Annexure IV

Check-List For Review Of Research Proposals
INSTITUTIONAL ETHICS COMMITTEE
HM PATEL CENTER FOR MEDICAL CARE AND EDUCATION, KARAMSAD

1. Purpose and Background

a) Is the research question clearly stated?
b) Is suitable justification for the study with human?

Comments:

2. Social and Scientific Value

Will the research generate knowledge that could reasonably lead to improvements in health or well-being?

Comments:

3. Participant Population (s)

a) Are criteria for inclusion/ exclusion?
b) Does the study include vulnerable participants? (Circle) Minors – Pregnant women Prisoners – Foetuses - Mentally Disabled individuals - Economically or educationally disadvantaged persons?
c) Is the justification for using vulnerable participants clearly stated?
d) Are additional safeguards in place to protect vulnerable participants?

Comments:

4. Participant Recruitment

a) Do you have any concerns about inappropriate inducement?
b) Does the recruitment process violate participant's privacy in any way?

Comments**:**

(Bibliography: ICMR Ethical Guidelines & St Joseph's Healthcare, Hamilton, Fogarty International, NIH, USA)

5. Methodology / Data Description

a) Is the methodology/design described in sufficient detail?
b) Is the methodology / design adequate to answer the research question?
c) Is the data analysis adequately described?
d) Is the data analysis appropriate?
e) For Phase III trials, is genuine null hypotheses present (clinical equipoise)?

Comments**:**

6. Placebo Controls in Phase III Trials:

Is a placebo control ethically justified in this trial?

Comments**:**

7. Protocol risk / Benefit Assessment

a) Are activities involving more than minimum risk adequately described?
b) Are risks to participants minimized?
i) By sound research design?

ii) By using procedures already being performed for diagnostic or treatment purposes?

c) Are risks to participants reasonable in relation to

i) Anticipated benefits to participants?

ii) The importance of the knowledge that may reasonably be expected to result?

d) Are there adequate procedures for monitoring the safety of the research participants?

e) Are there appropriate stopping rules?

f) Is an annual report to the IEC adequate to monitor the safety of the research participants?

g) Are adequate provisions made to protect the privacy of participants and to maintain the confidentiality of the data?

Comments**:**

8. Information Sheet and Consent Form – General Requirements:

a) Are information/consent documents appropriately headed and printed in large enough type?
b) Are information / consent documents free of unexplained technical terms and jargon?
c) Are information/consent documents free of language that waives the participant's legal right, or that releases the investigator, institution, or sponsor from liability?
d) Is the information sheet written consistently in the second person (you / your)?
e) Is the name of the study sponsor on the front page?

Comments**:**