

Project Index page Format

A. Project Index Page Format

Project Index Page

Project Title	
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Index

No	Document Name (Please specify in "Page Nos" column NA if not applicable)	Page Nos.	PI Chk	Check (SRS use)
1.	Research Project Format *			
	a. Project Summary *			
	b. Research Protocol Application Format *			
	c. References *			
	d. Patient Information Sheet in 3 languages *			
	e. Patient Informed Consent Form in 3 languages *			
	f. Case Record Form / Questionnaire / Patient Diary *			
2.	Additional Documents (As may be required)			
	a. Investigator Brochure for Sponsored project			
	b. Clinical Trial Agreement			
	c. Insurance Policy with suitable validity			
	d. DCGI Approval Letter for Phase I/ II/ III study			
	e. Investigator's undertaking to DCGI (for Phase I, II, III, studies)			
	f. Ethics Committee Clearance /status- (Multicentric / Multinational study only) Letter from Ethics Committee / Letter from Sponsor for status			
	g. Food and Drug Administration (FDA) marketing/manufacturing license for herbal drugs.			
	h. **Please specify if Clearance of other Bodies as may be required (Sample List enclosed below)			
3.	Project Completion Letter *			

- * Mandatory

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Health Ministry Screening Committee (HMSC) /

- Bhabha Atomic Research Centre (BARC) /

- **Genetic Engineering Advisory Committee (GEAC) /**
- **Director General of Foreign Trade (DGFT)**
- **Etc.**