing or drop in blood pressure. Your clinical situation will be monitored closely at all times. To the best or our knowledge, treatment of marrow with monoclonal antibody and rabbit serum does not damage the cells necessary for engraftment, but it is possible that engraftment will not occur following such treatment. In this case, a second marrow transplant would be necessary.

This type of treatment is of unproven value: it is not known whether the risk of graft-versus-host disease will be decreased. There are no established methods for preventing graft-versus-host disease.

OTHER INFORMATION

The antibody will have been prepared in mice. If you are aware of any allergies to these animals you should let your physician know of this. Participation in this form of therapy is voluntary and you may withdraw at any time without prejudice.

Personal identity and records are confidential. Access will be restricted to responsible hospital personnel.

The patient and/or his insurance carrier is responsible for all costs accrued during this therapy except for extraordinary or unusual costs unrelated to therapy but related solely to experimental aspects. These extraordinary costs will be assumed by the Division of Oncology. No compensation is available for