A REVIEW FORM TEMPLATE

Meeting Date		**Review number**	
Project Title			
Applicant Name			

A. CONFLICT OF INTEREST STATEMENT

☐ I declare that I have no financial or other involvement or relationship with persons involved in this research project, which may negatively influence my ability to carry out an objective review of this study.

☐ I declare financial or other competing interests with respect to this project, which may present a potential conflict of interest.

Name of Reviewer; _____

Signature_____

Date_____

	Yes	No	Comments
1. Social and Scientific Value			
Does the research have any social value to the community?			
Does the research have any scientific value?			
2. Scientific Validity			
Is the literature review recent and adequate?			
Are the aims and objectives clearly specified?			
Is there appropriate justification for this study?			
Is the study design clear and appropriate?			
Do the principal and co-investigators have appropriate academic and clinical credentials and experience to conduct this study?			
Is there detailed explanation of the study procedures?			
Is there a clear distinction between research procedures and standard clinical practice and/or standard care			
Are the proposed tests/measurements appropriate, valid and reliable to answer the study question in the local context?			
Are the plans for data and statistical analysis defined and justified			
1. **Selection of participants**			

Is the choice of participants appropriate for the study question?			
Does the study exclude a particular group?			
Is the number of participant justified (sample size calculation)?			
Are inclusion and exclusion criteria clearly stated and reasonable?			
Does the study include any vulnerable groups?			
Can the study be conducted without involving vulnerable populations?			
Is the inclusion of the vulnerable groups adequately justified?			
Are adequate safeguards in place to protect the rights and welfare of these vulnerable groups?			
2. **Subjects Recruitment**			
Are the methods of subject's recruitment clearly explained**?**			
Is the locations and setting for recruitment acceptable?			
Do recruitment procedures involve any coercion to research subjects?			
Is there any screening procedure prior to recruitment ?			
3. **Risks and Benefits**			
Are the risks Identified: □ Physical □ Social			

□ Psychological □ Economical □ Legal			
Are there any measures to minimize risks of harm to individuals or communities?			
Are the benefits identified?			
Is there any direct benefit to research participants?			
Is there any measures to minimize Physical risks			
Are risks reasonable in relation to anticipated benefits?			
4. **Clinical Trials**			
Does the study needs approval by the NMPB?			
Is there a placebo group?			
Is the use of a placebo group justified?			
Is there clear explanation of trial monitoring including the involvement of a DSM?			
Is the DSM approved to monitor the trial?			
5. **Compensations**			
Is the amount of compensation appropriate?			
Does the amount of compensation undue inducement?			
6. **Privacy and confidentiality**			
Are there adequate measures to protect the privacy of the research subjects?			
Will there be any type of recordings?			

In case of recordings is there adequate explanation of how these will be protected?			
For focus groups, are participants informed that confidentiality cannot be guaranteed?			
Is there an explanation of procedures to protect the confidentiality of the data obtained?			
7. **The Informed Consent Process**			
Is the process adequately described?			
Has a waiver of informed consent or waiver of documentation of informed consent been requested and adequately justified?			
Does the informed consent include the basic requirements?			
Does the process provide sufficient time, privacy and adequate settings for the research participants to make an informed decision?			
Is the language of the consent acceptable?			
Are any potential participants be in a dependent relationship with the researcher/recruiter?			
Has the researcher taken steps to ensure that the participant's decision to enroll will not be inappropriately influenced by this relationship?			
Is there a clear description of plans to inform participants of specific research results e.g. Incidental findings, clinically relevant findings			
8. **Community participation**			
Is the community involved in the planning and implementation of the study?			

Are post trial benefits explained?			
How will communities and participants be informed of significant findings?			
Are there plans to disseminate the results of the study?			
9. Others			
Are the researchers trained in human subject's protection?			

OTHERCOMMENTS

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RECOMMENDATIONS:

- □ APPROVED
- □ APPROVED WITH CLARIFICATIONS
- □ APPROVED AFTER MODIFICATIONS
- □ DEFERRED
- □ DISAPPROVED