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Goodwyn Institutional Review Board

Indemnity Agreement

Parties to Agreement:

This agreement is made as of the _____ day of _____ 20___, between the Goodwyn Institutional Review Board, Ltd (“Goodwyn IRB”) and _____ (“Sponsor”).

Purpose of Agreement:

In consideration of Goodwyn IRB reviewing and evaluating the consent form and human protection elements of a study to determine the effectiveness and safety of the drugs named and used in the Clinical Protocol No. _____ before and during its conduct and in forwarding the results of its review and evaluation to the clinical investigators conducting the study, Sponsor agrees to indemnify, defend, and hold harmless Goodwyn IRB and its agents, servants, etc. from and against any judgments, lawsuits, claims, demands, liabilities, damages or expenses, including reasonable attorneys’ fees, which may be made against, suffered or incurred by Goodwyn IRB and its agents, servants, etc. by reason of injury or alleged injury to a study patient from the administration of the study drug or arising from actions required under the Protocol; or by reason of any act or omission on the part of Sponsor, its agents or employees (including without limitation clinical investigators) or their agents or employees.

Conditions to Indemnify:

The covenant provided above to indemnify, hold harmless and defend Goodwyn IRB and its agents, servants, etc. is conditioned on the following terms:

- a. The particular terms and conditions under which Goodwyn IRB shall evaluate and approve the clinical study shall be governed by Title 45 Part 46 and Title 21 Parts 50 and 56 of the Code of Federal Regulations.
- b. It is expressly understood and agreed that this indemnification agreement in no way covers any claim against Goodwyn IRB which is determined by a court of law to arise solely from any fault, malpractice, negligent act or omission of Goodwyn IRB or its agents, servants, employees, representatives or associates.
- c. Goodwyn IRB shall comply with all relevant requirements of the Food and Drug Administration and with any state or local government having jurisdiction of such matters.
- d. In the event a claim is made against Goodwyn IRB by a third party arising or resulting from the Clinical Protocol, Goodwyn IRB shall provide Sponsor with written notice of such claim within thirty (30) days after being first apprised of the claim. Such notice shall set forth all information known to Goodwyn IRB relating to claim and shall be sent by overnight mail to the General Counsel of Sponsor or other person who Sponsor may wish to receive this notice.

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- e. It is understood and agreed that Sponsor shall have the right to fully control the defense of any claim to which this indemnity agreement applies, including but not limited to the selection of counsel and settlement.
- f. Goodwyn IRB agrees to cooperate fully with Sponsor in the defense of any such claim, attend hearings and trials and assist in securing and giving evidence and testimony, and obtaining the attendance of necessary and proper witnesses at such hearing and trials.

This agreement is executed as of the day and year signed below.

Sponsor _____

by _____

(Title)

Date _____

Goodwyn Institutional Review Board, Ltd.

by _____

(Title)