Patient Information Sheet

IMPORTANT: Each point should be explained clearly. Please do not remove the text written under points 1-17. Clear distinction should be made between 'Heading' and 'Description'. Don't write "not applicable" everywhere

Title of the study

1. Nature and purpose of study stating it as research
2. Duration of participation with number of participants
3. You are being invited to take part in the study as you have ….this disease (brief description of disease) your participation in the study is voluntary, If you disagree to participate your medical health care will not be affected.

   If you agree the following procedure will be followed.....
4. Procedure of study
5. Investigations, if any, to be performed: Please mention clearly that no financial burden (other than routine investigation) to be borne by the patient
6. Foreseeable risks and discomforts adequately described and whether project involves more than minimal risk
7. Benefits to participant, community or medical profession as may be applicable
8. Policy on compensation: If any adverse effect takes place in the subject as a result of research study will be treated by the institute at its own cost. No claim for award of financial compensation will be maintainable against the institute for the same
9. Availability of medical treatment for such injuries or risk management
10. Alternative treatments if available
11. Steps taken for ensuring confidentiality
12. No loss of benefits on withdrawal
13. Benefit sharing in the event of commercialization
14. Contact details of PI or local PI/Co-PI in multicentric studies for asking more information related to the research or in case of injury
15. Contact details of Member Secretary of the IEC for appeal against violation of rights: *Name and contact no. of Dean*
16. If test for genetics and HIV is to be done, counselling for consent for testing must be given as per national guidelines
17. Storage period of biological sample and related data with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results