

INSTITUTIONAL ETHICS COMMITTEE (IEC)

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

Annexure 3 AX 03/SOP 05-A/V 7 Application Form for Human Genetics Testing Research

Principal Investigator (Name, Designation & Affiliation):
IEC No. of the Project:
Study Title:
Describe the nature of genetic testing research being conducted. (e.gscreening/gene therapy/newer technologies/human embryos/foetal autopsy)
Explain the additional safeguards provided to maintain confidentiality of data generated.
 3. If there is a need to share the participants information/investigations with family/community, is it addressed in the informed consent? Yes No NA 4. If findings are to be disclosed, describe the disclosure procedures (e.g. genetic counselling)
5. Is there involvement of secondary participants? If yes, will informed consent be obtained? State reasons if not. Yes No NA Yes No NA
6. What measures are taken to minimize/mitigate/eliminate conflict of interest?
7. Is there a plan for future use of stored samples for research? Yes No
If yes, has this been addressed in the informed consent? Yes No
8. Is the study a gene therapy? If yes, is there approval from local EC and DBT? Yes No NA
Signature of Principal Investigator (PI) with Date: