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 applicable)	Version No. and effectivity date:
Title:		
Principal Investigator: (Title, Last Name, First Name)		
Telephone No.:	Mobile No:	Email:
Name of Adviser: (if applicable)		
Type of Submission: ☐ Initial	☐ Continuing review of approved protocols	

BASIC DOCUMENTS (must submit for initial review)			
	Document type	**Version / Date**	**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 workflow (IEC Form 016/V1/2025)		

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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 DOCUMENTS (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)		

DECLARATION OF AUTHENTICITY

I understand that this application for IEC Review and approval will NOT be accepted unless all necessary documents are submitted.

I declare the authenticity of the documents submitted with this application.

Principal Investigator: (Signature over printed name)	Date signed: (mm/dd/yyyy)

CHECKLIST VERIFICATION (to be filled up by DLSMHSI-IEC Staff)

Date Received: (mm/dd/yyyy)	IEC Tracking No.:

Decision Point: (Accepted or Rejected)

☐ Accepted ☐ Rejected

Reason for rejection:

Verified complete by: (printed name and signature)

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