



Indian Council of Medical Research (ICMR)

Department of Health Research

(Ministry of Health and Family Welfare)

Investigator-Initiated Research Proposals

Proposal in Draft Stage

Proposal Id: Not Generated Yet	
Proposal Title: Feasibility of high fibre diet intervention in newly diagnosed multiple myeloma patients and its effect on gut microbiome and myeloma control	
Personal details of Principle Investigator (PI)	
Name of PI (IN BLOCK LETTERS), Designation, Email, Contact No., Gender, DOB, Date of Superannuation	DR SREERAJ V, Assistant Professor, sreerajfleming@gmail.com, 8826752985, Other, 28-01-1984, 31-01-2046
Nature of Employment	Permanent
Institute	Amala Cancer Research Centre, Private academic institutions with valid UGC/AICTE/PCI or NMC approved Medical colleges , UNDERPROCESS
Proposal Details PART-A	
Are you currently under regular employment in Medical Institutes, Research Institutes, Universities, Colleges, recognized Research & Development laboratories, Government and semi-government organizations, and NGOs?	Yes
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Summary (up to 250 words): A structured summary should contain the following subheadings: Rationale/ gaps in existing knowledge, Novelty, Objectives, Methods, and Expected outcome.

Rationale: Gut microbiome and role of dietary fibre in modification of gut microbiome have a role in cancer prevention,contro.Recommended dietary allowance of fibre is 30 to 40 gram per day.But average dietary fibre consumption is very low .Indian patients are keen on dietary modifications to be followed once diagnosed with major illness like cancer because of the influence of ayurveda. Multiple myeloma(MM) is a common cancer in india. The incidence of cosntipation in MM is 23%.After MM diagnosis the fibre intake reduces for varying reason contributing to constipation. Recently Urvi sha etal showed high fibre plant based diet has better disease control in MM patient in maintence chemotherapy. Novelty :No indian study peromed high fibre diet intervention in induction therapy in MM or any active cancer.I feasible need randomised control trial to assess impact. Additional role of dietary intervention will be of great impact. Objective:Our study proposes for a feasibility study of high fibre diet during intial induction treatment of multiple myeloma and look in the tolerability,safety,quality of life with high fibre dietary interventior (40gram/day) during induction chemotherapy to MM and exploratory outcome is to look in to the gut microbiome change and correlation with diease response Outcome:Tolerability and feasibility of high fibre diet,Change in gut microbiome and SCFA from baseline,correlation between SCFA change,Gut microbiome change and disease response.

<p>Priority Area/Priority Area diseases</p>	<p>Non-Communicable Diseases / NCD risk factors – diet,activity, alcohol, tobacco etc</p>
<p>Keywords Six keywords separated by comma which best describe your project may be provided.</p>	<p>Multiple myeloma,High fibre diet,Gut microbiome,Short chain fatty acids,butyrate,remission</p>
<p>Abbreviations Only standard abbreviations should be used in the text. List of abbreviations maximum of ten may be given as a list.</p>	<p>MM-Multiple myeloma RDA-Recommended dietary allowance SCFA-Short chain fatty acids VLDL-Very low density lipoprotein Bortezomib,Lenalidomide,Dexamethasone Dsat-45-45 item diet satisfaction quetionnaire GSRS-Gastro intestinal symptoms rating scale CTCAE-Common terminology criteria for adverse event: EORTC QLQ 30-European organisation for research and treatment of cancer quality of life questionnaire 30 PRO-Patient reported outcome</p>

Problem Statement (up to 500 words): State the currently available information to present the problem adequately.

Indian patients are keen on dietary advice while diagnosed with major illness like cancer because of the influence of traditional ayurveda. Indian diet lacks sufficient gut fibre. Recommended dietary allowance per day for dietary fibre is 40gram per day. But average Indian diet contains fibre 15 to 30 gram per day. In disease state the fibre intake substantially reduces. Rice consuming ethnic group and women have lower average daily fibre intake. The role of gut microbiome in immune regulation and its role in cancer control and prevention is well evident. Fibre in the diet influences the gut microbiome. Gut microbiome produces short chain fatty acids by fermentation of fibre in the gut. There is evidence that stool butyric acid (type of short chain fatty acid) produced by firmicutes actinobacteria, bacteroidetes and fusobacteria orders have direct immunomodulatory role and implicated in cancer prevention and control. There is recent study by Urvi sha et al and Pianko et al showed butyrate producing gut microbiome have role in disease response in patients with multiple myeloma. The abundance of butyrate producers were correlated with high fibre dietary intake. Multiple myeloma (MM) is a common cancer in India treated initially with immunomodulatory drugs like lenalidomide, proteasome inhibitor like bortezomib with less impact on satiety and hunger making dietary intervention feasible in this group. The major problem with treatment is drug induced constipation accounting to 25% of patients getting treatment. Average fibre intake of newly diagnosed MM patient is low due to various causes. Fibre rich diet will be useful in relieving constipation. There are no Indian studies looking in to role of dietary intervention as an additional treatment to chemotherapy in newly diagnosed MM. Because the fibre rich diet is useful in chemotherapy related constipation, its role in gut microbiome change and associated disease control need further exploration. Once feasible high fibre intervention should be tested in phase 3 randomised trial for confirmation of its additional role in cancer control.

Rationale of the study (up to 250 words) Mention how the research question addresses the critical barrier(s) in scientific knowledge, technical capability, and/or programmatic/ clinical/lab practice and its relevance to local, national and international context with relevant bibliography.

Our research looks in the role of fibre in change in gut microbiome and its role in disease control. We don't have Indian data regarding the baseline gut microbiome profile in any cancer including MM. We also don't know about the levels of major short chain fatty acids produced by the gut microbiome. Although RDA for fibre in Indian recommendation is 40gram per day average Indian diet is very low in fibre content. We need to know the feasibility of high fibre diet (40gram /day) by modifying diet menu -Including nuts, pulses, legumes in diet in these patients. The tolerability, acceptability, complications of intervention need patient reported outcome measurements through various standardised questionnaires. If high fibre diet is feasible and there is a correlation in change in gut microbiome to high fibre diet and correlation with disease control, this will be a first study in the to look in to fibre intervention in active cancer control in MM which should pave way for phase 3 randomised control trial of fibre dietary intervention. Bibliography: 1.RDA for Indian -Reviewd 2024 .ICMR.NIN 2.Fibre content in Indian diet, Singh,A, Asian journal of pharmaceutical and clinical research, Vol 8, no 3, May 2015, pp 58-61 3.Sun.J, Butyrate as promising therapeutic target in cancer, from pathogenesis to clinic, review, Int J Oncol, 2024 Feb 29, 64(4)44 4.Pianko MJ, Minimal residual disease negativity in multiple myeloma is associated with intestinal microbiota composition, Blood adv. 2019 July 9, 3(13)2040-4 5.Shah U, Sustained minimal disease negativity in multiple myeloma is associated with stool butyrate and healthier plant based diet, Clin Cancer Res. 2022 Dec 1, 28.(23), 5149-55

Hypothesis/ Research question (up to 100 words) : Hypothesis: High fibre diet is tolerable, feasible and improve outcome in new MM patient taking induction chemotherapy. Primary Objective: Establish the feasibility, tolerability of high fibre diet in MM Secondary Objective: 1). To assess gut microbiome changes from baseline after intervention. 2). To assess the changes in stool and serum SCFA from baseline after diet intervention 3). To assess the association between stool microbiome changes with changes in SCFA and response in MM Design: Feasibility study Intervention: Dietary menu suggestions based on legumes, pulses, nuts meeting protein and energy requirement with daily average fibre intake of 40gram per day during 4 months of VLD chemotherapy induction for newly diagnosed MM

Methodology

Include objective-wise work plan under the following sub-headings:

Study Objective No. 1

Study Objective : 1.To establish feasibility and tolerability of high fibre diet (40gram per day) in multile myeloma patients 2.To assess changes in Gut microbiome from baseline after introduction of high fibre diet to butyrate producing stool microbiome in MM patients receiving induction chemotherapy and correlate with disease response

Study Design : Feasibility /Phase I study

Study Area : Tertiary cancer hospital

Sample Size : 40 number.Sample size arrived from observational studies.We feels sample size is adequate for feasible studies based on one observational studies 1)Shah U,Clin Cancer Research,2022.Deember.5149-55

Project Implementation Plan : We will recruit 1 patient per week for 18 months to acquire sample size.Inclusion criteria is all newly diagnosed MM patients less than 60 years of age.Exclusion criteria is patients with contra indication for fibre,patients with renal failure.Once recruited participant will be taught for 40 gram fibre per day .Diet diary maintenance will be daily basis.Participants baseline stool sample will be freezed in -80degree for gut microbiome.Stool and serum sample will be processed for SCFA by Liquid chromatography/mass spectroscopy.Participants will be weekly reviewed by study dietician for verifying diet diary,estimating previous week average daily fibre intake, participants will be asked to answer patient related outcome questionnaire GSRs,EORTC QoQ 30 weekly and Dsat45 Questionnaire monthly.Adverse events will be noted as per CTCAE adverse event grading on a weekly basis.Intercurrent antibiotics use will be noted on weekly review.Patients will receive VLD chemotherapy induction for 4 month. At the end of 4 months MM disease response testing will be done.Along with that stool sample will be taken and freezed for Gut microbiome.Stool and serum sample will be processed for SCFA estimation

Design of Statistical analysis : Feasibility outcome will be summarised descriptively using standard statistical techniques including means,median,ranges for continuous variables,frequency and percentage for categorical measurements.Gut microbiome is assessed as relative abundance of each species.The levels and relative abundance will be summarised non parametrically using medians,interquartile ranges,compared with baseline using wilcoxon signed rank test.SCFA levels and changes will be summarised using means and standard deviation,compared with baseline by paired t test.The association between gut microbiome changes and SCFA levels and changes will be explored using spearman correlation coefficient.A two tailed p value less than 0.05 will be taken as statistical significance.SPSS version 29 will be used.The association between Microbiome levels and changes and disease response using spearman's correlation coefficient

Expected outcome/ Deliverables aligned with research question (up to 100 words): Primary outcome: Tolerability and acceptability of dietary intervention assessed by 1)Percentage of days of diet recommendations followed. 2)Percentage of patients with high GI symptoms score based on GSRS questionnaire weekly. 3)Percentage of patients with tolerability based on DSat-45 questionnaire monthly. 4)Average daily fibre intake. Secondary outcome: 1)Percentage change in gut microbiome alpha diversity from baseline. 2)Percentage of patients with relative abundance of butyrate producers at 4 months intervention. 3)Mean change in serum/stool SCFA after 4 months of intervention Exploratory outcome: 1)Correlation between disease response to changes in SCFA levels and Changes in Gut microbiome after 4 months of induction

Immediate next steps following the end of the project(up to 100 words): Once feasible and found to have correlation with MM outcome will proceed with phase II/Phase III randomised control trial to establish treatment effect

Whether the study is going to generate new intellectual property: No

Timelines with achievable targets

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Proposal Details (PART-B)

Preliminary work done by the PI including the source of funding (up to 250 words): No

Skill and experience of the research team (Highlight only salient points (along with 5 relevant publications) that provides confidence to reviewers that team can implement the project with quality.): Co PI Dr.Sunu Cyric heads the clinical research unit funded by BIRAC conducting phase 4 clinical trials. Co PI Dr.Manu Aryan heads the translational immunology lab in cancer research with interest in stem cell biology,cancer immunology,GI cancer and editor in various journals.He heads the gut microbiome lab in our centre.

Institutional Support/ Facilities: We have BIRAC funded clinical research unit which conduct phase IV clinical trials and other trials in our institute.Co PI Dr.Sunu heads the CRU. We have gut microbiome research lab in our centre.Dr.Manu Aryan heads the gut microbiome lab

Laboratory facilities (in-vitro/ in-silico) Institutional resources such as instruments/ equipment and other physical resources available for use in the project proposed animal house etc. Our centre have Gut microbiome centre with Oxford nanopore facility Our biochemistry department will be able to process stool and serum sample for SCFA testing We will partner with neighbouring Kerala Veterinary science university (Within 20 km) for Liquid chromatography and mass spectroscopy We have -80 degree freezer for sample storage

Conflict of Interest declaration (if any) nil

Duration (in Months)

18 Months

Investigator Details

#	Name	Institute	Designation	Email	Contact No.	Role in Proposal
1	Dr sreeraj v	Amala Cancer Research Centre	Assistant Professor	sreerajfleming@gmail.com	8826752985	PI
2	Dr Sunu Lazar Cyriac	Amala Institute of Medical Sciences	Associate Professor	drsunucyriac@gmail.com	9567602426	Co-PI
3	Dr Manu Kanjoormana Aryan	Amala Cancer Research Centre	Assistant Professor	manu.aryan@amalaims.org	7356410639	Co-PI
4	Dr Reena K Chittilappilly	Amala Institute of Medical Sciences	Manager	reenadiet@gmail.com	9633681802	Co-PI
5	Dr Sreejith J Kishore	Amala Institute of Medical Sciences	Assistant Professor	sjkofficial89@gmail.com	9447308523	Co-PI

Documents consideration

#	Document Name	Is Applicable?	Uploaded Document	Remarks
1	Declaration & Attestation Form(duly signed by Head of Department/ Director)	Yes	View	Certificate issued by director,amala cancer hospital society
2	Additional supplementary information including figures tables flow diagrams etc can be shared as PDF	Yes	View	PDF showing table of sequence of events of study participants with time point

Proposed Budget Details

Institute	Budget Year	Manpower Budget (Rs.)	Contingency	Consumables	Equipment	Travel	Overhead	Total(Rs)
Amala Cancer Research Centre	1	0	0	0	0	0	0	0
Amala Institute of Medical Sciences	1	1497120.00	445000.00	35000.00	109200.00	40000.00	0	2126320
Amala Cancer Research Centre	2	0	0	0	0	0	0	0
Amala Institute of Medical Sciences	2	1120480.00	655000.00	35000.00	0	40000.00	0	1850480
Total in (Rs.):		2617600	1100000	70000	109200	80000	0	3,976,800.00

Budget Breakup Details (Staff/Manpower)

#	Budget Year	Institute	Designation	No. of Person(nos)	Require Month(nos)	Cost Per Person(Rs.)	Overhead(Rs.)	Total Cost(Rs.)
1	Year: 1	Amala Institute of Medical Sciences	Data Entry Operator	1	12	29,200	0.00	350,400.00

Justification :for data collection

Total Cost (Rs.)

including overhead

2,617,600.00

Budget Breakup Details (Staff/Manpower)

2	Year: 1	Amala Institute of Medical Sciences	Project Technical Support - III	1	12	32,480	0.00	389,760.00
Justification : for performing microbiome and SCFA at lab with transportation								
3	Year: 1	Amala Institute of Medical Sciences	Senior Project Assistant	1	12	30,600	0.00	367,200.00
Justification : For project management and team cordination								
4	Year: 1	Amala Institute of Medical Sciences	Project Technical Support - III	1	12	32,480	0.00	389,760.00
Justification : for preparation of diet menu, follow up, counselling, Monitoring								
5	Year: 2	Amala Institute of Medical Sciences	Data Entry Operator	1	8	29,200	0.00	233,600.00
Justification : for data collection								
6	Year: 2	Amala Institute of Medical Sciences	Project Technical Support - III	1	8	32,480	0.00	259,840.00
Justification : for performing microbiome and SCFA at lab with transportation								
7	Year: 2	Amala Institute of Medical Sciences	Senior Project Assistant	1	12	30,600	0.00	367,200.00
Justification : For project management and team cordination								

Total Cost (Rs.)

including overhead

2,617,600.00

Budget Breakup Details (Staff/Manpower)

8	Year: 2	Amala Institute of Medical Sciences	Project Technical Support - III	1	8	32,480	0.00	259,840.00
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Justification :for preparation of diet menu, follow up, counselling, Monitoring

Total Cost (Rs.) including overhead **2,617,600.00**

Contingency budget breakup details

#	Budget Year	Institute	Overhead Charges (Rs.)	Total Cost(Rs.)
1	Year: 1	Amala Institute of Medical Sciences	0.00	320,000.00

Contingency Name :Stool Microbiome

Justification :Stool microbiome testing at base line and end of 4 months for 20 patients in first year

2	Year: 1	Amala Institute of Medical Sciences	0.00	25,000.00
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Contingency Name :contingency fund

Justification :contingency fund for first year

3	Year: 1	Amala Institute of Medical Sciences	0.00	100,000.00
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Contingency Name :Printing questionnaire

Total Cost (Rs.) including overhead **1,100,000.00**

Contingency budget breakup details

Justification :4 quetioonaire per patient per week for 40 patients

4	Year: 2	Amala Institute of Medical Sciences	0.00	320,000.00
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Contingency Name :Stool microbiome testing

Justification :stool microbiome testing at baseline and end of 4 months for 20 patients

5	Year: 2	Amala Institute of Medical Sciences	0.00	50,000.00
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Contingency Name :Publishing fees

Justification :Article publishing fees

6	Year: 2	Amala Institute of Medical Sciences	0.00	100,000.00
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Contingency Name :Article processing fees

Justification :Article processing fees

7	Year: 2	Amala Institute of Medical Sciences	0.00	25,000.00
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Contingency Name :contingency fund for second year

Justification :contingency fund for second year

8	Year: 2	Amala Institute of Medical Sciences	0.00	160,000.00
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Total Cost (Rs.)

1,100,000.00

including overhead

Contingency budget breakup details

Contingency Name :Stool and serum SCFA mesurement

Justification :Per person 4 times testing of SCFA serum and stool based on liquid chromatography/mass spectroscopy.approximately 20 patient recrutemnt in second year

Total Cost (Rs.) **1,100,000.00**
including overhead

Consumables Budget Breakup Details

#	Budget Year	Institute	Consumables Name	Overhead	Total Cost(Rs.)
1	Year: 1	Amala Institute of Medical Sciences	Dry ice for transportation	0.00	10,000.00
Justification : dry ice for sample transportation					
2	Year: 1	Amala Institute of Medical Sciences	office stationary	0.00	25,000.00
Justification : office stationary					
3	Year: 2	Amala Institute of Medical Sciences	Dry ice for sample transportation	0.00	10,000.00
Justification : dry ice purchase					
4	Year: 2	Amala Institute of Medical Sciences	office stationary	0.00	25,000.00
Justification : office stationary					
Total Cost (Rs.) including overhead					70,000.00

Equipment Budget Breakup Details

#	Budget Year	Institute	Equipment Name	Equipment Model	Equipment Manufacturer	Equipment Type	Total Cost(Rs.)
1	Year: 1	Amala Institute of Medical Sciences	Printer			Domestic	15,000.00
Justification : for office purpose							
Mode of Proposed disposal : As per electronic waste disposal policy of hospital							
2	Year: 1	Amala Institute of Medical Sciences	Laptop/Desktop		Dell	Domestic	75,000.00
Justification : For Data collection							
Mode of Proposed disposal : As per electronic waste disposal policy of hospital							
3	Year: 1	Amala Institute of Medical Sciences	Deep freezer stool sample container			Domestic	16,000.00
Justification : 100 rupees per unit x 160 units							
Mode of Proposed disposal : as per hospital waste disposal policy							
4	Year: 1	Amala Institute of Medical Sciences	Blood and stool sample container for SCFA estimation	Serum sample container for		Domestic	3,200.00
Justification : 20 rs per vial x 160 sample							
						Total (Rs.):	109,200.00

Equipment Budget Breakup Details

Mode of Proposed disposal :as per hospital waste disposal policy

Total (Rs.): 109,200.00

Travel Justification

#	Year	Amount(Rs.)
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1	Year: 1	40000.00
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Justification :1000 rs per travel for 2 times for each patient ,for 20 participants

2	Year: 2	40000.00
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Justification :1000 rs per travel for 2 times for each study participant ,20 participants in second year

Total: 80,000.00

Short resume PI/Co-PI

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
Dr Sreejith J Kishore	1989-06-09	biochemistry	0	0	society of clinical biochemitry	Co-PI

Short resume PI/Co-PI***Maximum of 10 primary research publications related to the proposal***Publication details in
AMA styleImpact factor of
journalAuthor type (first, corresponding,
coauthor)Name of policy/programme/ protocol document or patent/commercialization of
products where cited.***Experience as Investigator***

Title of the project

Role

Funding Agency

Amount of Funding

Reference of main publications

Ongoing research projects (funded by ICMR)

Project Id

Title

Grant Amount

Start Date

End Date

Name of PI/Co-Pi**DOB****Domain Expertise****Number of articles
in Pub Med (Past
10 years)****h-
index****Fellow of Academics****Role in
Proposal**Dr Sunu Lazar
Cyriac1976-
06-10cell therapy,stem cell
transplantation, leukemia

13

9

ASCO,ESMO, ASH

Co-PI

Maximum of 10 primary research publications related to the proposalPublication details in
AMA styleImpact factor of
journalAuthor type (first, corresponding,
coauthor)Name of policy/programme/ protocol document or patent/commercialization of
products where cited.

Short resume PI/Co-PI***Experience as Investigator***

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications
Randomised control trial of effectiveness of pain control with sublingual buprenorphine versus oral tramadol	PI	icmr	11600000.00	Ongoing

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date
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Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
Dr Manu Kanjoormana Aryan	1980-12-11	cancer immunology,cancer stem cells	13	24	Indian association of cancer research,American association of cancer research,European association of cancer research	Co-PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.
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Short resume PI/Co-PI***Experience as Investigator***

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications
Effect of VCNO on inhibition of inflammatory bowel disease in mice	PI	Target institute of medical education and research	1000000.00	Prabha.S, Virgin coconut alleviate dextran sulphate induced inflammatory bowel disease and modulate inflammation and immune response in mice, J Am Nutr Asso, 2023, Oct 31, 1-11,
study the role of APT2 mediated SCRIB depalmytylation on regulating self renewal ability, tumorigenicity, therapy resistance in breast cancer	PI	DST-SERB	2900000.00	Ongoing

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date		
Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
Dr sreeraj v	1984-01-28	Hematology, Acute leukemia, Myeloma	0	0	Member of Indian society of hematology and blood transfusion	PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.
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Short resume PI/Co-PI

Experience as Investigator

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications
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Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date
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Declaration

I hereby declare that the entries in this form and the additional particulars, if any, furnished herewith are true to the best of my knowledge and belief. I understand that in the event of my information being found false or incorrect at any stage, my project/proposal shall be liable to cancellation / termination without notice or any compensation in lieu thereof.

I hereby certify that the research proposal I have submitted to ICMR, New Delhi, for potential funding is entirely my original idea and has not been copied or replicated from any other source. Furthermore, I confirm that this proposal has undergone scrutiny using a standard plagiarism detection tool, verifying its originality and confirming that its contents have not been directly taken from any other sources. Additionally, I declare that there have been no established or pending plagiarism charges against me in the last five years.

In the event that the funding agency identifies any form of plagiarism or inconsistencies in the aforementioned proposal, I acknowledge and agree to comply with any actions deemed necessary by ICMR. I take full responsibility for any such discrepancies and will adhere to the consequences as required.