



INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth G. S. Medical College and KEM Hospital, Mumbai.

Annexure 7

AX 07/SOP 20/V 7.1

Checklist - Considerations for Research in Stigmatized / Rare Diseases / HIV participant

Principal Investigator (Name, Designation & Affiliation):

IEC No. of the Project:

Study Title:

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No.		Yes	No
1.	Was the consent taken voluntarily?	☐	☐
2.	During the consent process, is the privacy maintained?	☐	☐
3.	Is the pre testing counseling provisions are in place?	☐	☐
4.	Will the samples be made anonymous to maintain confidentiality? If yes, stop here in stored sample study.	☐	☐
5.	Has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?	☐	☐
6.	Where is the test being carried out? Is the laboratory provide high-quality testing services, and quality assurance mechanisms.	☐	☐
7.	The disclosure of the test results will be done only to the study team/sponsors/regulators with the participant consent.	☐	☐
8.	Has the appropriateness of the various strategies for recruiting participants and their care takers been considered?	☐	☐
9.	Does the proposed study require family members/caretakers permission?	☐	☐
10.	Will confidentiality be maintained?	☐	☐



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11.	Will family members/care takers be disclosed about the test results?	☐	☐
12.	Will the samples be destroyed in the future?	☐	☐
13.	Will the samples be stored for future?	☐	☐
14.	Is post HIV testing counseling being offered and given? (If HIV participant included)	☐	☐
15.	Will the participant provided with effective referral to appropriate follow-up services as indicated, including long term prevention and treatment support?	☐	☐

Signature of Principal Investigator: Date:

IEC Office use only	
Comments	
Primary Reviewer Signature & Date:	