

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

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**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]*