

**Annexure 05/SOP-06/V2.1**

**For Human Genetics Testing Research**

**(Additional information to be provided with application form)**

SMVMCH-EC Ref. No. (for office use) :

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Describe the nature of genetic testing research being conducted.

(e.g.- screening/gene therapy/newer technologies/human embryos/foetal autopsy)

1. Explain the additional safeguards provided to maintain confidentiality of data generated.
2. If there is a need to share the participants’ information/investigations with family/community, is it addressed in the informed consent? Yes No NA
3. If findings are to be disclosed, describe the disclosure procedures (e.g. genetic counseling)
4. Is there involvement of secondary participants? Yes No NA

If yes, will informed consent be obtained? State reasons if not.

1. What measures are taken to minimize/mitigate/eliminate conflict of interest? Yes No NA
2. Is there a plan for future use of stored samples for research? Yes No

If yes, has this been addressed in the informed consent ?

1. Is the study a gene therapy trial? If yes, is there approval from local EC and DBT (*Department of Biotechnology)*? Yes No

Signature of PI with date: