DAIDS Protocol Registration Translation Confirmation Document

I. Protocol/Clinical Research Site (CRS) Information:

DAIDS/Network Protocol ID Number:	
DAIDS Protocol Version Number:	
CRS Name and Site ID Number:	
Local Language(s):	
Investigator of Record (IoR) listed on Form FDA 1572/DAIDS IoR Form	
Will any participants be consented in English?	☐ **Yes** ☐ **No**

II. Other Local Language Documents Submitted with Protocol Registration Submission:

☐ **IRB/EC approval letter(s)**	☐ **Other Regulatory Entity (RE)/Approving Entity approval(s) (specify):**
☐ **Other (specify):**	

III. IRB/EC-approved local language Informed Consent Forms (ICF) submitted for registration:

☐ **Main ICF**	☐ **Screening ICF**	☐ **Pregnancy ICF**	☐ **Stored Specimen ICF**
☐ **Short ICF**	☐ **Sub-study ICF**	☐ **Assents**	
☐ **Other ICF(s), specify:**			

By signing this form, the IoR or designee confirms that the attached site-specific English ICFs and/or English Back translation(s) are a true and accurate translation of the above-listed IRB/EC/Other RE-approved local language ICFs and IRB/EC/Other RE approval letter(s) and that all local language ICFs contain the required informed consent elements as detailed in the DAIDS Sample Informed Consent.

Investigator of Record (IoR) Signature:	**Date:** **(Format: DD-MMM-YYYY)**

NOTE: The original signed form should be kept in the regulatory file of the clinical research site.