

**Declaration to be signed by Project Investigator (PI) and
Head of the Institute**

**(To be enclosed with each Project Proposal that requires the use of large
animals in Regulatory Testing)**

*The PI must submit the following information along with each project proposal
which contains the protocol for undertaking studies using mammals of higher
sentience, such as dogs, goats, pigs, cattle, monkeys etc.*

INFORMATION REGARDING TOXICITY TESTS / PK STUDY CONDUCTED BY PI

- I. Has the toxicity /PK Study test been conducted in rodent model? Yes / No
- II. If the answer is YES, kindly provide the following information:
 - 1. What was the time period of the study?
 - 2. What were the doses used?
 - 3. Did any animal/s die during the study? Yes / No.
 - 4. If yes, how many?
 - 5. How many days after dosing did the animal/s die?
(Please provide information/reasons for each animal death)
- III. If the answer is NO, kindly provide the following information:
 - 1. Whether rat study needed? If so, why it has not been done so far?
 - 2. If rat study is not needed substantiate with appropriate reasons.
- IV. Any additional information that you wish to provide?
[You may use additional sheets if required]

Declaration

I (Name of PI), do solemnly declare that the information given by me is true and correct to the best of my knowledge and that nothing relevant to the toxicity test has been concealed. I understand that if any false or incorrect information has been provided by me, I will be held responsible for the same and liable for action taken by the CPCSEA.

..... (Signature with date)
..... (Name of PI)

I (Name of Head of the Institute), state that this institute has approved the project proposal to be conducted by the above named PI and that the information provided above is in accordance with the records produced before me by the PI.

..... (Signature of Head of Institute with date)
..... (Seal of Institute)