Review Sheet

Institutional Review Board (IRB)
Bangladesh Medical University

[Use the review sheet to review the research protocol. Give your valuable comments]

Title of the project: .....

.....

Follow the following guidelines to prepare written comments on research protocol / projects.

01. Description (Comments on research question, hypothesis, objective, procedures and background; as appropriate to clear the protocol).

a) Background information (Does the protocol / project provide thorough understanding about the state of knowledge of the field of interest?)

Comments:

b) Research question & / or hypothesis: Are these correctly stated?

Comments:

c) Rationale: Is it clearly stated and supported by the background information?

Comments:

d) Study design: Is it correctly stated? ❑Yes ❑No

- ❑ Case Control Study
- ❑ Randomized Controlled trial
- ❑ Clinical Trial (Phase I, II, III, IV)
- ❑ Community Based Trial
- ❑ Cross Sectional
- ❑ Cohort Study (Prospective and retrospective)
- ❑ Health Programme Evaluation/ Quality Improvement
- ❑ Systemic Review
- ❑ Pilot/Feasibility Study
- ❑ Registry-Based Studies
- ❑ Curriculum Evaluation Study
- ❑ Teaching Methodologies Study
- ❑ Interventional studies (non-clinical trials): behaviour, educational, psychological, lifestyle modifications
- ❑ Longitudinal study
- ❑ Observation Clinical Study
- ❑ Meta-Analysis and systemic Reviews
- ❑ Secondary Data Analysis
- ❑ Surveillance /Monitoring
- ❑ Mixed methods research combining qualitative and quantitative
- ❑ Outbreak investigation
- ❑ Risk factor analysis
- ❑ Retrospective Chart Reviews
- ❑Use of existing Databases
- ❑ Medical wearables and Sensors Study
- ❑ Investigational Device Exemption (IDE) Study
- ❑ Others……..

e) Proposed Sample size and sampling: Is it justified and appropriate?

Total Sample Size:

f) Confounding variable(s): Has provision been made to control confounders?

Comments:

g) Outcome variable (data generated): Can it answer research question?

Comments:

02. Facilities required: Is it adequately presented? Are the requirements justified by research plan?

Comments:

03. Research subject

- ❑ Human
- ❑ Animal
- ❑ Microorganism
- ❑ Other (specify): _____

Special Group:

Pregnant Women	❑Yes ❑No ❑Not applicable
Fetuses	❑Yes ❑No ❑Not applicable
Prisoners	❑Yes ❑No ❑Not applicable
Service Providers	❑Yes ❑No ❑Not applicable
Cognitively Impaired	❑Yes ❑No ❑Not applicable
Immigrants	❑Yes ❑No ❑Not applicable
Refugee	❑Yes ❑No ❑Not applicable
Others (specify):	

04. Comments on consent form
Does the consent form clearly describe all the issues to the participant?

Process

- ❑ Written
- ❑ Oral
- ❑ Audio
- ❑ Video
- ❑ Picture Permission
- ❑ None

a) Will there be any legally authorized representative (LAR)?	❑ Yes	❑ No	❑ NA
b) Will there be an impartial witness (If the participant is illiterate)?	❑ Yes	❑ No	❑ NA
c) In order to participate in research with children, is assent being taken?	❑ Yes	❑ No	❑ NA
d) For research involving pregnant woman, consideration of risks with potential benefit for the fetus and pregnant women has been properly addressed?	❑ Yes	❑ No	❑ NA

05. MOU / letter of consent from supportive department / Institute / Organization: As needed
Collaborating Institute/ Department

Submitted:

❑ Yes	❑ No

06. Determination of Risk

a) Human exposure to radioactive agents/ infectious agents/foetal tissue/abortus	❑Yes ❑No ❑Not applicable
b) Investigational new drug use	❑Yes ❑No ❑Not applicable
c) New treatment regimen pathological/ diagnostic clinical specimen only	❑Yes ❑No ❑Not applicable
d) Pathological or diagnostic clinical specimen only?	❑Yes ❑No ❑Not applicable
Others	❑Yes ❑No ❑Not applicable

07. Does the research deal with sensitive aspect of study participants?

a) Sexual behavior	❑Yes ❑No ❑Not applicable
b) Alcohol abuse	❑Yes ❑No ❑Not applicable
c) Drug abuse	❑Yes ❑No ❑Not applicable
Others	❑Yes ❑No ❑Not applicable

08. Biological Specimen:

a) Will the biological specimen be stored for future use?	❑Yes ❑No ❑Not applicable
d) Will the consent be obtained from the study participants for use of the preserved specimen for other initiative(s) unrelated to this study, without their re-consent?	❑Yes ❑No ❑Not applicable
e) Will the specimens be shipped to other country/countries?	❑Yes ❑No ❑Not applicable
f) Does the study involve any biohazardous materials/ agents or microorganism?	❑Yes ❑No ❑Not applicable
j) Has a MoU been signed with regards to collection, storage, use and ownership of specimen? If the response is 'yes', is a copy of the MoU attached? If the response is 'no', appropriate justification should be provided for not signing a MoU.	❑Yes ❑No ❑Not applicable

19. Plagiarism:

a) Suspected plagiarism?	❑ Yes	❑ No
b) Prefer to check plagiarism?	❑ Yes	❑ No

10. Do you consider the research?

a) Minimal risk	❑Yes ❑No ❑Not applicable
b) No more than minimal risk	❑Yes ❑No ❑Not applicable
c) Greater than minimal risk	❑Yes ❑No ❑Not applicable

11. Budget: Is it justified? Is it inflated?

Funding:

Is the protocol fully funded?	❑ Yes	❑ No
If the answer is yes, provided sponsor(s)'s name	❑ Yes	❑ No
Is the proposal being submitted for funding?	❑ Yes	❑ No
If the answer is yes, provided sponsor(s)'s name	❑ Yes	❑ No

Conflict of interest: Does the researcher declare any conflict of interest?	
❑ No	❑ Yes

13. Anticipated Impact of Research

❑ Knowledge

❑ Capacity building

❑ Information Policy

❑ Health Sector Benefit

❑ Economic Benefit

14. Conclusion

❑ The project is acceptable

❑ The project is not acceptable

❑ The project is acceptable after proposed modification

❑ The project is not ethically acceptable

Signature of the Reviewer

Seal, Name & Designation