

Clinical Trial Indemnity Form

To: insert (“the Clinical Organisation”)

insert (“the **Authority**¹”)

insert (the “**Principal Investigator**”)

From: insert (“the Sponsor”)

RE: insert (“the Study”)

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 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 keeps indemnified the Authority, its employees and agents, including the Investigator and designate(s)² 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):
 - (a) 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 injury³ (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 which the Subjects would not have been exposed but for their participation in the Study;

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.

³ Personal Injury - Personal injury includes any disease and any impairment of a person’s physical or mental condition, including minor injuries.

Exclusions are listed in S.I. No. 390 of 2017 - the National Treasury Management Agency (Delegation of Claims Management Functions) Order 2017.

- (b) 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:
- (a) to the extent that such bodily 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);
- (b) to the extent that such bodily 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;
- (c) 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;
- (d) 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:
- (i) such statement is required by law or
- (ii) 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, shall notify the Authority of the nature of any defence to be advanced and shall not settle any such claim or proceeding without notification to the Authority.
6. Without prejudice to the provisions of paragraph 4(c) 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(a) above.
8. Without prejudice to the foregoing, in the case of trials of investigational medicinal products, 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 drug or device, if applicable, under study and is not required to obtain independent verification of any information supplied.

SIGNED for and on behalf of
[SPONSOR]

By: _____

Name: _____

Title: _____

Date: _____

SIGNED for and on behalf of
[CLINICAL ORGANISATION]

By: _____

Name: _____

Title: _____

Date: _____