

Quick Reference Card Protocol Registration At A Glance

Below is a list of the required documents for each specified registration submission.	
1. INITIAL PROTOCOL REGISTRATION	
A complete initial protocol registration submission must include:	
	Copy of the Form FDA 1572 signed and dated by the Investigator of Record (IoR) (for studies conducted under an IND) or Copy of the DAIDS IoR Form, signed and dated by the IoR (for non-IND studies)
	loR Curriculum Vitae (CV), signed and dated and other required documentation
	Copy of all IRB/EC and other applicable Regulatory Entity (RE) approval letter(s) and any other appropriate documentation from the IRB/EC and other applicable REs with information linking the approval to the current DAIDS approved version of a protocol
	Documentation of Pediatric risk/benefit category per 45 CFR 46 & 21 CFR 50 – if applicable
	Institutional Biosafety Committee (IBC) approval – if applicable
	Copy of all IRB/EC other applicable RE approved site-specific Informed Consent Forms (ICFs)
_	- all languages including English translations, if applicable
ч	Translation Confirmation Document – if applicable
2. F	ULL VERSION PROTOCOL AMENDMENT REGISTRATION
A c	omplete full version protocol amendment registration submission must include:
	Copy of all IRB/EC and other applicable RE approval letter(s) and any other appropriate documentation from the IRB/EC and other applicable REs with information linking the approval to the current DAIDS approved version of a protocol
	Documentation of the date the amended protocol and any revised site-specific ICF(s) were submitted to the local IRB/EC
	Documentation of Pediatric risk/benefit category per 45 CFR 46 & 21 CFR 50 – if applicable
	Institutional Biosafety Committee (IBC) approval – if applicable
	Copy of all IRB/EC other applicable RE approved revised site-specific ICFs - all languages including English translations, if applicable
_	Translation Confirmation Document – if applicable
3. LETTER OF AMENDMENT (LoA) REGISTRATION	
	omplete LoA registration submission must include:
	Copy of all IRB/EC and other applicable RE approval letter(s) and any other appropriate documentation from the IRB/EC and other applicable REs with information linking the approval to the current DAIDS approved version of the LoA
	Documentation of the date the LoA and any revised site-specific ICF(s) were submitted to the local IRB/EC
	Institutional Biosafety Committee (IBC) approval – if applicable
	Copy of all IRB/EC other applicable RE approved revised site-specific ICFs
	- all languages including English translations, if applicable Translation Confirmation Document – if applicable
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	DMINISTRATIVE REGISTRATION
	omplete administrative registration submission must include:
	Copy of all IRB/EC and other applicable RE approval letter(s) and any other appropriate documentation from the IRB/EC and other applicable REs with information linking the approval to the current DAIDS approved version of the protocol including the IRB/EC decision regarding protocol review and approval
_	Copy of the Form FDA 1572, signed and dated by the Protocol/Grant PI/Protocol Chair/Co-Chair (for studies conducted under an IND) <i>OR</i> Copy of the DAIDS IoR Form, signed and dated by the Protocol/Grant PI/ Protocol Chair/Co-Chair (for non-IND studies)
Ч	Protocol/Grant PI/Protocol Chair/Co-Chair IoR CV, signed and dated and other required documentation



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