Reviewer Checklist-

Title : ……

Applicant name : ……

Code number : ……

Date of review : ……

	YES	NO	N/A
Is the title concise and informative?			
Does the introduction discuss the domain of the problem?			
Does the introduction discuss the boundaries of the problem?			
Is the research gap explained?			
Is the hypothesis stated?			
Are the objectives well defined and achievable?			
Is the study design stated & scientifically sound?			
Are the inclusion and exclusion criteria complete and appropriate?			
Is the locality of the study mentioned?			
Is the duration of the study mentioned?			
Are the types and methods for subject allocation appropriate?			
Are the procedures for participant recruitment, admission, follow up and completion appropriate?			
Do the measures collected relate specifically to the purpose?			
Are the drugs and/or devices to be used fully described?			
Are the clinical procedures to be carried out fully described and appropriate?			
Are the laboratory tests and other diagnostic procedures fully described and appropriate?			
Is the statistical basis for the study design appropriate?			
Are references updated and appropriate?			

Ethical considerations:

Is a vulnerable population being studied? If yes, tick the vulnerable population being studied:

☐ Pregnant women ☐ Adolescent ☐ Children ☐ Elderly

☐ Those who can't give consent (unconscious)

☐ Those with mental or behavioural disorders

☐ Others

Risk assessment:

☐ Minimal risk* ☐ Greater than minimal risk

What type of risks if any is present

☐ Psychological ☐ Physical ☐ Economic

☐ Breech of confidentiality ☐ Loss of benefits

Others……...

……..

Potential Benefits

☐ Generalised knowledge ☐ Improve treatment or system

☐ Decrease existing risk or hazard ☐ Reduce costs

Others ……

……

	YES	NO	N/A
Is the justification for studying this vulnerable population adequate?			
Have adequate provisions been made to ensure the confidentiality of participants' data?			
Are the research participants free not to participate or to leave the research at any time, without penalty?			

***Minimal risk:** where the probability and magnitude of harm anticipated, by using procedures which are consistent with sound research design, are not great, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. **For example,** the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

Study Design:

Type of the study

Please tick the relevant item

Observational:

- ☐ Case series
- ☐ Cross sectional
- ☐ Retrospective
- ☐ Cohort
  - ⬭ Controlled (case- control)
  - ⬭ Noncontrolled
    - ☐ Others (Specify) ……..……

Interventional

- ☐ Human ☐ Randomized ☐ Controlled ☐ Cross-over
- ☐ Animal ☐ Nonrandomized ☐ Non-controlled
  - ☐ Others (Specify) ……..……

For randomized controlled trials (RCT)

Calculation of sample size : ☐ Present ☐ Absent

CONSORT flowchart : ☐ Present ☐ Absent

Masking

- ☐ Open table
- ☐ Blind
- ☐ Double blind

For pharmaceutical studies:

- ☐ Phase I: Animals, volunteers
- ☐ Phase II: Pilot
- ☐ Phase III: Randomized controlled trial (RCT)
- ☐ Phase IV: Post marketing

Other comments:

Kindly tick a mark, if yes:

1- The study needs in depth statistical review (Board decision) ☐

2- The study needs further in depth Ethical review (Board decision) ☐

3- In case you recommend some modifications to the protocol, would you like to check them after the candidate adds them? ☐

Decision:

☐ Accepted ☐ Major modifications required ☐ Minor modifications required ☐ Denied

Date / / /