

**Annex B**

**Sworn Assurance**

I, (name of Head of Sponsor/CRO), (legal age), (citizenship), resident of (address), after being sworn according to law, hereby depose and state:

- 1. I am the Head of the Sponsor/CRO, (Name of Applicant Company), with business address at (address).
- 2. I am applying for the issuance of a (Approval to Conduct Initial Clical Trial/Amendments) of the (name of investigational product) under Abridged Regulatory Pathway Review addressing any public health emergency, and emergenging or re-emerging infectious diseases considered as public health threat.
- 3. That all aspects of the clinical trial application, including but not limited to the protocol and investigational product information, are identical to that currently approved by the following identified RDRA at the time of submission, not withstanding changes made in adherence to local regulations or guidelines (e.g. local customization of information consent form or other patient materials):

RDRA	Date of RDRA approval
1.	1.
2.	2.
.	.
.	.
.	.

- 4. The documents submitted to the RDRA are in accordance with the requirements of ICH GCP, and if not, I hereby submit the necessary technical documents to comply with the dossier requirements and format following existing guidelines.
- 5. The clinical trial protocol and investigational product has not been rejected, withdrawn, suspended, or pending deferral by any RDRA for any reason.
- 6. That there is full compliance with the eligibility requirements provided under the FDA Circular on clinical trial regulatory reliance, and all data and information submitted in connection with this application as well as other submissions in the future are true and correct and reflect the total information available.
- 7. I understand that the Philippine Food and Drug Administration (FDA) may verify through both government and private entities the authenticity of all the information and documents submitted. I fully consent and authorize the Philippine FDA to conduct such verification for purposes of evaluation of my application.

IN WITNESS WHEREOF, I have hereunto set my hand this (date) in (city).

(Name of Head of Sponsor/CRO)  
Affiant

SUBSCRIBED AND SWORN to before me this \_\_\_\_\_ at \_\_\_\_\_, Philippines.

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