



Check List of Documents for Submission to IRRC MGMDCH

Title of the project:

Sr. No.	Document	Yes	No	NA
1	IRRC MGMDCH application form			
2	Summary of protocol			
3	Protocol (Soft and hard copies along with power point presentation)			
4	Amendments to protocol			
5	Informed consent document in English (If applicable)			
6	Informed consent documents in Regional languages (Total No.:) (If applicable)			
7	Back translations of Informed consent documents (If applicable)			
8	Amendments to the informed consent document (If applicable)			
9	Case Record Form / Questionnaire			
10	Principal investigators Current Curriculum Vitae			
10	Subject recruitment procedures: advertisement, letters to doctors, notices			
11	Investigator Brochure			
12	Ethics Committee clearance of other centres (Total No.)			
13	Auxillary documents like a. Insurance policy, b. Drugs Controller General (India) [DCG(I)] clearance, c. Investigator's agreement with sponsor, d. Investigator's undertaking to DCG(I), e. Health Ministry Screening Committee (HMSC) approval f. Bhabha Atomic Research Centre (BARC) approval g. Genetic Engineering Advisory Committee (GEAC) approval h. Director General of Foreign Trade (DGFT) approval i. FDA marketing/manufacturing license for herbal drugs			
22	Any other related Documents			