Project Submission Checklist [s] for Investigators
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

Annexure 7

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

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

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

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

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

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]*