Information Sheet and Informed Consent Checklists for PIs

The informed consent process should include an information sheet for the participant and an informed consent form. Although there is no template provided for each, the study PI should ensure that all of the information below is covered in the appropriate document/s. **Please complete and submit this checklist along with the proposal.**

Information Sheet Checklist	
Information	**Tick if covered**
Name of the study	
Nature and purpose of study, stating it as research	
Study treatments and the probability of random assignment	
Study procedures to be followed, including invasive procedures and investigations if any	
If any aspects of the study are experimental	
Expected effects of the intervention	
Expected duration of subject's participation	
Approximate number of subjects involved in the trial	
Subject's responsibilities	
Benefits to participant, community or medical profession as may be applicable	
Foreseeable risks and discomforts adequately described and whether project involves more than minimal risk	
Availability of medical treatment for such injuries or risk management	
Alternative procedures if available, and their potential benefits/risks	
Expected participant expenses and compensation as part of the study	
Process of informing primary physician of participation if applicable	
That participation is completely voluntary	
Foreseeable circumstances/ reasons for termination of subject's participation	

No loss of benefits on withdrawal or refusal to participate	
The consequences of a subject's decision to withdraw from the research and procedures for orderly termination	
Access to unidentifiable raw data and personal medical records for auditors, IEC, regulatory authority	
Steps taken for ensuring confidentiality, including if study is published	
What will happen after the study is over	
Benefit sharing in the event of commercialization	
Dissemination of new information in a timely manner	
If test for genetics and HIV is to be done, counseling for consent for testing must be given as per national guidelines	
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	
Contact details of PI or local PI/Co-PI in multi-centric studies for asking more information related to the research or in case of injury	
Contact details of Chairman of the IEC for appeal against violation of rights	
Informed Consent Form Checklist	
Information	**Tick if covered**
Name of study, protocol version, date	
That the study has been explained	
That the participant has had a chance to ask questions	
That voluntary consent is being given	
Reference to confidentiality	
Right to compensation	
Consent for Storage of biological samples (if applicable)	
That the participant will receive a copy of the information sheet and informed consent form	
That the participant knows whom to contact if more information is required/wants to raise concerns	

Procedures for obtaining informed consent appropriate (written/verbal)	
Translations of all forms consistent	
Language is non-technical, practical, and understandable to participant	
A space for witness name / signature / date/ relationship to subject	
A space for investigator's name / signature / date	