

Self-Assessment Checklist for Participant Information Sheet

Participant Information Sheet (PIS)

- On a separate sheet (avoid writing page number),(in a language that class VIII student understands)
- Enclose in English+ Kannada, Malayalam; AS APPLICABLE
- Do not use google translator for converting to regional languages
- Appropriate language copy of the PIS should be given to study participant
- Investigator will address the subject while writing this sheet

SL. No.	COMPONENTS	
1	Heading: Participant Information Sheet	
2	Study title	
3	Details of all the investigators (Name, designation, affiliation)	
4	Purpose of the study	
5	Duration of entire study + number of times and duration for which participant should be there at the study site(Follow up time)	
6	Reason why the participant is chosen for the study	
7	Detailed study procedure avoiding medical jargons- in simple language	
8	Furnish complete details on the samples that will be collected including answering questions like how? From where? How much? Stored/ not stored, if stored: how long it will be stored, what will happen to the sample if it remains?	
9	Benefits from the study (to participant/ society/ scientific advancement)	
10	Harms from the study and how it will be tackled	
11	Participants responsibility and cooperation	
12	Participating in study is subject's choice. Can refuse/ accept/withdraw. It will not affect treatment/ medical care/ legal rights	
13	No force/ influence on the subject	
14	Subject can take enough time to decide- time can be mentioned	
15	Subject's doubts can be asked and cleared at any given time during the study period	
16	Compensation should be addressed with respect to time lost/ additional treatment, investigations/ serious adverse events	
17	Participant protection A) Privacy B) Data confidentiality (how and where will it be stored, who has access to it, where will the data be analysed and by whom, data will be stored for how long and its future prospects) and how is it anonymised(anonymous data/ anonymised by reversible coding or irreversibly coding/ identifiable data) C) If photograph is taken, disclose it and mention how it will be masked	
18	Publication, benefit sharing, Commercial use of the outcome of the study	
19	Details of the Ethics Committee that has cleared the protocol	
20	Details of contact person/ investigator (Name, designation, affiliation, contact number, email id)	
21	Details of person (Member Secretary of YEC2) to contact in case of adverse events, problems in research(Name, designation, affiliation, contact number, email id)	•

- **This Checklist is for self-assessment and need not be submitted**