



## 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: .....

.....

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



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

**Signature of Principal Investigator:** ..... **Date:** .....

### IEC Office use only

<b>Comments</b>	
<b>Primary Reviewer Signature &amp; Date:</b>	