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UNIVERSITY
HEALTH SCIENCES

Office of Research
INSTITUTIONAL REVIEW BOARD.

MEMORANDUM

To: James Urbanic, M.D.
Radiation Oncology

From: Chair, IRB # 4
Institutional Review Board

Date: 10/6/2010

Subject: Human Protocol: IRB00012793
A Randomized Phase II Dose Finding Study of ArginMax for its Effect on Erectile Function and Quality of Life in Survivors of Prostate Cancer Previously Treated with Radiotherapy

Study Documents:
Protocol Version: Male ArginMax 98110 Protocol ; Informed Consent Version: Male Arginmax Clean Consent 10-04-10 (approved); Investigator's Brochure: Male ArginMax Ingredients List

The Institutional Review Board (IRB) has approved the above-named protocol and study documents. IRB approval was activated on 9/29/2010. A written request for renewal together with a summary progress report must be submitted to the Board at least one month prior to 9/29/2011.

This approval includes a limited waiver of HIPAA authorization to identify potential subjects for recruitment into this research study, as allowed under 45 CFR 164.512. This temporary waiver provides access to protected health information (PHI) to confirm eligibility and facilitate initial contact, after which research consent and HIPAA authorization will be sought. Access and use is limited to the minimum amount of PHI necessary to review eligibility criteria and contact potential subjects.

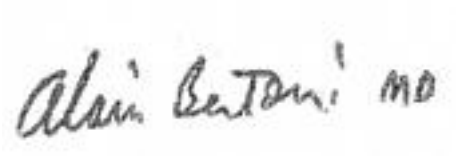
Federal regulations and Board policy require that you promptly report to the Board for review/approval:

- Proposed changes in the research activity (e.g., protocol amendments; consent form revision; advertisements). Changes may not be initiated without IRB review and approval, unless necessary to eliminate an immediate hazard to subjects.

- Serious adverse events and unanticipated problems involving risks must be reported to the Board, institutional officials, FDA, sponsor and other regulatory agencies as required by the protocol, local policy and state or federal regulation.

Please provide a final report to the Board when the project is completed and Board approval can be terminated.

This IRB is in compliance with the requirements in Part 56, Subchapter D, Part 312 of the 21 Code of Federal Regulations published January 27, 1981 and Part 46, Subpart A of 45 CFR published January 26, 1981.



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