**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 Department  2.3 Degree/course  2.4 Batch of admission to course  2.5 Month & year of submission of thesis  2.6 Email ID of the Candidate  2.7 Email ID of the Chief Guide  2.8 Mobile No. of the Candidate  2.9 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. Methodology  6.1 Study Design:  6.2 Sample Size with calculation:  6.3 Inclusion criteria:  6.4 Exclusion criteria  6.5 Control(s):  6.6 Outcome parameters:  6.7 Assessment tools/ scales:  6.8 Permission to use copyrighted tools/ questionnaire/scales  6.9 Intervention if any (Dosages of drug, Duration of treatment, Operative procedure etc)  6.10 Investigations specifically related to research protocol  6.11 Brief Methodology  6.12 Follow up plan  6.13 Flow Chart  6.14 Statistical Analysis Plan  6.15 Dissemination Plan  6.16 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 required  3. Received 4. Applied when: |
| 7.2 Permission from Drug Controller  General of India (DCGI) | 1. Required 2. Not required  3. Received 4. Applied when: |
| 7.3 Permission from Collaborators (if any) | 1. Required 2. Not required  3. Received 4. Applied when: |
| 7.4 Permission from resource site | 1. Required 2. Not required  3. Received 4. Applied when: |
| 8. Do you plan to withdraw the standard therapy during the research period? | Yes No  Remarks:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 9. How will you maintain Confidentiality of subject? |  |
| 10. **Costs Involved (Appx. in Rs.)**  10.1 Investigations  10.2 Disposables  10.3 Implants  10.4 Drugs / Contrast Media  10.5 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 required  3. Attached |
| 11.2 Participant Information Sheet (PIS)  - Hindi *(mark √ if yes)* | 1. Required 2. Not required  3. Attached 4. True Translation of English |
| 11.3 Participant Information Sheet (PIS)  - Gujarati *(mark √ if yes)* | 1. Required 2. Not required  3. Attached 4. True Translation of English |
| 12.1 Participant Informed Consent Form (PICF)  - English *(mark √ if yes)* | 1. Required 2. Not required  3. Attached |
| 12.2 Participant Informed Consent Form (PICF)  - Hindi *(mark √ if yes)* | 1. Required 2. Not required  3. Attached 4. True Translation of English |
| 12.3 Participant Informed Consent Form (PICF)  - Gujarati *(mark √ if yes)* | 1. Required 2. Not required  3. Attached 4. True Translation of English |
| 13. Any Conflict of Interest can be revealed here. | *Yes No (If Yes, Please give details).* |