Review Checklist

STUDY PROTOCOL INFORMATION

FEU-NRMF IERC Code:[1]	
Study Protocol Title:	
Principal Investigator:	
Study Protocol Submission Date:	
Verified Complete by:	

Basic Documents (must submit)

- ☐ Review Checklist **[FEU-NRMF IERC FORM 2(A) 2022]**
- ☐ Printed Registration and Application Form **[FEU-NRMF IERC FORM 2(B) 2022]**
- ☐ Study Protocol Assessment Form **[FEU-NRMF IERC FORM 2(C) 2022]**
- ☐ FEU-NRMF Proposal Review Form 1A
- ☐ Study Protocol
- ☐ Data collection forms (including CRFs)
- ☐ CV of PI and study team members
- ☐ Proof of payment of ethics review fee (as applicable)
- ☐ Research Ethics Training

Study-specific Documents (submit as needed)

- ☐ Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document (for clinical trials phase IV and clinical trials on marketed drugs or products)
- ☐ Informed Consent Assessment Form (for studies with human participants) **[FEU-NRMF IERC FORM 2(D) 2022]**
- ☐ Informed consent form in English (for studies with human participants)
- ☐ Informed consent form in local language (for studies with human participants)
- ☐ Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
- ☐ Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
- ☐ Request to Waive of Written and Verbal Informed Consent **[FEU-NRMF IERC FORM 2(N) 2022]**
- ☐ Good Clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team (for clinical trials), Residents and Consultants.
- ☐ Recruitment advertisements (as needed by the study protocol)
- ☐ Other information or documents for participants (such as diaries, etc.)
- ☐ Material Transfer Agreement (for any research involving transfer of biological specimens)
- ☐ Memorandum of Agreement (for collaborative studies)
- ☐ Memorandum of Agreement/Understanding (for outside stakeholders)
- ☐ RCD-endorsed Clinical Trial Agreement (for clinical trials done in FEU-NRMF; processed separately by the FEU-NRMF Legal Office and to be submitted to RDO upon receipt of notification of ethical approval from FEU-NRMF IERC)
- ☐ FEU-NRMF Data Privacy Office (DPO) Research Clearance Form (for studies involving FEU-NRMF students, faculty, employees, or patients as participants or fata source)
- ☐ Site Resources Checklist for Clinical Trial Outside FEU-NRMF MEDICAL CENTER By FEU-NRMF Personnel **[FEU-NRMF IERC FORM 2(E) 2022]**
- ☐ Site Resources Checklist for Clinical Trial Outside FEU-NRMF MEDICAL CENTER By non-FEU-NRMF Personnel **[FEU-NRMF IERC FORM 2(F) 2022]**
- ☐ Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)

[1] To be issued upon initial processing by FEU-NRMF IERC

- ☐ National Commission for Indigenous People (NCIP) Clearance (for studies with indigenous populations; can be processed while FEU-NRMF IERC review is ongoing)
- ☐ Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)