

PROTOCOL SUBMISSION CHECKLIST

To the Principal Investigator:

Be advised that IEC receives complete proposal submission packages only between the 1st and the 15th day of each month from 8:00 am to 5:00 pm to ensure consideration at the following month's meeting. The cut-off period will not be extended under any circumstance.

Please obtain a copy of this form, fill-out the requested information, and make your submission both in electronic version and hard copy.

PROTOCOL INFORMATION (to be filled by Principal Investigator)						
Date Submitted: (mm/dd/yyyy) Protocol No.: (if applica				<u> </u>		
Date Submitted: (mm/dd/yyyy)		able)	VEISIOITIN	o. and enectivity date.		
Title:						
Tiue.						
Principa	al Investigator: (Title, Last Name, First Name)					
Telephone No.:		Mobile No:		Email:		
Name o	of Adviser: (if applicable)					
Type of	Submission:					
☐ In	itial		☐ Continuing review of approved protocols			
	BASIC DOC	CUMENTS (must s	submit for initial re	view)		
Document type		Version / Da	te	Remarks		
	Accomplished Protocol Review Application (IEC Form 014/V2/2025)					
	Accomplished Protocol Submission Checklist (IEC Form 013/V3/2025)					
	Study Protocol (complete with relevant documents)					
Data Collection Forms (including Case Report Forms or CRFs)						
	Protocol Synopsis and Diagrammatic v Form 016/V1/2025)	workflow (IEC				

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Curriculum Vitae of PI, the study team members, and the Adviser if applicable (IEC Form 004/V2/2024)		
Technical Review Certificate		
STUDY-SPECIFIC DOCUME	NTS (submit as needed)	
Document type	Version / Date	Remarks
Institutional Endorsement from the Vice Chancellor, Dean, or Medical Director (for research by students, faculty, staff, or medical residents)		
Investigator's Brochure (for Clinical Trials Phase I , II, III) or Basic Product Information Document (for Clinical Trial Phase IV)		
Informed Consent Form or ICF (for studies with human participants) - must include an English version and a Tagalog and/or other local language version/s - must have Version No., Date, Page No. in the footer		
Parent's Consent Form (for studies involving children/minor and relevant populations) - must include an English version and a Tagalog and/or other local language version/s - must have Version No., Date, Page No. in the footer Tagalog and/or other local version/s		
Assent Form (for studies involving minors and relevant populations deemed incompetent to sign an ICF) - must include an English version and a Tagalog and/or other local language version/s - must have Version No., Date, Page No. in the footer Tagalog and/or other local version/s		
Training Certificate in Health Research Ethics of PI, Co-investigator (Co-I), and the rest of the study team or Certificate of Good Clinical Practice (GCP) for clinical trials obtained within the last three years		
Recruitment advertisements (as needed by the study protocol)		
Other information or documents for participants (such as diaries, etc.)		
Certificate of Approval from the Institutional Biosafety Committee (for studies involving hazardous biological materials)		

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	Material Transfer Agreement (for any research involving transfer of biological specimens)		
	Memorandum of Agreement or Terms of Reference (for collaborative studies)		
	Grants Acquisition and Management (GAM)-endorsed Clinical Trial Agreement with approval from the Institutional Contract Review Committee (ICRC) (for sponsor-initiated clinical trials done in DLSMHSI)		
	Site Resources Checklist (for clinical trials outside DLSMHSI done by DLSMHSI staff)		
	Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)		
	National Commission for Indigenous People Clearance (for studies with indigenous populations) *can be processed while DLSMHSI-IEC review is ongoing		
	Insurance/Indemnity Policy		
	Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and		
	DENR local transport permit, as applicable)		
	DENR local transport permit, as applicable) DECLARATION O	F AUTHENTICITY	
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