

Research Protocol Submission/Re-Submission Form

1. Proposal ID No. (e.g. 001/01/2015)	
2. Research title (with version no.)	
3. Date of submission	
4. If re-submission, number of re-submission, with date of previous submissions	<p>Resubmission no.</p> <p>Date(s) of previous submission</p>
5. Name of Principal Investigator (PI), with qualification, designation, and department	
6. Name of Co-PI/Co-Investigator(s), with qualification, designation and department	
7. Expected duration of the research	
8. Name of funding agency 8.1 Allocation	
9. Name of institution(s) where research is to be conducted	
10. Has proposal been reviewed and approved by the Scientific Review Board of Samarth?	

10.1 If yes, month and year of approval	
11. Nature of IEC clearance requested (tick)	<ul style="list-style-type: none"> a. Full Board Review b. Expedited Review c. Exempt from Review
12. List of documents enclosed for review (with version number and date)	
13. Research proposal background information (precise yet relevant)	
14. Research proposal main objectives	
15. Hypothesis if any	
16. Research design	
17. If clinical trial, plan to prospectively register in CTRI registry	
18. Data analysis plan	
19. Sample size	
20. Participant recruitment process	
21. Sample inclusion and exclusion criteria	
22. Methodology (in brief; provide references to relevant page in proposal for more details)	
23. Usefulness of the research	
24. Expected 'benefits' to volunteer/community	

25. Explain all anticipated risks of the research (adverse events, injury, discomfort)	
26. Steps to minimize risks	
27. Plans to maintain confidentiality of records/data	
28. Whether compensation for travel and incidental expenses to the research participants are provided?	
29. Describe the Informed Consent Process Mention: written/oral/audio-visual	
30. Special ethical issues as identified by the investigating team (for e.g. vulnerability; storage of biological samples etc)	
31. Disclose Conflict of Interest if any	
32. Plans for publication of results	
33. Signature of Principal Investigator with date	
34. Signature of Co-Investigator (s) with date	