Checklist [s]
INSTITUTIONAL ETHICS COMMITTEE
HM PATEL CENTER FOR MEDICAL CARE AND EDUCATION, KARAMSAD

Faculty proposal checklist [Full Committee/ Exempt/ Case report/ Case Series]

- ☐ Project submission form [bearing signatures of all investigators as well as HOD [s]] for all academic (non-sponsored) studies duly filled ***[Annexure 4/ 6]***
- ☐ Application form for requesting waiver of consent *[if applicable]*
- ☐ Log of delegation of responsibility of the study team members
- ☐ Protocol ***[Annexure 4.1/ 6.1]***
- ☐ Informed consent document in English (includes both PIS and ICF) ***[Annexure 4.2, 4.4/ 6.2]***
- ☐ Informed consent documents in Regional languages(Hindi, Gujarati, etc.) ***[Annexure 4.3, 4.5/ 6.3]***
- ☐ Case Record Form/ Proforma
- ☐ Questionnaire *[if applicable]*
- ☐ Scales *[if applicable]*
- ☐ Research participants recruitment procedures: advertisement, notices *[if applicable]*
- ☐ Memorandum of Understanding (as applicable, for collaborators from outside) *[if applicable]*
- ☐ Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions / foreign agencies (one copy) *[if applicable]*
- ☐ Administrative sanction from the Head of the Institution for the samples to be sent to outside host institution (one copy) *[if applicable]*
- ☐ Ethics Committee clearance of other centers *[if applicable]*
- ☐ Declaration for vulnerable participants for research involving children *[if applicable]*
- ☐ Declaration for vulnerable participants for research involving pregnant women & fetuses *[if applicable]*
- ☐ Declaration for vulnerable participants for research involving cognitively impaired adults *[if applicable]*
- ☐ Declaration for vulnerable participants for research involving students, employees or residents *[if applicable]*
- ☐ Any other Documents submitted

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Clinical trial checklist

- ☐ Project submission application form for initial review for industry and government sponsored studies duly filled [bearing signatures of all investigators as well as HOD [s]] ***[Annexure 5]***
- ☐ Log of delegation of responsibility of the study team members
- ☐ Summary of protocol (in not more than 500 words)
- ☐ Protocol
- ☐ Informed consent document in English (Includes both PIS and ICF)
- ☐ Informed consent documents in Regional languages(Hindi, Gujarati etc.)
- ☐ Case Record Form
- ☐ Investigator Brochure
- ☐ Insurance entire policy
- ☐ Insurance certificate
- ☐ Investigator's undertaking to DCG(I)
- ☐ Clinical Trial Agreement for drug trial / Memorandum Of Understanding, as applicable, for collaborator & Govt. sponsored trials (draft if final not ready)
- ☐ Current Status of Ongoing Studies approved by IEC and conducted by principal investigator (information may be submitted separately)
- ☐ Back translation of Informed Consent Documents
- ☐ Translation and Back translation certificates (ICDs)
- ☐ Audio Visual Consent Form in English (if using vulnerable group)
- ☐ Audio Visual Consent Form in regional languages (Hindi, Gujarati etc. (if using vulnerable group))
- ☐ Translation and Back translation certificates (Audio visual consent)
- ☐ Research participants recruitment procedures: advertisement, notices *[if applicable]*
- ☐ Patient instruction card, identity card, diary etc.
- ☐ Research participants Questionnaire/s *[if applicable]*
- ☐ DCG(I) approval letter
- ☐ If DCGI approval letter is awaited, upload the application letter to DCGI
- ☐ FDA marketing/manufacturing license for herbal formulations/ nutraceuticals
- ☐ Bhabha Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ ionizing radiations
- ☐ Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy
- ☐ Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions / foreign agencies (one copy)
- ☐ Administrative sanction from the Head of the Institution for the samples to be sent to outside host

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institution (one copy)

- ☐ Ethics Committee clearance of other centers (Total No _____)
- ☐ Documentation of CTRI registration/ any other WHO platform registry (whenever applicable)
- ☐ Declaration for vulnerable participants for research involving children *[if applicable]*
- ☐ Declaration for vulnerable participants for research involving pregnant women & fetuses *[if applicable]*
- ☐ Declaration for vulnerable participants for research involving cognitively impaired adults *[if applicable]*
- ☐ Declaration for vulnerable participants for research involving students, employees or residents *[if applicable]*
- ☐ Checklist - Considerations for Genetic Research
- ☐ Any other Documents submitted

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Clinical Trial Checklist [Amendment]

- ☐ Covering letter to Member Secretary
  (A covering letter should be submitted mentioning reason/s for amendments, summary of changes and the amended text must be highlighted in the amended Documents)
- ☐ Protocol amendment request and assessment form ***[applicable columns of Annexure 5]***
- ☐ Amended Documents (amendment must be highlighted)
- ☐ Amended Protocol
- ☐ Amended Informed consent document in English *[if applicable]*
- ☐ Amended Informed consent documents in Regional languages in Hindi, Marathi, Gujarati *[if applicable]*
- ☐ Amended Case Record Form *[if applicable]*
- ☐ Amended Investigator Brochure *[if applicable]*
- ☐ Amended / Renewed Insurance certificate *[if applicable]*
- ☐ Amended Investigator's undertaking to DCG(I) *[if applicable]*
- ☐ Amended Clinical Trial Agreement for drug trial / Memorandum Of Understanding, as applicable, for collaborator & Govt. sponsored trials (draft if final not ready) *[if applicable]*

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INFORMED CONSENT [As per Schedule Y, Appendix V]

1.1 Essential Elements:

1. Statement that the study involves research and explanation of the purpose of the research
2. Expected duration of the subject's participation
3. Description of the procedures to be followed, including all invasive procedures and
4. Description of any reasonably foreseeable risks or discomforts to the subject
5. Description of any benefits to the subject or others reasonably expected from research. If no benefit is expected subject should be made aware of this.
6. Disclosure of specific appropriate alternative procedures or therapies available to the subject.
7. Statement describing the extent to which confidentiality of records identifying the subject will be maintained and who will have access to subject's medical records
8. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)
9. Compensation and/or treatment(s) available to the subject in the event of a trial-related injury
10. An explanation about whom to contact for trial related queries, rights of subjects and in the event of any injury
11. The anticipated prorated payment, if any, to the subject for participating in the trial
12. subject's responsibilities on participation in the trial
13. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled
14. Statement that there is a possibility of failure of IP to provide intended therapeutic effect
15. Statement that in case of placebo controlled trials, the placebo administered to the subjects shall not have any therapeutic effect
16. Any other pertinent information

1.2 Additional elements, which may be required:

a. Statement of foreseeable circumstances under which the subject's participation may be terminated by the Investigator without the subject's consent.

b. Additional costs to the subject that may result from participation in the study.

c. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by subject.

d. Statement that the subject or subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the subject's willingness to continue participation will be provided.

e. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable

f. Approximate number of subjects enrolled in the study

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RESEARCH PROPOSAL

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

1. Purpose and Background

Is the research question clearly stated?

Is suitable justification for the study with human?

2. Social and Scientific Value

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

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?

4. Participant Recruitment

17. Do you have any concerns about inappropriate inducement?
18. Does the recruitment process violate participant's privacy in any way?

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)?

6. Placebo Controls in Phase III Trials:

Is a placebo control ethically justified in this trial?

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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?

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?