## Project Index page Format

1. **Project Index Page Format**

**Project Index Page**

|  |  |
| --- | --- |
| **Project Title** |  |

**Index**

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

* \* Mandatory

**\*\***

**Health Ministry Screening Committee (HMSC) /**

* **Bhabha Atomic Research Centre (BARC) /**
* **Genetic Engineering Advisory Committee (GEAC) /**
* **Director General of Foreign Trade (DGFT)**
* **Etc.**