Self-Assessment Checklist for Informed Consent Document

Informed Consent Sheet (ICS)
- On a separate sheet, in a language that class VIII student understands
- Enclose in English+ Kannada, Malayalam; AS IS APPLICABLE
- ***Do not use Google translator for converting to regional languages***
- Appropriate language copy of the Informed consent sheet should be given to study participant and one copy retained by the PI
- ***Draft the ICS in first person's language (eg: I, Mr. X have been informed)***

Sl. No.	Components	
1	***Heading:*** Informed Consent Document	
2	***Details*** about study including title and PI name	
3	Includes statement which affirms that ICS has been provided in a language which the participant understands	
4	Statement on opportunity to ask questions from the PI or a member of the study team	
5	Statement affirming the comprehension of the participant as to the research he/she will be subjected to	
6	Statement confirming that the participant's consent is voluntary and ***free of coercion***	
7	Statement on ***option to refuse*** without comprising patient rights	
8	Mentions option to ***voluntarily withdraw*** at any stage of the research without compromising patient rights/ treatment offered	
9	Maintaining ***privacy*** of the participant and ***confidentiality*** of the data	
10	Statement on ***permission to present/ publish*** the data while protecting privacy and confidentiality	
11	Invitation to contact the PI or a study team member for clarification with adequate contact details	
12	Place for ***signature, name and date*** for the participant and/or legally authorized representative and a study team member	
13	Place for name, date and signature of ***an independent witness***, in case the participant is illiterate or unable to sign	
14	Sample of the informed consent document provided in English+ Kannada/Malayalam	
15.	If the informed consent is administered electronically then the link for the same has to be furnished	

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