**Annual Progress Report**

**1. Principal Investigator details**

**2. Study details-**

a.Title

b.IEC Number

c.IEC Approval date

d.Sponsor

 e. CTRI number(in case of Clinical Trial):

If not registered, give reason

 f.Date of start of study

(if not started, give reason and expected start date)

g.Date of last status report (if submitted)

**3. Summary of work done**

a.Till date

b.Within last one year

**4. Serious Adverse Events (SAEs)** /**any unexpected adverse event**

 Were all SAEs/ unexpected adverse event reported to IEC

 (if no, give reason)

**5. Protocol amendments within last one year (if any)**

 Were these amendments approved by the IEC

 (if no, give reason)

**6. Protocol violations within last one year**

* Any major protocol violations (if any)
* If yes, were they reported to IEC

 (if no, give reason)

**7. New information**

 Any new information that can alter the risk/benefit assessment

 (If yes, give details)

**8. Other issues within the last 1 year**

 Any issues that PI wishes to report to IEC (change of Co-I, addition/deletion of sites, etc)

 If yes, give details

**9. Signature of PI with date**