## Project Summary Format

1. **Project Summary Format**

**Project Summary**

**The Principal Investigator is required to fill the details in the summary in their own handwriting**

**Please circle appropriate option / provide details where required**

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| --- | --- | --- |
| **Abbreviated Project Title** | | |
| **Project Title** | | |
| **Sponsored Study Not Sponsored Study** | | |
| **Name & Address of Sponsor** ( If sponsored ) | | |
| **Estimated Duration of the project**  I / we understand that the sanction will be granted for one year only at a time and only on submission of the Trial report along with communication of for extending the duration of the project further as per the estimated Time of the project shall the project be allowed to continue after 1 year. | | |
| 1. **Type of Study** : Prospective Retrospective  Single center Multicenter Multinational  No. of centers\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 2.Does the study involve use of : Drug/Vaccine Device Alternative Medicine  Any Other  If other, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Not Applicable  i) Is the test drug/device marketed in India Yes No  Is marketed in other countries: Yes No  Please Specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  If not marketed in India, is DCG(I) permission attached . Yes No  In Additional Documents Chapter On Page no \_\_\_\_  ii) Is the test drug an Invistigational New Drug(IND)? Yes No  If yes, is the Investigator’s Brochure which contains  data of pre-clinical studies attached. Yes No  In Additional Documents Chapter On Page no \_\_\_\_  If IND, is attach DCG(I) permission. Yes No  In Additional Documents Chapter On Page no \_\_\_\_  iii) Does the test drug involve a change in use, dosage,  route of administration? Yes No  If yes, is copy of DCG(I) permission attached  In Additional Documents Chapter On Page no \_\_\_\_ | | |
| 3. Clinical Study is : Phase I Phase II Phase III Phase IV | | |
| 4. Subject Selection :  i) Number of subjects at this centre  ii) If multicentric, Total number of subjects \_\_\_\_\_\_\_  iii) If multinationational , Total number of Subject In Indian Centres \_\_\_\_\_\_\_  Total Number of patients in all centres \_\_\_\_\_\_\_ | | |
| iv) Vulnerable subjects: Yes No  (If yes, circle the correct options)  Pregnant women Children Elderly Fetus Illiterate  Handicapped Seriously/terminally Mentally challenged  Economically/socially backward Any other  If other, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| v) Special group subjects: Yes No (If yes, circle the correct options)  Employees Students Nurses/dependent staff Any other  If other, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 5.Does the study involve use of  i) fetal tissue or abortus | Yes | No |
| ii) organs or body fluids | Yes | No |
| iii) recombinant/gene therapy  If yes, is copy of GEAC permission permission attached  In Additional Documents Chapter On Page no \_\_\_\_ | Yes  Yes | No  No |
| iv) ionizing radiation/radioisotopes  If yes, is copy of BARC permission permission attached  In Additional Documents Chapter On Page no \_\_\_\_ | Yes  Yes | No  No |
| v) Infectious/biohazardous specimens | Yes | No |
| vi)Will pre-existing/stored/left over sample be used? | Yes | No |
| vii)Will samples be collected for banking/future research | Yes | No |
| viii)Will any sample collected from patients be sent abroad?  If yes, is copy of DGFT approval /permission attached  In Additional Documents Chapter On Page no \_\_\_\_ | Yes  Yes | No  No |
| ix)Is there any collaboration with any foreign lab., clinic or hospital?  If yes, is copy of HMSC approval / permission attached  In Additional Documents Chapter On Page no \_\_\_\_ | Yes  Yes | No  No |
| 6. Will any advertising be done for recruitment of Subjects?  (Posters, flyers, brochures, etc.)  If yes, is a copy for IEC(HR) review  In Additional Documents Chapter On Page no \_\_\_\_ | Yes  Yes | No  No |
| 7. Data Monitoring  i)Is there a separate data & safety monitoring board (DSMB)? | Yes | No |
| ii)Is there a plan for interim analysis of data? | Yes | No |
| iii)For how long will the trial data be preserved? \_\_\_\_\_\_\_\_\_years | | |
| 8. Is there compensation for participation?  If yes, Monetary In kind  Specify amount/type:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Yes | No |
| 9. Is there any arrangement for compensation for trial related injury? Yes No  If yes, is copy of HMSC approval / permission attached  Additional Documents Chapter On Page no \_\_\_\_ | | |
| We hereby declare the information given above to be true and that we do not have any financial or non-financial conflict of interest.  Name of PI /Designation and Department of PI / Signature of PI | | |