

08 December 2011

To Whom It May Concern:

9380 Main Street

RE: Compliance and Operational Statements

Cincinnati, OH 45242

Goodwyn Institutional Review Board, Ltd. (Goodwyn IRB®) is an independent institutional review board. Goodwyn IRB is accredited by the Association for Accreditation of Human Research Protection Programs.

Guidance

Goodwyn is guided by the ethical principles regarding all research involving human subjects as set forth in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*.

Operations:

Goodwyn IRB® is a fully accredited human research protection program by AAHRPP® and operates in compliance with applicable predicate rules, guidance and Information Sheets on Good Clinical Practice in FDA-regulated clinical trials, and:

- U.S. Code of Federal Regulations, DHHS (CFR), Title 45 Part 46, entitled *Protection of Human Subjects*;
- CFR Title 45 Parts 160 and 164, entitled *Standards for Privacy of Individually Identifiable Health Information*;
- FDA regulations on human subjects research (CFR Title 21 Parts 50, 56, *Protection of Human Subjects and Institutional Review Boards*, respectively); and
- International Conference on Harmonization of Requirements for Pharmaceutical Products; *Good Clinical Practices: Consolidated Guideline*; Part II 62 FR 25692, May 9, 1997.
- Division 5 of the Food and Drugs Act (Canada)

Goodwyn IRB is registered with the Office for Human Research Protections (OHRP) and FDA as IRB00000833.

Roles and Responsibilities

Key roles and responsibilities defined in Goodwyn IRB policies and procedures are identified and summarized on the next page.

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Managing Member – Point of contact with regulatory authorities, bearing ultimate responsibility for ensuring compliance with the federal regulations. The primary responsibilities of the Managing Member are to:

- Appoint the Board Chair, Vice-Chairs and Review Board Members (Members).
- Provide resources to the IRB sufficient for it to carry out its duties
- Report to regulatory authorities any occurrence of serious or continuing non-compliance with the regulations or subject risk problems.

Chair/Vice-Chair(s) – Lead convened meetings, delegate review responsibilities, help distinguish project/modification eligibility for expedited review, and interact with sponsors/investigators in support of Board actions. Vice-Chair(s) assists the Chairman where delegated.

Administrative Vice-Chair – Non-voting officer, carries day-to-day responsibility for the administration and operation of the IRB. Ensures that all operations are in compliance with federal regulations. Provides written communication to sponsors/investigators regarding research activities and operations.

Review Board Member (Member) – Review research activities, exercising independent judgment (given his/her background) in the research subjects' best interests. Report to the review board (Board) what he/she thinks about how studies are being conducted and about how the IRB and Board are conducting themselves.

IRB Administrative Staff – responsible for all administrative functions and support of the Board, e.g., prepare minutes, keep records and archives, and prepare applications for review. Provides written communication to sponsors/investigators regarding research activities and operations.

Sincerely,

Ellen Kelso
Managing Member &
Administrative Vice-Chair
for Goodwyn IRB