

Annexure 7 AX 07/SOP 20/V6.1



Checklist - Considerations for Research in HIV participant INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No.

Investigator: _____ **IEC #:** _____

Study Title: _____

	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 .	<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 requires family members/caretakers permission ?	<input type="checkbox"/>	<input type="checkbox"/>
10. Would the confidentiality will be maintained ?	<input type="checkbox"/>	<input type="checkbox"/>
11. Will family members / care takers will 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?	<input type="checkbox"/>	<input type="checkbox"/>
15. Would 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 _____

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Comments:	
Primary Reviewer Signature & Date	