

DMID Language and Translation Requirements Summary Essential Document Requirements and Instructions

This chart is a summary/worksheet of the requirements for translation for essential documents. The responsibility for translation lies with the contract or grant. This chart may also be used as a worksheet. The first column with boxes indicates documents which must be translated and submitted to DMID before the study can start.

	DOCUMENT	ENGLISH REQUIREMENT	LANGUAGE FAMILIAR TO LOCAL SITE REQUIREMENT	ADDITIONAL COMMENTS AND INSTRUCTIONS
<input type="checkbox"/>	FINAL PROTOCOL	YES	YES	The protocol may be in English if English is understood by the key local staff. If the key local staff, other than the PI, do not understand English, specific operational sections of the protocol may be required to be translated to support accurate protocol implementation. Determinations of specific sections will be made between the DMID Branch and OCRA
<input type="checkbox"/>	PROTOCOL REVISIONS	YES	YES	See comment for Final Protocol
<input type="checkbox"/>	INFORMED CONSENT	YES	YES	<p>Informed Consent Forms must be in a language familiar to study participants. For further guidance on informed consent regulations see 45 CFR 46.116, (http://m#46.116 21) and CFR 50.20 (http://www.accessdat)</p> <p>FOR NON-U.S. SITES- If the original document was written in English and participants do not speak English, once translated, it must be back translated from the local language to English.</p> <p>-If the original document was written in a language other than English it must be translated into English and submitted with the DMID Translation Equivalence Form.</p> <p>FOR U.S SITES-If the performance site(s) are in the U.S. using non-English documents, the DMID will accept the DMID Translation Equivalence Form.</p>
<input type="checkbox"/>	Standard Operating Procedures (SOPs) (Site-specific)	SEE COMMENTS	YES	A list in English of SOPs should be provided. A decision between the DMID Branch and OCRA will be made about which SOPs need translating. This translation may depend on the language of the monitor and the information on which DMID needs verification (i.e., product handling or specifics on an invasive procedure that is not covered in the protocol.

	DOCUMENT	ENGLISH REQUIREMENT	LANGUAGE FAMILIAR TO LOCAL SITE REQUIREMENT	ADDITIONAL COMMENTS AND INSTRUCTIONS
<input type="checkbox"/>	Manual of Procedures (MOP) per Protocol	SEE COMMENTS	YES	A list in English of MOP procedures should be provided. A decision between the DMID Branch and OCRA will be made about which procedures need translating. This translation may depend on the language of the monitor and the information on which DMID needs verification (i.e., product handling or specifics on an invasive procedure that is not covered in the protocol.
<input type="checkbox"/>	Investigator Brochure	YES	N/A	IB language is English as required by IND application regulations 21 CFR 312 . Contact the DMID Protocol Champion / Clinical Project Manager.
<input type="checkbox"/>	Advertisements and Other Information given to	YES	YES	See informed consent comments
<input type="checkbox"/>	IRB/IEC Approval of: -Final Protocol -Informed Consent -Protocol Amendment(s) -Annual/Bi-Annual Trial Renewal -Information given to Trial subjects -Advertisement/Recruitment	YES	N/A	Document must be translated and accompanied by DMID Translation Equivalence Form.
<input type="checkbox"/>	FDA Form 1572 (for IND studies) or Investigator of Record Form (IOR) for non-IND studies	YES YES	N/A	The 1572 is required for all studies under IND. The IOR form is for non-IND studies and the DMID form should be used
<input type="checkbox"/>	Foreign regulatory/government approval and other agency approval (If applicable)	YES	N/A	Document must be translated and accompanied by a signed equivalence statement. Use the DMID Translation Equivalence Form

Requirements for Essential Documents for DMID Interventional Studies (involving study/investigational product)

Note: If the clinical research does not involve a study/investigational product, those related essential documents will be not required.

	DOCUMENT	ENGLISH REQUIREMENT	LANGUAGE FAMILIAR TO LOCAL SITE REQUIREMENT	ADDITIONAL COMMENTS AND INSTRUCTIONS
<input type="checkbox"/>	SAE Reports to DMID	YES		DMID SAE reporting form should be used
<input type="checkbox"/>	SAE Report Supporting Documentation To DMID	YES		
<input type="checkbox"/>	FDA Form 1572 (for IND studies) or Investigator of Record Form (IOR) non-IND studies	YES		The 1572 is required for all studies under IND. The IOR form is for non-IND studies and the DMID form should be used
<input type="checkbox"/>	Data Collection Tools	See Comments	YES	Language used must be one the local staff filing in the forms understands. Program may want all or specific forms translated
<input type="checkbox"/>	Principal Investigator CV/Biosketch	See Comments		The credentials of the investigator must be translated for interventional and invasive studies, but it is not necessary to translate publication citations. For other studies DMID may need to verify their credentials through translation
<input type="checkbox"/>	Sub-Investigator CV/Biosketch	See Comments		The credentials for sub-investigator must be translated for IND must be translated, but it is not necessary to translate publication citations. For non-IND studies DMID may need to verify their credentials through translation.
<input type="checkbox"/>	DMID Financial Disclosure Form	YES		Required for IND studies only
<input type="checkbox"/>	Investigational Product label (if applicable)	YES	YES	Document must be translated into appropriate language and accompanied by a signed equivalence statement. Please use the DMID Translation Equivalence Form.
<input type="checkbox"/>	Shipping Records for Investigational Product and Trial-Related Materials		YES	
<input type="checkbox"/>	Investigational Product Accountability Logs (if applicable)	See comments		Shells/ templates for the test article accountability logs must be translated if the study is to be monitored in English. Documents that must be translated should be accompanied by a signed DMID Translation Equivalence Form
<input type="checkbox"/>	Lab Normal Value(s) or Range(s)		YES	Site may submit documents in available language/ language

	DOCUMENT	ENGLISH REQUIREMENT	LANGUAGE FAMILIAR TO LOCAL SITE REQUIREMENT	ADDITIONAL COMMENTS AND INSTRUCTIONS
<input type="checkbox"/>	for medical, technical, or laboratory tests and procedures			issued. NOTE: If lab values provided in the Latin alphabet, translation will be required using the DMID Translation Equivalence Form.
<input type="checkbox"/>	Laboratory Certifications/Qualifications for procedures and tests		YES	Site may submit documents in available language/ language issued.