DEPARTMENT OF HEALTH

FOOD AND DRUG ADMINISTRATION

STANDARD REQUIREMENTS FOR ISSUANCE OF PERMIT TO IMPORT CLINICAL TRIAL MATERIALS

Requirements	Guidelines
☐ Letter of Application	➢ Itemized, detailed description of the clinical trial materials with corresponding quantity for each approved investigator per site/ hospital
☐ Proof of Payment	➢ 500 php per request
☐ Waiver statement	➢ Indicating that FDA will not be held liable from any damage or injury arising from the use of the investigational drug product.
☐ Copy of the approval of the Clinical Trial Protocol	➢ Includes the lists of approved investigators with corresponding site/ hospital
☐ Copy of the approval of the Pharmaceutical Data	➢ Should include: GMP statement from manufacturing/Certificate from Regulatory Body, Certificate of Analysis, Stability Data , Manufacturing Data , Formulation and Product labeling
☐ Copy of the proforma invoice	➢ Includes proforma invoice per approved investigators with corresponding site/ hospital
☐ Copy of previously approved import permit	➢ If applicable