



Indemnification Agreement Sponsor for Solo Investigator

Phone: 415-485-0717 www.irb-irc.com Fax: 415-485-0328

Form 4.50A ver.11/20/07

IRC has agreed to provide Institutional Review Board (IRB) services for a site conducting your study. Although you may have provided an indemnification agreement for the investigator, it did not cover IRC or our IRB. IRC is requesting a specific indemnification to cover this site.

1. Sponsor understands and acknowledges that in reviewing and approving the clinical investigation(s), neither IRC nor the individual members of IRC's IRB are assuring safety or freedom from injury for human subjects who participate in the Study. The investigator is responsible for compliance with the protocol.
2. Accordingly, Sponsor agrees to hold harmless and indemnify IRC and its IRB members against any claim, loss, liability, expense, cause of action or judgment by verdict, settlement or otherwise, including attorneys' fees, arising out of or related to the Study(ies). This includes but is not limited to any Claim by reason of any injury to or death of, any human subject who participates in the Study, whether based on alleged negligence of Sponsor, its investigators or any other person, strict liability, products liability or any other legal theory of liability. This indemnification shall not extend to any such matter which is based on the negligence or knowing misconduct of IRC or its IRB. Sponsor agrees to maintain insurance sufficient to cover this agreement.
3. NOTICE: IRC shall promptly notify Sponsor in writing upon obtaining actual knowledge of any claim as to which such indemnity may be sought. Sponsor shall assume the defense of each indemnified claim or litigation resulting therefrom.

The failure of IRC to give the required notice shall not relieve Sponsor of its indemnification obligations except to the extent such failure resulted in actual detriment to Sponsor.

- 5 SELECTION OF COUNSEL: Counsel selected by Sponsor shall be approved by the IRC whose approval may not be withheld unreasonably. If IRC rejects Counsel selected by Sponsor it must notify Sponsor in writing within ten days of notice by Sponsor, in which case Sponsor's indemnification obligation shall cease. Absent timely rejection by IRC, Counsel selected by Sponsor shall be deemed accepted.
- 6 CONTROL: The parties agree that sponsor shall, at all times, have the right to control the conduct of any defense or settlement of any claim for which indemnity is sought hereunder subject to the provisions in the next paragraph.
- 7 SETTLEMENT: IRC and the IRB members hereunder shall not enter into any settlement to any claim for which indemnification will be or has been sought hereunder without the prior written consent of Sponsor. IRC and the indemnified parties shall have ten calendar days from notification by Sponsor to reject in writing any proposed settlement, such rejection shall cause Sponsor's indemnification obligation to cease.

7. This agreement applies to (investigator name):

8. This agreement applies to site(s):

Sponsor

Company Name _____

Address _____

City, State, Zip _____

Name & Title _____

Signature _____

Date _____

