**PIEC Application Form Annex H – Institutional Declaration and Indemnity Form**

**Instructional Notes:**

**Who should sign this form?**

*For an industry-sponsored drug trials, the authorized sponsor’s representative should sign this form.*

*For an investigator-initiated study, the institutional representative should sign this form.*

*If the proposed research is regulated under the Human Biomedical Research Act, the institutional representative of the Research Institution should sign this form.*

Parkway Independent Ethics Committee (PIEC) agrees to provide review and continuing oversight of the following research study involving human participants subject to the Sponsor/Institution agreeing to the following terms and conditions.

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| **I. Details of Research Study** |
| Study Title: Text FieldList of Principal Investigator(s) and Study Site(s):

|  |  |
| --- | --- |
| **Name of Principal Investigator**  | **Name of Study Site**  |
| Text Field | Text Field |
| Text Field | Text Field |
| Text Field | Text Field |
| Text Field | Text Field |

Name of Sponsor / Institution: Text Field |
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| **II. Terms and Conditions** |
| 1. The Sponsor/Institution declares that the study site submitted to PIEC for the review of the proposed research study:
	1. does not have an in-house Institutional Review Board (IRB) that operates according to ICH Good Clinical Practice (ICH-GCP) in which the Sponsor/ Institution has submission obligation; and/or
	2. is not legally affiliated with any other IRBs that preclude the Sponsor/Institution from submission to another IRB.
2. The Sponsor/Institution declares that the proposed research study has not been submitted and rejected by any other local and/or overseas IRB.
3. The Sponsor/Institution understands and acknowledges that in reviewing and approving the above research study, neither PIEC nor its individual members are assuring safety or freedom from injury for human subjects who participate in the research study.
4. The Sponsor/Institution agrees to indemnify and hold harmless the PIEC and its individual members in respect of and against any claim, loss, liability, expense and proceedings including any settlements or *ex gratia* payments, arising out of or related to the research study. This includes but is not limited to any claim by reason of injury to or death of, any human subject who participates in the research study, whether based on alleged negligence of Sponsor/Institution. The indemnification will not extend to any such matters which are based on negligence or knowing misconduct of the PIEC and/or its individual members.
5. PIEC will provide reasonable prior notice to The Sponsor/Institution in writing upon obtaining knowledge of any claim as to which such indemnity may be sought.
6. PIEC, its individual members and their legal representatives shall reasonably cooperate with the Sponsor/ Institution in the investigation and defense of any indemnified claim or litigation for which indemnification is sought.
7. The Sponsor/ Institution and Investigator(s) remain responsible for ensuring compliance with the protocol, applicable regulations, institutional and PIEC policies and requirements.
8. The Sponsor/ Institution understands and acknowledges that the proposed research can only be initiated after written approvals from PIEC and relevant regulatory authorities have been obtained.
9. **For research regulated under the Human Biomedical Research Act:** The Sponsor/Institution understands and acknowledges that, if the proposed research is regulated under the Human Biomedical Research Act, the proposed research must be conducted under the control and supervision of the Research Institution (RI) for each study site/researcher listed above. The Sponsor/Institution further undertakes to ensure that notification of operation as RI to MOH is completed prior to study commencement.
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| **III. Declaration of Sponsor’s/ Institution’s Representative** |
| I, on behalf of the Sponsor/ Institution, as an authorized decision-making representative, understand and agree to the above terms and conditions.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*Signature of Sponsor’s/Institution’s Representative Date**Full Name:* Text Field *Position Held:* Text Field*Name of Sponsor /Institution:* Text Field*Contact Number:* Text Field*Email address:* Text Field*Mailing address:* Text Field |