Informed Consent for the Participation in Human Research: prototype

Consent for …….	**Protocol Number**	
	Approval date	
	Account	
Title of the study:		
Principal Investigator/co investigators		
Sponsor: Agency /Society /organization		

The consent form for research participation / trials includes the details, relevance and outcomes of the study. The participation in the research explained is voluntary and the participant is allowed to discuss any matter openly to the investigators and also have the freedom to leave the study at any time.

Participation in the study may result in minor or serious unsafe effects and may/may not be benefited by the participant. New informations will be provided regularly during the course of the study and at any time you may decide to take part or to stop participation in the study. In order to consider participation in the study one should understand the following reasons, explained below.

1. Study target
2. Total number of people participate in the study
3. Study outcomes
4. Period of study
5. Discontinuation during the study
6. Benefits received by the study
7. Risks or side effects during the study period
8. Confidentiality of the entire study
9. Institutional ethical committee, sponsors and insurance agencies may review, store and revise all - the data pertaining to the participating volunteers
10. Costs involved for taking part in the study
11. Remunerations may be given as per the institutional ethical committee regulations
12. All the participants are eligible for complete medical care during the study period
13. All the rights of participants are to be protected by agreeing the terms and conditions of the study.
14. The institutional ethical committee members are responsible for answering and explaining any – questions or complaints arise during the study period.

Consent form

No.	Name of the participant	Signature	Date & time	Verification by the research staff

(Note: The proposed research protocol must be explained to the participants before obtaining the consent for participation)

Institutional ethical committee members

Name	Signature	Designation	date /time