

## 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

<b>Abbreviated Project Title</b>	
<b>Project Title</b>	
<b>Sponsored Study</b>	<b>Not Sponsored Study</b>
<b>Name &amp; Address of Sponsor ( If sponsored )</b>	
<b>Estimated Duration of the project</b> 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.	
<b>1. Type of Study :</b>	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 Investigational 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 multinational ,		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		Yes	No
i) fetal tissue or abortus		Yes	No
ii) organs or body fluids		Yes	No
iii) recombinant/gene therapy		Yes	No
If yes, is copy of GEAC permission permission attached In Additional Documents Chapter On Page no ____		Yes	No
iv) ionizing radiation/radioisotopes		Yes	No
If yes, is copy of BARC permission permission attached In Additional Documents Chapter On Page no ____		Yes	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?		Yes	No
If yes, is copy of DGFT approval /permission attached In Additional Documents Chapter On Page no ____		Yes	No
ix) Is there any collaboration with any foreign lab., clinic or hospital?		Yes	No
If yes, is copy of HMSC approval / permission attached In Additional Documents Chapter On Page no ____		Yes	No
6. Will any advertising be done for recruitment of Subjects? (Posters, flyers, brochures, etc.)		Yes	No
If yes, is a copy for IEC(HR) review In Additional Documents Chapter On Page no ____		Yes	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?		Yes	No
If yes, Monetary _____ In kind _____			
Specify amount/type: _____			

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		