

INFORMED CONSENT

Santiago, April 2001

PHASE I/II STUDY OF IMMUNIZATION WITH DENDRITIC CELLS LOADED WITH TUMOR EXTRACTS IN PATIENTS WITH ADVANCED MELANOMA.

I, _____
Identity Card No. _____ declare that I am aware of suffering from malignant melanoma of the skin in stage III/IV. I have been explained to and have accepted an experimental treatment with the aim of curing my disease. I understand that this treatment involves taking cells from my own body through the extraction of 500 ml of blood, which are then cultured to mature into activated dendritic cells using biological factors. Subsequently, these cells are mixed with melanoma cell extracts and reintroduced subcutaneously to stimulate an immune response against the tumor cells present in my body.

I have been informed of the results obtained in patients treated in a similar manner in other countries. I have been explained that I may not necessarily achieve a complete cure and that this outcome is only expected in a proportion of treated patients.

I understand that the administration of these vaccines may be accompanied by some adverse effects such as mild fever, induration at the vaccination site, and, in some cases, areas of skin depigmentation.

I comprehend that all information derived from this study will be kept confidential and anonymous and that my participation in this research is entirely voluntary. I may withdraw from this treatment at any time of my own free will, without it affecting my regular treatment plan.

After receiving and understanding the information provided to me here and having had the opportunity to clarify my doubts, I have agreed to participate in this protocol, under the care and clinical responsibility of the doctors leading this treatment.

Patient's Signature

Dr. Carlos Ferrada Valenzuela
MD. Oncologist

Dr. Mercedes López Nitsche
MD. Immunologist



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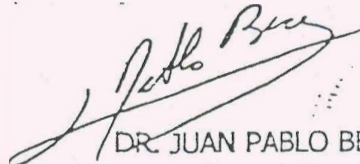
**UNIVERSIDAD DE CHILE
FACULTAD DE MEDICINA
COMITE DE ETICA PARA INVESTIGACION EN SERES HUMANOS**

Santiago, 29 ENE. 2002

CERTIFICADO DE APROBACION

El Comité de Etica para la Investigación en Seres Humanos de la Facultad de Medicina de la Universidad de Chile certifica haber estudiado los antecedentes del proyecto ESTUDIO FASE I/II DE INMUNIZACION CON CELULAS DENDRITICAS PULSADAS CON EXTRACTOS TUMORALES, EN PACIENTES CON MELANOMA AVANZADO cuyo Investigador Responsable es el Dr. FLAVIO SALAZAR del Programa de Inmunología del Instituto de Ciencias Biomédicas de esta Facultad.

La Comisión no encontró objeciones éticas y le otorgó su aprobación.


DR. JUAN PABLO BECA I.
Presidente

JPBI/mis
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