Research Grant Application form (Ch01-A01-V5.0)

FORMAT FOR SUBMISSION OF RESEARCH PROJECTS FOR NCG FUNDING

(To be filled by applicant)

Research Project Title
Participating NCG centres (please list all centres – Name, City)
Duration of study :
Total Budget:
Project Category-Please tick the appropriate option below:

Clinical Research ☐

Basic Research ☐

Medical Oncology ☐

Radiation Oncology ☐

Surgical Oncology ☐

Translational Research ☐

Technology Development ☐

Any other _____

Sponsor Principal Investigator and Site Principal Investigator(s) – please add additional rows if necessary

Name	Designation and Department	Institute name and address	Telephone	Email
Sponsor Principal Investigator				
Site Principal -Investigator(s)				

I.Research Project Title(full and short title):_____

Registration No.....(to be filled by NCG secretariat)

II. Sponsor Principal Investigator (along with institutional affiliation)

III. Principal Investigators (along with institutional affiliation)

IV.Project summary (maximum 250 words) : Preferably point wise

V.Key words (maximum 6)

VI.Introduction (please provide background information, previous research on the subject, define the research question and the aims, objectives and hypothesis of the research question)

VII.Justification (please provide information on importance of the proposed research in the context of national needs)

VIII.Study methodology plan (please include information on methodology including inclusion/exclusion criteria, study design, primary/secondary/exploratory objectives,efficacy/safety variables, detailed methodology, statistical methods and plan, any potential risks and mitigation plan, feasibility of the study, implementation plan after the study is over, and other work elements)
Describe the extent of patient/public involvement in the development of research proposal

IX.BUDGET SUMMARY ESTIMATES: (please add additional rows or columns as necessary)
(To be submitted with initial proposal)

Please add here that the budget is to be submitted in the same format:
1) Cumulative (Total) study budget
2) Cost Head wise Budget with justification
3) Site Wise Budget

1) **CUMULATIVE (TOTAL) STUDY BUDGET:**

Please note that the amounts will be inclusive of all applicable e.g TDS

Sr. No.	**Particulars/Cost Heads**	**BUDGET**			**(in Rupees)**
		1st Year	2nd Year	3rd Year	Total
.	Recurring				
A1	Remuneration of research study Coordinator/Research Fellow/Project Manager				
A2	Research consumables				
A3	Patient-related research costs				
A4	Research-related patient safety costs				
A5	Ancillary research costs				

A6	Capacity-building cost				
A7	Administrative and dissemination costs				
B.	Research infrastructure cost				
C.	Travel-related Cost*				
	Grand total (A+B+C)				

***Depending on the number of sites and complexity of study and visits, an amount of 15-20 percent of total budget should be considered for Travel-related costs.**

Note:

- Institutional overheads will not be provided as per the NCG Funding policy.
- TDS will be deducted at the time of payment release to the site. The respective site may claim the deducted TDS as per applicable tax regulations.

The list of common Cost Heads in research studies have been listed below:

Sr. No.	**Research Cost Heads used conventionally in the budget**	**Proposed Research Cost Heads**
1	Salary (designated as research studyCoordinator or Research Fellow or Project Manager etc).	Grant support towards remuneration of research study Coordinator/Research Fellow/Project Manager engaged by the Institute for conduct of the research project
2	Consumables [drugs, laboratory consumables, kits, development of research study specific software (not very common), etc.]	Research consumables — reimbursement/grant towards cost of drugs, laboratory consumables, kits and study-specific software required for conduct of the approved research protocol
3	Patient reimbursements for e.g. blood investigations, radiology like scans, travel to research study site, etc	Patient-related research costs — grant support towards reimbursement of patient investigation, radiology/imaging and travel costs incurred for trial participation, as approved in the research budget
4	Medical management of Adverse Events (SideEffects due to research study participation)	Research-related patient safety costs — grant support towards medical management/treatment costs of Adverse Events arising from research study participation, as required under applicable ethical and regulatory guidelines
5	Insurance, translations, shipment, and vendor payments	Ancillary research costs — grant support towards clinical trial insurance premium, translation of research study documents, shipment of research study materials/samples, and payments to approved vendors engaged for conduct of the research project

6	Data management/Data capture tool	Research infrastructure cost — grant support towards data management and data capture tools required for the conduct and monitoring of the research protocol
7	Training related travel Costs	Capacity-building cost — grant support towards travel expenses for training of site personnel in study-specific procedures
8	Miscellaneous (publication,office supplies, printing costs, courier costs, purchase of legal papers for agreements, financial audit fees)	Administrative and dissemination costs — grant support towards publication charges, office supplies, printing, courier, stamp/legal paper for research agreements, and statutory financial audit fees relatable to the research project
9	NCG CRO monitoring head: A team from NCG travels to different sites to monitor study progress. This is usually 05-20 percent of the total budget.	Travel related cost – grant support towards travel, stay, etc undertaken for the research project site monitoring.

- If there are other cost heads than the ones listed above for a particular study, the same will be discussed with NCG.

2) COST HEAD WISE BUDGET FOR EACH SITE (INCLUDING THE COORDINATING CENTRE) WITH JUSTIFICATION FOR EACH COST HEADS:

A1: BUDGET FOR REMUNERATION OF RESEARCH STUDY COORDINATOR/RESEARCH FELLOW/PROJECT MANAGER with justification for manpower resources at each site (please add additional rows or columns as necessary)

BUDGET					**(in Rupees)**
		1st Year	2nd Year	3rd Year	Total
Designation & number of persons	Monthly Emoluments				
Total					

Justification for the manpower requirement:

A2:BUDGET FOR RESEARCH CONSUMABLES (please add additional rows or columns as necessary)

		BUDGET			(in Rupees)
Sr. No.	Particulars/Cost Heads	1st Year	2nd Year	3rd Year	Total
Total					

A3:BUDGET FOR PATIENT-RELATED RESEARCH COSTS with justification – add a row for justification (please add additional rows or columns as necessary)

		BUDGET			(in Rupees)
Sr. No.	Particulars /Cost Heads	1st Year	2nd Year	3rd Year	Total

A4:BUDGET FOR RESEARCH-RELATED PATIENT SAFETY COSTS with justification – add a row for justification (please add additional rows or columns as necessary)

		BUDGET			(in Rupees)
Sr. No.	Particulars /Cost Heads	1st Year	2nd Year	3rd Year	Total

A5:BUDGET FOR ANCILLARY RESEARCH COSTS with justification – add a row for justification (please add additional rows or columns as necessary)

		BUDGET			(in Rupees)
Sr. No.	Particulars /Cost Heads	1st Year	2nd Year	3rd Year	Total

A6:BUDGET FOR CAPACITY-BUILDING COST with justification – add a row for justification (please add additional rows or columns as necessary)

		BUDGET			(in Rupees)
Sr.	n Particulars /Cost Heads	1st Year	2nd Year	3rd Year	Total

No.					

A7:BUDGET FOR ADMINISTRATIVE AND DISSEMINATION COSTS with justification – add a row for justification (please add additional rows or columns as necessary)

		BUDGET			**(in Rupees)**
Sr. No.	n Particulars /Cost Heads	1st Year	2nd Year	3rd Year	Total

B:BUDGET FOR RESEARCH INFRASTRUCTURE COST with justification – add a row for justification(please add additional rows or columns as necessary)

Sr. No.	Generic name of the Equipment along with make & model	Imported/Indigenous	Estimated Costs (in Foreign Currency also)*

C:BUDGET FOR TRAVEL-RELATED COST with justification – (please add additional rows or columns as necessary)

		BUDGET			**(in Rupees)**
Sr. No.	**n Particulars /Cost Heads**	**1st Year**	**2nd Year**	**3rd Year**	**Total**

3) **SITE WISE BUDGET: only the amounts which will be disbursed from the coordinating centre to each site on an yearly basis should be specified.**

The cost heads which will be borne from the coordinating centre should not be listed here. Like Insurance/ICD Translation costs etc.

		BUDGET			**(in Rupees)**
Sr. No.	Name of the sites	1st Year	2nd Year	3rd Year	Total

X. Schedule of Activities (e.g. Gantt chart etc)

XI. Feasibility (please provide information to support the feasibility of the proposed project with respect to infrastructure, expertise, patient recruitment (if applicable) and logistics)

XII. Short CV (Annexure 08) of the Sponsor Principal Investigator(s)/ Principal Investigators of the collaborating sites including Name, Address, Date of Birth, Institution's Address etc. Academic Qualifications (University/College from where attained, year of passing, class, Thesis title etc.)
Publications list (Title of paper, authors, Journal details, pages, year etc
XIII.Previous research on the proposed topic

XIV. List of NCG funded Projects implemented till date (if applicable)

XV. Any other relevant information

Note: Kindly attach the following documents along with the application.
1. Detailed Protocol with the details of Sponsor PI and Coordinating Centre (word copy and PDF copy). The protocol should have version number and running page numbers.
2. A copy of the proposed Budget
3. Investigator Undertaking
4. Letter of intent from each site PI confirming willingness to participate.
5. Details of the involvement of Patient advocacy representative during the development of the Protocol

Short CV template (Ch01-A08-V5.0)

Curriculum Vitae

First and Family Name	
Date of Birth (dd/mmm/yyyy) (Optional information)	
Present Appointment(s) (Job title/Department)	
Address (Full work address including post/zip code)	
Contact Details & email Id	
Qualifications (Degree and other professional qualifications) (✔ Relevant qualifications, or specify)	MD or equivalent ☐ Year: Specialist, Field Year: PhD ☐ **MSc** ☐ BSc ☐ RN ☐ Year: 2016 Other (specify)
Physician's Reference/Licence Number (if applicable)	
Previous Appointments/ Experience (include only relevant therapeutic/ practical experience after gaining qualifications, most current date first)	
Publications (✔ appropriate box) (Number of articles published)	0 ☐ 1-5 ☐ 6-10 ☐ 11-20 ☐ >20 ☐
Previous Experience in Clinical Trials (eg, 3 trials in the cardiovascular field and 2 in the respiratory field)	
GCP Training received	

Documented GCP training at investigators meetings (enter study name and year) or GCP courses (enter name of course and year)	
Date of Signature	
Signature	

Investigator Undertaking Format (Ch01-A09-V5.0)

1. Full name, address and title of the Sponsor Principal Investigator

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Sponsor Principal Investigator for the clinical trial (Attach details including Medical Council registration number, and / or any other statement(s) of qualification(s)):

3. Name and address of all clinical laboratory facilities to be used in the study:

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study:

5. Names and site details of all participating Principal Investigators.):

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator:

7. Commitments:

(i) I have reviewed the Clinical Protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary ethics committee, CTRI registration and any other applicable approvals have been obtained.

(ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

(iii) I agree to personally conduct or supervise the clinical trial at my site.

(iv) I agree to inform all trial subjects, that the drugs/procedures/processes are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the relevant rules, regulations and guidelines are met.

(v) I agree to report and record all adverse experiences that occur in the course of the study in accordance with the regulatory requirements and Good Clinical Practices guidelines.

(vi) I have read and understood the information available including the potential risks and side effects of the drug/procedures/processes.

(vii) I agree to ensure that all associates, colleagues and employees (including site PI and staff) assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the study.

(viii) I agree to maintain adequate and accurate records and to make those records available for monitoring by NCG CRO, Ethics Committee or their authorized representatives as per applicable rules, regulations and guidelines. I will fully cooperate with any study related audit conducted by NCG or authorized representatives. .

(ix) I agree to promptly report to the ethics committee all changes in the clinical trial activities and all unanticipated problems involving risks to human subjects or others.

(x) I agree to inform all serious adverse events as per applicable timelines as mentioned in the Protocol, SOP and Guidelines.

(xi) The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Chairperson of the Ethics Committee and other parties (as applicable) with timelines as per Protocol, SOP and Guidelines.

(xii) I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.

(xiii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

Signature of Investigator with Date:

NOTE: The Undertaking has been adapted from NDCT Rules 2019-Second Schedule-Table 4.