Appendix G: Sample Indemnification Clause

The following is an example of an indemnification clause drawn up by the University to be used in experimental drug and device testing protocols. The signed indemnification agreement between the Trustees of William Paterson University (not an individual faculty or staff person) and the Sponsor should be attached to the original copy of the protocol when it is submitted to the IRB. This agreement should be forwarded as a separate document and not part of the information in an investigator agreement or a study consent form.

(Company) undertakes to indemnify, defend and hold harmless (Investigator) and Trustees of the (University), its officers, agents and employees from any and all liability, loss, damage and expenses (including attorney fees) they may suffer as the result of claims, demands, costs or judgments which may be made or instituted against them or any of them by reason of personal injury (including death) to any person or damage to property arising out of or connected with the performance of the activities to be carried out pursuant to the clinical research protocol designated as "(Name of Study)" Study No.________; provided, however, that any such liability, loss or damage resulting from (i) a failure to adhere to the terms of the protocol or (Company's) written instructions relative to the use of the investigational drug, (ii) failure to comply with any applicable FDA or other governmental requirements or (iii) negligence or willful malfeasance by (Investigator) or Trustees of the (University), its officers, agents and employees is excluded from this agreement to indemnify, defend and hold harmless.

(Investigator) and Trustees of the (University) agree to notify (Company) as soon as they become aware of a claim or action and to cooperate with and to authorize (Company) to carry out sole management and defense of such claim or action. (Company) agrees, at its own expense, to provide attorneys to defend against any actions brought or filed against (Investigator), Trustees of the (University), its officers, agents and employees with respect to the subject of indemnity contained herein, whether such claims or actions are rightfully brought or filed.

Neither (Investigator), Trustees of the (University), nor its officers, agents or employees shall compromise or settle any claim or action without the prior written approval of (Company).

______________________________  ______________________________
Date                            Signature of Institutional Official

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Name and Title of Institutional Official

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Date                            Signature of Manufacturer Representative

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Name and Title of Manufacturer Representative