Self-Assessment Checklist-II

A. PROPOSAL (SCIENTIFIC AND TECHNICAL ISSUES)	YES	NO	NA
1. Is the rationale for the study clearly stated in the context of present knowledge?			
2. Is the hypothesis to be tested fully explained?			
3. Is the project design scientifically sound?			
4. Where present, is the control arm adequate?			
5. Are the inclusion and exclusion criteria complete and appropriate?			
6. Are the types and methods for subject allocation appropriate?			
7. Are the procedures for participant recruitment, admission, follow up and completion appropriate?			
8. Are the drugs and/or devices to be used fully described?			
9. Are the clinical procedures to be carried out fully described and appropriate?			
10. Are the laboratory tests and other diagnostic procedures fully described and appropriate?			
11. Is the statistical basis for the study design appropriate and is the plan for analysis of the data appropriate?			
12. Is the study appropriately powered to answer the research question?			
13. Is the plan for statistical analysis of the data appropriate?			
B. PROPOSAL (ETHICAL ISSUES)	**YES**	**NO**	**NA**
1. Is a vulnerable population being studied?			
If yes, tick the vulnerable population being studied: ☐ Pregnant women ☐ Adolescents ☐ Children ☐ Elderly ☐ Refugees ☐ Prisoners ☐ Those who can't give consent (unconscious) ☐ Persons ☐ Those with mental or behavioural disorders ☐ Others			
2. Have the risks vs. the benefits for the research participants been discussed in the research protocol?			
3. Does the protocol describe how (if at all) the communities from which the participants			
4. are to be drawn likely to benefit from the research?			
5. Does the protocol describe whether the research outcome is likely to benefit communities beyond the research population?			
6. Is the design free of undue inducements to participate in the research?			
7. Does the recruitment procedure include adequate protection for the privacy and psychosocial needs of the individuals?			
8. Have adequate provisions been made to ensure the confidentiality of participants' data?			
9. Are the research participants free not to participate or to leave the research at any time, without penalty?			
10. When appropriate, do provisions exist in the protocol for counselling research participants during and after the research?			
11. Do provisions exist in the proposals to deal with adverse reactions associated with the research (medical/ physical/ emotional/ psychological)?			

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