Annexure IV

To
The Chairperson
Institutional Ethics Committee
Symbiosis International (Deemed University)
Lavale, Pune 412115
Email id: iec@siu.edu.in

Application for Review of Research Protocol / Project by Ethics Committee
(All the fields are mandatory. Mention 'NA' if item not applicable.)

A. Basic Information

1	**Research Study Title**	
2	**Project ID / PRN (In case of PhD Scholar)**	
3	**Full Name of Principal Investigator (PI)**	
4	**Designation of PI**	
5	**Faculty / Department**	
6	**Affiliation of PI**	
7	**Name sponsor for the Research, if any**	

B. Details about Co-Investigators

Sr. No.	**Full Name of Co-Investigator**	**Designation**	**Affiliation**
1.			
2.			
3.			
4.			
5.			
6.			

C. Research Related Information

1	**Type of Review requested**	exemption/expedited/full review
2	**Are you seeking waiver of consent ? if Yes, Specify Reason**	
3	**Whether study approved by IRC / RAC/ Any other scientific committee (Attach copy of approval)**	Yes / No

4	**Whether study needs collection of data from the participants/constituents of SIU? [If Yes, attach the approval from the Data Access Review Committee (DARC) of SIU]**		Yes / No
5	**Does your project involve ethical review by other ethics committee (Attach copy)**		Yes / No
6	**Type of Study**	Drug Trial or Clinical Trial	
		Biomedical and Health Research	
		Multi-centric / Single Center	
		Any other (specify)	
7	**If Clinical Trial**	Does study involve Drugs, Devices or Vaccines (specify)	
8		Does study involve a change in dose, route or indication of the drug? (if yes specify)	
9		Statutory authority's permission is obtained? (if yes date of permission)	
10		CTRI Registration Number (if registered)	
11		Phase of the clinical study	
12		Is similar study being conducted elsewhere? (if yes, attach details)	

D. Checklist of the documents to be attached with this form

1	Protocol / Plan of study	**Yes**	**NA**
2	Case Report Form / Study Tool / Questionnaire		
3	Subject Information Document: In English		
4	Subject Information Document: In Local Language		
5	Approval by RAC/IRC or equivalent Technical Committee		
6	Informed Consent Form: In English		
7	Informed Consent Form: In Local Language		
8	Investigator's Brochure (Only Applicable to Drug Trials)		
9	Subject Recruitment Materials: In English		
10	Subject Recruitment Materials: In Local Language		
11	Details of remuneration to the participants		
12	Details of the research grant		
13	CVs of PI and Co-Investigators		

E. Participant Related Information

	Does your study involve any of the following	**Yes**	**No**
1	Research involving pregnant women or the human fetus		
2	Participants unable to give consent due to high dependency on medical care		
3	Participants with a cognitive impairment or mental illness		
4	Participants involved in illegal activities		
5	Use of invasive Interventions / Therapies		
6	Human Genetics / stem cells related research		
7	Projects involving ionizing radiations		

8	Projects involving active concealment or planned deception of participants		
9	Collection of identifiable personal information, without permission from the person identified.		
10	Risk of harm to participants (More than discomfort)		
11	Participants unable to give consent due to language difficulties		
12	Are there any risk to the researchers (e.g. unsafe environment, trouble spots)		
13	Are there any other risks not covered in the above assessment that you consider maybe relevant		

F. If your answer is 'yes' to any items on the checklist E, you may comment any additional information related to Ethical consideration in following text box.

G. Vulnerable Populations

	Does the research specifically target participants from any of the following groups?	**Yes**	**No**
1	Children under age of 18 years		
2	Participants with physical disability		
3	Participants whose ability to give consent is impaired		
4	Residents of custodian institutions		
5	Participants with dependent relationship with the researchers (e.g. teacher-student, doctor-patient, professional-client)		
6	Research involving sensitive cultural issues		

H. If your answer is 'yes' to any items on the checklist G, you may comment any additional information related to Ethical consideration in following text box.

I. Declaration of Categorization of the Research Proposal for Ethics Review:

The following document is prepared as per ICMR guideline for reference of the researcher so that the categorization of the proposal is made at the level of researcher. It is provisional categorization declared by researcher, subsequently it will be discussed in the EC meeting and recommendation/ approval or suggestions will be given by Ethics Committee.

Sr. No.	Type of Review for the proposal submitted		Yes/No/Not Applicable
1.	**Exemption from review**	**Proposals with less than minimal risk where there are no linked identifiers, for example;**	
		Research conducted on data available in the public domain for systematic reviews or meta-analyses	
		Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;	
		Quality control and quality assurance audits in the institution;	
		Comparison of instructional techniques, curricula, or classroom management methods	
		Consumer acceptance studies related to taste and food quality; and	
		Public health programmes by Govt agencies, such as programme evaluation, where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).	
2.	**Expedited review**	**Proposals that pose no more than minimal risk may undergo expedited review, for example**	
		Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;	
		Research involving clinical documentation materials that are non-identifiable (data, documents, records);	
		modification or amendment to an approved protocol, including administrative changes or correction of typographical errors and a change in researcher(s);	
		revised proposals previously approved through expedited review, full review or continuing review of approved proposals;	
		minor deviations from the originally approved research causing no risk or minimal risk;	
		Progress/annual reports where there is no additional risk, for example, activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by the SAE subcommittee; and	

		For multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site-specific requirements in addition to the full committee common review.	
		Research during emergencies and disasters (See Section 12 for further details).	
3	**Full committee review**	**All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are;**	
		Research involving vulnerable populations, even if the risk is minimal;	
		Research with minor increase over minimal risk (see Table 2.1 for further details);	
		Studies involving deception of participants (see section 5.11 for further details);	
		Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;	
		Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk;	
		Major deviations and violations in the protocol;	
		Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment;	
		Research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need;	
		Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.	

J. Elements of an informed consent document

The consent form can be created with the help of National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, ICMR (2017) and New Drugs and Clinical Trials Rules (2019).

As per ICMR guidelines (2017), an informed consent form must include the following:

1. Statement mentioning that it is research
2. Purpose and methods of the research in simple language
3. Expected duration of the participation and frequency of contact with estimated number of participants to be enrolled, types of data collection and methods
4. Benefits to the participant, community or others that might reasonably be expected as an outcome of research
5. Any foreseeable risks, discomfort or inconvenience to the participant resulting from participation in the study
6. Extent to which confidentiality of records could be maintained, such as the limits to which the researcher would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality
7. Payment/reimbursement for participation and incidental expenses depending on the type of study
8. Free treatment and/or compensation of participants for research-related injury and/ or harm
9. Freedom of the individual to participate and/or withdraw from research at any time without penalty or loss of benefits to which the participant would otherwise be entitled
10. The identity of the research team and contact persons with addresses and phone numbers (for example, PI/Co PI for queries related to the research and Chairperson/Member Secretary/ or helpline for appeal against violations of ethical principles and human rights)

K. Key Terms:

1. **Deception in human subject research** means deliberately misleading subjects about the nature of a study.

2. **Concealment** means deliberately withholding certain information. Studies involving deception or concealment must meet all criteria for a waiver or alteration of informed consent.

3. **IRC / RAC approval** means technical approval of the study at the level of institute or the University (in case of Ph D students) respectively.

4. **Trouble Spots** means areas where researcher might find it unsafe due to happenings in the field for example areas prevalent with highly infectious diseases, disaster prone areas.

L. Declarations:

1. I/we declare that the information filled in this form is complete and correct.
2. I/we confirm that the study will be conducted in accordance with all applicable statutory guidelines and regulations.

Signature of the Principal Investigator

Date: