**Government Medical College, Surat**

**Clinical Trial Protocol Format**

**Title Page**

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| 1. Full Title of Clinical Trial: |  |
| 2.1 Name & signature of the candidate 2.2 Department2.3 Degree/course2.4 Batch of admission to course2.5 Month & year of submission of thesis2.6 Email ID of the Candidate 2.7 Email ID of the Chief Guide2.8 Mobile No. of the Candidate2.9 Mobile No. of the Chief Guide  | 2.1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_2.2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_2.3 MBBS /MD/ MS /MCh/ DM/ Ph.D. (encircle)2.4 \_\_\_\_\_\_\_\_ (year)2.5 May/November \_\_\_\_\_\_\_\_(year)2.6 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_2.7 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_2.8 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_2.9 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 3. Name of Faculty & Department  (Guide/Co-guide) 3.1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3.2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 3.3 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   | Signatures (Guide/Co-Guides)3.1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_3.2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_3.3 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Clinical Trial Protocol Format - Main Protocol**

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| Full Title of Study: |  |
| 4. Goal & Objectives: | 4.1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_4.2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_4.3 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_4.4 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 5. Why this study is required? Please provide brief justification with brief Review of Literature |  |
| 6. Methodology6.1 Study Design:6.2 Sample Size with calculation: 6.3 Inclusion criteria:6.4 Exclusion criteria6.5 Control(s):6.6 Outcome parameters:6.7 Assessment tools/ scales:6.8 Permission to use copyrighted tools/ questionnaire/scales6.9 Intervention if any (Dosages of drug, Duration of treatment, Operative procedure etc)6.10 Investigations specifically related to research protocol6.11 Brief Methodology6.12 Follow up plan 6.13 Flow Chart6.14 Statistical Analysis Plan6.15 Dissemination Plan6.16 References (minimum 2 relevant National & International) | a)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_b)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_c)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_d)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_a)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_b)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_c)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_d)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Clinical Trial Protocol Format - Ethics related**

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| 7.1 Permission from Medical Superintendent | 1. Required 2. Not required3. Received 4. Applied when:  |
| 7.2 Permission from Drug Controller  General of India (DCGI) | 1. Required 2. Not required3. Received 4. Applied when: |
| 7.3 Permission from Collaborators (if any) | 1. Required 2. Not required3. Received 4. Applied when: |
| 7.4 Permission from resource site | 1. Required 2. Not required3. Received 4. Applied when: |
| 8. Do you plan to withdraw the standard therapy during the research period? |  Yes NoRemarks:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 9. How will you maintain Confidentiality of subject? |  |
| 10. **Costs Involved (Appx. in Rs.)**10.1 Investigations10.2 Disposables10.3 Implants 10.4 Drugs / Contrast Media10.5 Any other**Who will bear the costs of the requirements?** *(mark √ )* | 10.1\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_10.2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_10.3\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_10.4\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_10.5­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_1. Patient 2. Student 3. Exempted 4. Other Agencies (Name)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |
| 11.1 Participant Information Sheet (PIS) - English *(mark √ if yes)* | 1. Required 2. Not required3. Attached  |
| 11.2 Participant Information Sheet (PIS) - Hindi *(mark √ if yes)* | 1. Required 2. Not required3. Attached 4. True Translation of English |
| 11.3 Participant Information Sheet (PIS) - Gujarati *(mark √ if yes)* | 1. Required 2. Not required3. Attached 4. True Translation of English |
| 12.1 Participant Informed Consent Form (PICF) - English *(mark √ if yes)* | 1. Required 2. Not required3. Attached  |
| 12.2 Participant Informed Consent Form (PICF) - Hindi *(mark √ if yes)* | 1. Required 2. Not required3. Attached 4. True Translation of English |
| 12.3 Participant Informed Consent Form (PICF) - Gujarati *(mark √ if yes)* | 1. Required 2. Not required3. Attached 4. True Translation of English |
| 13. Any Conflict of Interest can be revealed here. |  *Yes No (If Yes, Please give details).* |