ANNEX F

Requirements for Application for the Certificate of IVD Listing

1. Notarized Application Form
2. Notarized letter addressed to the Director, Center for Device Regulation, Radiation Health, and Research, stating that the IVD will be used solely for research, analysis, or is being donated by a certain organization and is not intended for sale. The letter should contain the following information:
   - 2.1 Complete list of the IVD indicating the quantity, brand and the name of the manufacturer of the product
   - 2.2 Declaration that the organization shall be the sole entity responsible for the IVD and that the CDRRHR - FDA, DOH will not be held liable for any safety issue concerning the product.
3. Certificate of In-Vitro Diagnostic Notification or Certificate of In-Vitro Diagnostic Registration or any equivalent document attesting to the safety and effectiveness of the device issued by the regulatory agency in the country where the device will come from.
4. For a donated IVD (brand new), a certified true copy of the deed of donation, the deed of acceptance, and the packing list or any document that will show the quantity of the product.
5. Copy of SEC or DTI registration, when applicable