Patient Information Sheet

1. Informed Consent of Participants: For all biomedical research involving human participants, the investigator must obtain the informed consent of the prospective participant or in the case of an individual who is not capable of giving informed consent, the consent of a legal guardian. Informed consent protects the individual's freedom of choice and respect for individual's autonomy and is given voluntarily to participate in research or not. Adequate information about the research is given in a simple and easily understandable unambiguous language in a document known as the **Informed Consent Form with Participant/Patient Information Sheet**. The latter should have following components as may be applicable:

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
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
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
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

A copy of the participant/patient information sheet should be given to the participant for her/ his record. The informed consent should be brief in content highlighting that it is given of free will or voluntarily after understanding the implications of risks and benefits and s/he could withdraw without loss of routine care benefits. Assurance is given that confidentiality would be maintained and all the investigations/ interventions would be carried out only after consent is obtained. When the written consent as signature or thumb impression is not possible due to sensitive nature of the project or the participant is unable to write, then verbal consent can be taken after ensuring its documentation by an unrelated witness. In some cases ombudsman, a third party, can ensure total accountability for the process of obtaining the consent. Audio-visual methods could be adopted with prior consent and adequate precaution to ensure confidentiality, but approval of EC is required for

such procedures. For drug trials, if the volunteer can give only thumb impression then another thumb impression by the relative or legal custodian cannot be accepted and an unrelated witness to the project should then sign.