

**Check-List for Review of Research Proposals**  
**INSTITUTIONAL ETHICS COMMITTEE**  
**HM PATEL CENTER FOR MEDICAL CARE AND EDUCATION, KARAMSAD**

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### **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?

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**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?

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- 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: