Clinical Trial Indemnity Form

To:  

("the Hospital")
("the Authority")
("the Investigator")

Dr

From:  

("the Sponsor")

(Enter Name of pharmaceutical company or other)

RE:  

("the Study")

(Enter the full title of the protocol, including any protocol numbers and version dates)

1. This agreement made on date signed by the parties is between………………………………..
("Name of Pharmaceutical Company or other")
("the Sponsor") and …………………………………….. ("the Hospital") and the …………………….. ("the Authority").

1.1 It is proposed that the Authority should agree to participate in the above sponsored study ("the Study") involving patients of the Authority ("the Subjects") to be conducted by Dr ………………………….. ("the Investigator") in accordance with the Protocol annexed, as amended from time to time with the agreement of the Sponsor and the Investigator. The Sponsor confirms that it is a term of its agreement with the Investigator that the Investigator shall obtain all necessary approvals for the Study and shall resolve with the Authority any issues of a revenue and resource nature.

2. The Authority agrees to participate by allowing the Study to be undertaken on its premises utilising such facilities, personnel and equipment, as the Investigator may reasonably need for the purpose of the Study.

3. In consideration of such participation by the Authority, and subject to paragraph 4 below, the Sponsor indemnifies and holds harmless the Authority, its employees and agents, including the Investigator and designate(s) against all claims and proceedings (to include any settlements or ex gratia payments made with the consent of the parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise)

3.1 by or on behalf of Subjects taking part in the Study (or their dependants) against the Authority, its employees or agents including the Investigators and designate(s) for personal injury (including death) to Subjects arising out of or relating to the administration of the product(s) under investigation or any clinical intervention or procedure provided for or required by the Protocol to

1 Note that in the case of HSE owned hospitals the term ‘Authority’ refers to the HSE.
2 An individual, a company, an institution or an organisation to which the Investigator has delegated work relevant to the study.
which the Subjects would not have been exposed but for their participation in
the Study;

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 2013 by the Irish Pharmaceutical Healthcare Association (IPHA) and entitled “Clinical Trial Compensation Guidelines” 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_____________________________