Project Summary Format

A. 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

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