

- 3.2 by the Authority, its employees or agents including the Investigator and designate(s) by or on behalf of a Subject (or his dependants) for a declaration concerning the treatment of a Subject who has suffered such personal injury.
4. The above indemnity by the Sponsor shall not apply to any such claim or proceeding:
- 4.1 to the extent that such personal injury (including death) is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Authority, its employees or agents including the Investigator and designate(s);
- 4.2 to the extent that such personal injury (including death) is caused by the failure of the Authority, its employees or agents including the Investigator and designate(s) to conduct the Study in accordance with the Protocol;
- 4.3 unless as soon as reasonably practicable following receipt of notice of such claim or proceeding, the Authority shall have notified the Sponsor in writing of it and shall, upon the Sponsor's request, and at the Sponsor's cost, have permitted the Sponsor to have full care and control of the claim or proceeding using legal representation of its own choosing;
- 4.4 if the Authority, its employees or agents including the Investigator and designate(s) shall have made any admission in respect of such claim or proceeding or taken any action relating to such claim or proceeding prejudicial to the defence of it without the prior written consent of the Sponsor such consent not to be unreasonably withheld, provided that this condition shall not be treated as breached by a statement properly made by the Authority, its employees or agents including the Investigator and designate(s) where (a) such statement is required by law or (b) where the content and publication of such statement has been agreed by the Authority and the Sponsor.
5. The Sponsor shall keep the Authority and its legal advisers fully informed of the progress of any such claim or proceeding, will notify the Authority of the nature of any defence to be advanced and will not settle any such claim or proceeding without notification to the Authority.
6. Without prejudice to the provisions of paragraph 4.3 above, the Authority will use its reasonable endeavours to inform the Sponsor promptly of any circumstances reasonably thought likely to give rise to any such claim or proceeding of which it is aware and shall keep the Sponsor reasonably informed of developments in relation to any such claim or proceeding. Likewise the Sponsor shall use its reasonable endeavours to inform the Authority of any such circumstances and shall keep the Authority reasonably informed of developments in relation to any such claim or proceeding made or brought against the Sponsor in connection with the Study.
7. The Authority and the Sponsor will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any

claim or proceeding by or on behalf of Subjects (or their dependants) or concerning such a declaration as is referred to in paragraph 3.1 above.

8. Without prejudice to the foregoing, if injury is suffered by a Subject while participating in the Study, the Sponsor agrees to operate in good faith the Guidelines published in 1991 by The Association of the British Pharmaceutical Industry and entitled "Clinical Trial Compensation Guidelines" (where the Subject is a patient) and the Guidelines published in 1988 by the same Association and entitled "Guidelines for Medical Experiments in non-patient Human volunteers" (where the subject is not a patient) and shall request the Investigator to make clear to the Subjects that the Study is being conducted subject to those Association Guidelines.
9. For the purpose of this Indemnity, the expression "agents" shall be deemed to include any clinician or administrative official employed by the Authority under a contract of service but to exclude independent contractors.
10. This indemnity shall be governed by and construed in accordance with Irish law.
11. The Authority is entitled to rely fully upon the accuracy of all information supplied to it by or on behalf of the Sponsor concerning the drugs under study and is not required to obtain independent verification of any information supplied.

SIGNED on behalf of the Authority

Hospital Chief Executive

Date _____

SIGNED on behalf of the Sponsor

Date _____