

## ESSEX INSTITUTIONAL REVIEW BOARD, INC.

10 Apgar Way • Lebanon, New Jersey 08833-9570
Telephone 908/236-7735 • Mobile Cellular Phone 908/500-0409
Fax 908/236-2027

April 22, 1993

Bruce Frome, MD International Pain Research Institute 10780 Santa Monica Boulevard, Suite 100 Los Angeles, CA 90025

Dear Dr. Frome:

The Board reviewed the International Pain Research Institute clinical research project, "Ion Magentic Induction Device (PAP-IMI-300) As An Immunomodulator in Treating Patients with AIDS" (IPRI-PAP-0001, 4/21/93).

The protocol was reviewed on April 13, 1993, and approved on April 22, 1993. Your consent form (dated 4/22/93) and site were approved on April 22, 1993. These approvals expire on July 22, 1993.

The Board requests that you forward a study summary including adverse reactions within 30 days of study termination. In any event, reports must be made at intervals not exceeding three months. Any serious or unexpected experiences must be reported to the Board promptly. Enclosed is our brochure detailing your responsibilities associated with this research study.

The Essex Institutional Review Board is in compliance with the regulations of the Food and Drug Administration effective July 27, 1981, and all amendments thereto, contained in Title 21 of the Code of Federal Regulations, Parts 50 and 56.

Thank you.

Sincerely,

Wm. C. Waggoner, PhD, FAACT

cc: Ron Amen, PhD, ABIC International Consultants