Review Checklist

STUDY PROTOCOL INFORMATION

Reference Number:[1]	
BulSU-ERC Code:[2]	
Study Protocol Title:	
Principal Investigator:	<Title, Name, Surname>
Study Protocol Submission Date: *(to be accomplished by BulSU-ERC Staff)*	<dd/mm/yyyy>
Verified Complete by: *(to be accomplished by BulSU ERC Staff)*	<Signature over Printed Name>
Classification of Review: *(to be accomplished by BulSU ERC)*	⬜ **EXPEDITED** ⬜ **FULL BOARD**
Classified by the: ⬜ **BulSU-ERC CHAIR** ⬜ **BulSU-ERC COORDINATOR**	<Signature over Printed Name>

Basic Documents (must submit)

- □ Review Checklist **[BulSU-ERC FORM 2(A)2019]**
- □ Printed Registration and Application Form**[BulSU-ERC FORM 2(B)2019]**
- □ Study Protocol Assessment Form **[BulSU-ERC FORM 2(C)2019]**
- □ Research Grants Administration Office (RGAO) Endorsement (refer to **BulSU-**ERC General Policies and Guidelines for description of RGAO)
- □ Study Protocol
- □ Data collection forms (including CRFs)
- □ Diagrammatic workflow
- □ CV of PI and study team members
- □ Electronic copy of study protocol, **BulSU-REC FORM 2(A)2020, BulSU-ERC FORM 2(B)2020, BulSU-REC FORM 2(C)2020,** and **BulSU-ERC FORM 2(D)2020**
- □ Proof of payment of ethics review fee (as applicable)

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)
- □ Informed Consent Assessment Form (for studies with human participants) **[BulSU-ERC FORM 2(D)2020]**
- □ 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)

[1] To be issued upon RGAO registration
[2] To be issued upon initial processing by BulSU-REB

- □ Good Clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team (for clinical trials)
- □ 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)
- □ 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 (NCIP) Clearance (for studies with indigenous populations; can be processed while BulSU-ERC review is ongoing)
- □ Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)