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
☐	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.
☐	PROTOCOL REVISIONS	**YES**	**YES**	See comment for Final Protocol.
☐	INFORMED CONSENT	**YES**	**YES**	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) **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. -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. **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.
☐	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.

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☐	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.
☐	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.**
☐	Advertisements and Other Information given to	**YES**	**YES**	See informed consent comments.
☐	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.
☐	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.
☐	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.

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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 not be required.

	DOCUMENT	ENGLISH REQUIREMENT	LANGUAGE FAMILIAR TO LOCAL SITE REQUIREMENT	ADDITIONAL COMMENTS AND INSTRUCTIONS
☐	SAE Reports to DMID	**YES**		DMID SAE reporting form should be used.
☐	SAE Report Supporting Documentation To DMID	**YES**		
☐	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.
☐	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.
☐	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.
☐	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.
☐	DMID Financial Disclosure Form	**YES**		Required for IND studies only.
☐	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.
☐	Shipping Records for Investigational Product and Trial-Related Materials		**YES**	
☐	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.

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☐	Lab Normal Value(s) or Range(s) for medical, technical, or laboratory tests and procedures		**YES**	Site may submit documents in available language/ language issued. NOTE: If lab values provided in the Latin alphabet, translation will be required using the DMID Translation Equivalence Form.
☐	Laboratory Certifications/Qualifications for procedures and tests		**YES**	Site may submit documents in available language/ language issued.