

Annex B

Declaration of Undertaking

I assume primary responsibility and/or stewardship over the clinical trial in case of liability, adverse events, or other public health & safety issues arising from its conduct. I agree to have, in good faith, exerted due diligence in ensuring that third-party intellectual property rights are not infringed. Non-observance of any of the undertakings in this declaration is deemed a misrepresentation which is a ground for disapproval of this application or, if approved, the suspension or termination of the conduct of clinical trial.

I categorically declare full compliance with the following eligibility requirements provided under FDA Circular on clinical trial regulatory reliance:

1. The investigational product in the clinical trial will address any of the following:
 - a. Public health emergency
 - b. Rare disease (Orphan drug)
 - c. Cancer
 - d. Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS)
 - e. Emerging or re-emerging infectious diseases considered as public health threat
2. 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 identified RDRA at the time of submission.
3. The clinical trial protocol and investigational product has not been rejected, withdrawn, suspended, or pending deferral by any RDRA for any reason.

All data and information submitted in connection with this application as well as other submission in the future are true and correct and reflect the total information available.

WAIVER

I HEREBY GRANT AUTHORITY TO THE FOOD AND DRUG ADMINISTRATION TO VERIFY THROUGH BOTH GOVERNMENT AND PRIVATE RESOURCES THE AUTHENTICITY OF ALL THE INFORMATION AND DOCUMENTS SUBMITTED.

SPONSOR/AUTHORIZED CRO

Signature : _____
 Name : _____
 Date : _____

ACKNOWLEDGEMENT

SUBSCRIBED AND SWORN TO BEFORE ME this _____ day of _____
 20_____ at _____
 _____, Philippines, personally appeared the following:

Known to me and to me known to be the same persons who execute the application form and this declaration form, and they acknowledged to me that the same is their free and voluntary act and deed. WITNESS MY HAND AND SEAL on the date and place first above written.

Doc. No. : _____
 Page No. : _____
 Book No. : _____
 Series of : _____