

Application Procedure:

Principle Investigator (PI) should submit his/her research/dissertation proposal only in soft copy by email to irb_gmcb@yahoo.com. [Two zip folders as attachment]

During submission of proposal, the investigator has to create two different folders with the name

1. PI name_Department_SRC
2. PI name_Department_IRB.

Each folder should have following documents:

1. PI name_Department_SRC: (E.g. KDBhalani_PSM_SRC)

1. IRB form (Latest version)
2. Study Proposal in MS Word format (In the prescribed attached format)
3. Power point presentation in MS power point format (Max 10 slides; Font size 28 - Title, Introduction (1 slide), Aims/Objectives, Methods in detail, Dummy Tables - with title of the table and also of each row and column)
4. Case Record Form/ Study questionnaire in MS Word format
5. Patient Information Sheet & Informed Consent Form in MS Word format (English & Gujarati)
6. Scanned/downloaded copies of relevant/cited articles in PDF format
7. Investigator's brochure (For regulatory trial)

2. PI name_Department_IRB: (E.g. KDBhalani_PSM_IRB)

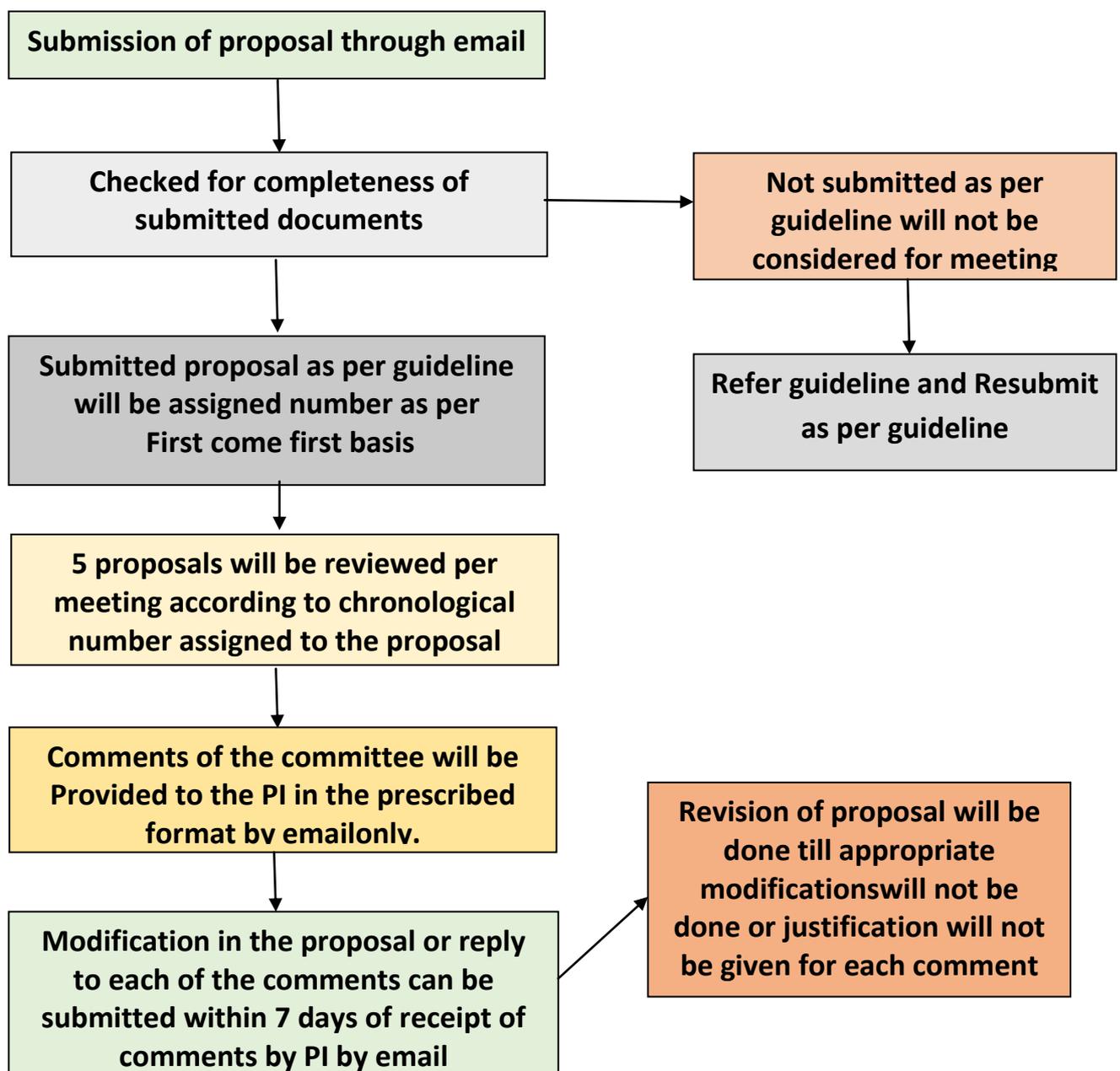
1. CV of all investigators in PDF
2. GCP training certificates in PDF
3. Medical Registration certificates in PDF
4. CTRI Reference number copy in PDF
5. Departmental Scientific Discussion attendance sheet (Scanned PDF copy)
6. DCGI approval letter (For regulatory trial)
7. Copy of insurance policy (For regulatory trial)
8. Clinical trial agreement draft copy (For Regulatory trial)
9. Participant diary (For regulatory trial)

1. Submission will be considered valid only when all the required documents will be sent in two separate zip folders (as mentioned earlier) as attachments of a single email.

2. Submission will be completely ignored in following scenario. Not even receipt or acknowledgement number will be provided for such submissions. They will not be lined up for the review till the complete proposal is submitted.

- Incomplete proposal with inadequate documents in the email
- Required documents sent by multiple mails
- Proposal sent from any other email ID than the email of PI (which is to mentioned in the proposal form.)

3. Email with the proposal and all the further communication related to the proposal will have to be sent from the email id of PI (as mentioned in the IRB form and Proposal form.) and all the communications from the review committee will be sent to the same email ID. Emails received from any other email IDs will be ignored and will not be processed.





Once everything will be “OK”, an email will be sent to the PI informing about the same and asking for submission of the

Final approved proposal for IRB review. The proposal with all the comments of the scientific review committee and the compliance thereon with **all the above mentioned final documents** in hardcopy (Signed and dated) is to be submitted to the Institutional Review Board, Government Medical College, Bhavnagar for final ethical approval **through proper channel with cover letter**.