

SOP on Protocol Development

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Written by:	Version: 1.0 dated 04/06/13	Amendment: None
Edited by:	Date of approval:	Valid from:
Approved by:	Appendices: 1	References: None

Glossary

- **CTS:** Clinical Trial Start Up
- **EC:** Ethics Committee
- **GCP:** Good Clinical Practice
- **ICH:** International Conference on Harmonisation
- **ICMR:** Indian Council of Medical Research
- **SOP:** Standard operating procedures

Introduction: The nature and conduct of a study will be described in a clear and detailed protocol. Protocols will be written in accordance with the principles of ICH Good Clinical Practice (GCP), Schedule Y, ICMR Guidelines and will describe the objective(s), design, methodology, statistical considerations and organization of a study. Protocols must be carefully designed to safeguard the health and safety of the participants, as well as answer specific research questions. All protocols must be submitted for approval from the Medanta Institutional Ethics Committee. Any substantial amendments made to the protocol must also be submitted for the required approvals. Amendments cannot be enacted until the required approvals have been obtained from Ethics Committee.

Objective: To describe the process for developing clinical research protocol of Investigator Driven studies at _____ which includes human research participants.

Scope: The SOP will be applicable to all clinical research staff including Investigators, Coordinators involved in the development and production of Clinical research protocol for Investigator driven studies undertaken at _____.

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Processes:

1. All Protocol will be created using the standard draft Template (Appendix 1)
2. All Protocol will have document name as header and document creation date and page number as footer on the document.
3. All documents will be created in English using the Calibri font and left align. Preferred font size is 11 and line spacing is 1.5.
4. Documents will use bold, capital and underlined words for emphasis or as headers. Italics are to be used for scientific names.
5. Investigator will develop a protocol that materially confirms the protocol template. (Protocol template See Appendix 1)
6. Investigator will circulate the draft proposal to designated research staff (E.g. Senior Scientist, Statistician) to ensure the proposed clinical protocol is scientifically, ethically sound and for setting up the objectives of the study, for the design, methodology and statistical consideration for the study which duly meets all applicable regulations and guidelines
7. Investigator will then repeat the review process until all the comments are addressed by the designated research staff.
8. The final draft protocol will be reviewed by all previously designated individuals and the Principal investigator in accordance with the departmental SOPs and policies, once reviewed internally, the investigator will give Protocol number with Controlled version number and date, and the Investigator will sign the final approved protocol.
9. Investigator will submit the final protocol, Informed consent form and all other requisite documents (Refer SOP CTS 202, CTS 203, CTS 204) in accordance with International, local and ethical guidelines to Ethics Committee for its review and approval.
10. Investigator must obtain copy of EC approval and register the approved study in the Clinical Trial Registry of India before the enrollment of first patient.
11. Further Changes made to the protocol and other essential documents, after approval of the original version requires sequential numbering from the original and amendment.
12. Document History

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Version number	Effective date	Reason(s) for change(s):

Appendices:

1. Appendix 1: Standard Draft Template Protocol Development

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1. Abbreviation
2. Study Title
3. Investigating team & Institute
4. Aim
5. Rationale & Background
6. Frequency of Disease
7. Study Objectives
8. Outcome Measures
9. Benefits
10. Risks / Discomforts
11. Study Design
12. Methodology
13. Ethics Committee
14. Confidentiality
15. Data Storage
16. Funding / Financial Implication
17. Publication
18. References