INDIAN COUNCIL OF MEDICAL RESEARCH

Policy on Contributions and Partnerships

2017

Contents

Preface

Central to the purpose of Indian Council of Medical Research (ICMR) is catalysing medical research of societal relevance. ICMR has 23 mission-oriented national institutes, 5 Regional Medical Research Centres and 5 Unit/Centres for specific domains located in different parts of India. The Institution has constantly evolved to address contemporary challenges and to retain organisational relevance. ICMR has periodically revised the policies and guidelines to ascertain progression.

In 2007 ICMR had revised and updated the Guidelines for research, consultancy, technical services etc. The policy of 2007 suggested certain mechanisms for establishing linkages between ICMR, Private Sector and other government organisations / laboratories / universities with a view to synchronising and synergising national R&D efforts. The prime models covered there under were of the nature of contract research and consultancy.

In 2017, ICMR by and by has initiated the policy reconsideration specifically to steer the Partnership efforts with other public and private entities and the handling of non- commercial contributions. A Committee was constituted to adopt two prong approach and propound on –amendment of the 2007 policy or on totally revamp of the earlier policy document by a superseding comprehensive Policy keeping into account the recent national and global developments.

The Committee that had eminent experts and ICMR personnel deliberated to bring out the present Policy document. The reasonable expectation of this Policy is that it will address the major concerns of the implementation elements related to Contributions and Partnerships though certain minutia may require additional considerations.

Acknowledgements

The deepest appreciation goes to the Committee that delved into the issues and brought out an overall guidance document in the form of the present Policy. Suggestions and comments were provided by many Scientists, Finance and Administrative officials at ICMR Hqrs that merit due acknowledgement.

Entitled to acknowledgement are various international guidelines available in public domain including the donation guidelines of the World Health Organisation, Institute of Fund raising of UK, Association of Fundraising Professionals reference series of Canada, non-commercial sponsorship policies of different Multi National Corporates, Gift acceptance policy- University of Toronto, NIH, USA- Policies, Procedures and forms related to sharing, sponsored research, research integrity etc., fundraising guidelines of UN Foundation and UN Women, OECD Guidelines for Multinational Enterprises, CSR Guidelines of Department of Public Enterprises, Government of India and resources on Public-Philanthropic-Partnerships of Council on Foundations, USA.

Composition of the Committee

ICMR constituted a Committee to deliberate and determine the proposed Policy under the Chairmanship of Dr. W. Selvamurthy. The Committee composition is as stated herein below;

S.No	Name	Particulars
1.	Dr. W. Selvamurthy (Chairman)	Distinguished Scientist & Former Chief Controller R&D, DRDO President & Chair Professor for Life Sciences, Amity Science, Technology & Innovation Foundation, Amity University, Noida
2.	Dr. Sanjay Mehendale	Additional Director General, ICMR Hqrs, New Delhi
3.	Ms. Ritu Dhillon, IAAS	Sr. Financial Advisor, ICMR Hqrs, New Delhi
4.	Dr. R.K. Srivastava	Former DGHS & Ex Chairman, Medical Council of India, National Institute of Health & Family Welfare, Munirka, New Delhi Advisor, WISH Foundation, New Delhi
5.	Dr. G.J. Samathanam	Ex-Advisor and Head, Technology Development and Transfer, DST Director, Research and Industrial & International Collaboration (S&T), SRM University, Haryana
6.	Dr. K. Satyanarayana	Formerly Scientist 'G', Head IPR and Coordinator DHR New Delhi
7.	Dr. R Saha	Ex Head Patent Facilitating Centre, Technology Information, Forecasting and Assessment Council, DST, New Delhi

8.	Dr. V.S. Bisaria	Professor, Biochemical Engineering and Biotechnology, IIT- Delhi, New Delhi
9.	Dr. Banusri Velpandian	Legal Consultant, RMPPS, ICMR Hqrs, New Delhi
10.	Dr. Shirshendu Mukherjee	Mission Director, DBT-BIRAC and Bill &Melinda Gates foundation CGO Complex, LodhiRoad, New Delhi
11.	Dr. Jatinder Kaur	Head R & D Molecular Quest Healthcare Pvt. LTD, Gurgaon
12.	Dr. Jitendar Sharma	Andhra Pradesh Medtech Zone Limited, Vishakapatnam
13.	Dr. ChanderShekhar (Member Secretary)	Scientist 'G' & Head, Innovation and Translation Research ICMR Hqrs, New Delhi
14.	Dr. Sadhana Srivastava	Scientist 'F', Intellectual Property Right Unit ICMR

Abbreviations

IRFA	Indian Research Fund Association
CSR	Corporate Social Responsibility
MRHRU	Model Rural Health Research Units
IDSP	Integrated Disease Surveillance Programme (
UC	Un-tied Contributions
PC	Purposive Contribution
FC	Foreign Contribution
FCRA	Foreign Contribution (Regulation) Act, 2010
CPC	Contributions and Partnerships Committee
ICG	Internal Contributions Group
IP	Intellectual Property
PAG	Partnership Assessment Group
MOU	Memorandum of Understanding
RADP	Research and Development Partnership
POC	proof of concept
GOCO	Government Owned and Company Operated Facility Partnership
PIU	Program Implementation Unit
LOI	Letters of Intent
ATS	Acceptance Term Sheet
EOI	Expression of Interest

PCC	Program Core Committee
PPP	Public Private Partnership
SPV	Special Purpose Vehicle
LPR	Licensed Patent Rights
ICADR	International Center for Alternate Dispute Resolution
DOP	Delegation of Power

1. Background

1.1 Introduction

The Indian Council of Medical Research (ICMR) was founded in the year 1911 and was erstwhile known Indian Research Fund Association (IRFA). IRFA was re-designated as the Indian Council of Medical Research in 1949. ICMR is a Society registered under the Societies Registration Act, 1860 and funded by the Government of India through the Department of Health Research, Ministry of Health & Family Welfare. The Governing Council of ICMR is presided over by the Union Health Minister. It is assisted by various scientific and technical bodies comprising of eminent experts in different biomedical disciplines. All efforts of ICMR are aligned with the national priorities and are undertaken with a view to reduce the total burden of disease and to promote health and well-being of the population.

ICMR promotes biomedical research in the country through intramural as well as extramural research. ICMR is perceived as being instrumental in recognizing health disparities and identifying priorities for health research and policy. Over the decades, the base of extramural research and also its strategies have been expanded. Efforts of ICMR in many top priority fields including tuberculosis, leprosy, diarrhoeal and viral diseases have been well recognised. ICMR has had numerous partners from public and private sector to carry out its endeavours till date and acknowledges that it works in dynamic equilibrium with the Government and private sectors. Their contributions as stakeholders are significant and the present policy provides for various means to address their enthusiasm rather than as an alternative source of funding.

Many who plan to contribute towards promotion of health can consider the organisational mandate of ICMR and become part of such feats. ICMR is registered under section 80G and hence the person or the organisation making a Contribution will get a deduction from his/its taxable income as applicable.

1.2 Organisational focus area

ICMR is one of the oldest medical research bodies in the world and has the objective to support;

1. Medical scientific research in India and promote and assist institutions for the study of diseases, their prevention, causation and remedy.

2. Bio-medical research, the propagation of knowledge and experimental measures in connection with –

a) Causation, mode of spread and prevention of Communicable Diseases;

b) Non-communicable Diseases;

c) Basic Medicine Sciences;

d) Traditional Medicine;

e) Problems of urban health;

f) Nutritional problems;

g) Reproductive and Child health issues;

h) Public health;

i) Bio-informatics;

j) Bio-medical Ethics, and

k) Other relevant biomedical aspects.

ICMR's research priorities coincide with the National health priorities such as control and management of communicable diseases, fertility control, maternal and child health, control of nutritional disorders, developing alternative strategies for health care delivery, containment within safety limits of environmental and occupational health problems; research on major non-communicable diseases like cancer, cardiovascular diseases, blindness, diabetes and other metabolic and haematological disorders; mental health research and drug research (including traditional remedies). ICMR encourages scientific rigor through promotion of collaboration, innovation, multi-disciplinary capacity building, technology translation and through advancements in health delivery and access equality. ICMR has also been able to facilitate the implementation of research to practice through developing state specific Model Rural Health Research Units (MRHRUs) focused on translational research.

Through its network of institutions, ICMR has contributed towards the strengthening of the Integrated Disease Surveillance Programme (IDSP), helping to provide reliable data and trends of top priority disease burdens. Among these programmes includes national level surveillance networks for rotaviral diarrhea, pneumonia, bacterial meningitis, poliomyelitis, acute encephalitis syndrome and HIV/ AIDS. ICMR has also implemented research and surveillance activities on many new emerging and transboundary diseases, such as Zika and Ebola, in order to be prepared to address and properly handle any outbreak situation. ICMR data from major projects like National Nutrition Monitoring Bureau, National Cancer Registry Program, Rotavirus Surveillance Network and Influenza Network have greatly impacted Government policies and programs. In doing so, ICMR has developed evidence-based research and subsequent health policies in response to emerging national priorities throughout the past century.

Health research initiatives of ICMR focus on field based studies, clinical research trials and basic bench based research. Additionally, research on health information technologies and evaluation of medical and public health interventions are given priority. National requirements, other than the development of drugs, diagnostics and devices, in which the ICMR is deeply involved as a premier vehicle of Medical Research, are mentioned below:

1. Strategizing for prevention of diseases of interest to India [like Malaria, Tuberculosis, Filariasisetc]

2. Conducting epidemiological studies

3. Providing expertise in identification of modified strains of pathogens

4. Undertaking studies for prediction of spread of diseases

5. Optimising combination therapy protocols based on available drugs

6. Carrying out basic studies to understand disease causing mechanisms and appropriate ways for their management

7. Assisting Govt. in formulating national health policies

8. Rendering expert assistance to Regulatory Authorities

9. Providing expert assistance to the courts of Law

10. Monitoring Adverse Drug Reactions on Indian Population on long term basis

11. Developing agents and strategies to combat bioterrorism

12. Developing strategies for herbals that will have a place in present day therapeutic regimens.

13. Any other objective in line with the national priority

ICMR's approach is to establish partnerships with all concerned stakeholders and find tenable solutions to improve the health of society. ICMR encourages use of this policy as a reference for such contribution and partnership related queries. Concerns about different sections of the policy should be addressed to:

1.2 Principles and scope

The purpose of this policy is to provide a resource of information about principles and procedures related to the Contributions and Partnerships. It has been prepared to help familiarize with responsibilities as a Contributor and Partner on one side and ICMR on the other for the various missions and programs implemented by ICMR to benefit the public.

The cardinal principles underlying the policy are-

a. attainment of ICMR mandate
b. maintenance of independence of citizen engagement and community empowerment
c. compliance of the government policies on acceptance of Contributions and Partnerships
d. transparency of the process and public disclosure
e. ethical administration of Contributions and Partnerships

Thus, Present Policy of ICMR provides for an effective handling of Contributions and Partnerships by eligible entities. Although ICMR has tried to be comprehensive, this Policy does not, and cannot, include policies which address every situation that may arise. ICMR reserves the right to revise, supplement, or rescind any portion of the Policy for handling contribution at any time, with or without prior notice. ICMR will endeavour to communicate such changes in a timely fashion.

Contributions	Partnerships
• Provided by external entities to ICMR without any claim to benefit sharing in any form including any royalty with regard to IP or Knowhow contribution	• Collaborative research endeavour of ICMR and external entities with intellectual contribution on either side or both sides OR Consultancy services offered by /taken by ICMR or its Institutes/centres
• No reciprocal financial liabilities for ICMR. Public accountability principles are applicable towards utilization of the Contribution	• Based on the specific case there can be obligations of ICMR towards the other partner with regard to technology know-how, IP, royalty, technical services, results and publications or any other financial obligations
• Can include any of the grant	• Can have elements of a Project and

schemes, extramural projects or other fellowships implemented by ICMR	can have application of terms accordingly.
• Can have the flexibility in utilization as determined by the Relevant Committee and as per the present policy.	• Can have flexibility aspects depending upon the source of funding (Grant from Government or other non-government resources).

2 Policy on Contributions

2.1 Principles and Scope of the Policy on Contributions

ICMR will not carry out any door to door campaign or appoint any agency for raising Contributions. Further, ICMR does not undertake any general telephonic solicitation of Contributions. Public outreach shall be through ICMR website, ICMR publications, ICMR events or through any specific public relations packet having the relevant feature. There are many private organizations in India that raise money for health care research and other support activities. Some of these private organizations may refer to ICMR in their fundraising literature. However, ICMR is not affiliated with any such organizations and does not participate in or endorse their fundraising activities. Nobody directly or indirectly employed by ICMR shall accept commissions or payments for Contributions on behalf of the organisation. All proposals for Contributions including under Corporate Social Responsibility (CSR) shall be addressed to;

Name:
Designation:
Address:

Telephone:

The Prospective Contributors should be mindful of the essential conditions stated hereunder while contemplating the nature of Contribution;

a. 'Contribution' denotes voluntary contribution of any item of value in terms of this policy in the absence of coercion or undue pressure of any sort.
b. Contributors cannot prescribe any particular deliverable, benefit, or item in exchange from ICMR for Contributions.
c. Contributions will have the only assurance that the intent of the contribution will be honoured in-line with the organisational mandate.
d. ICMR retains full authority over its activities implemented using any Contribution.

e. There cannot be any time limit on spending of the funds and unspent funds will not be returned to the Contributor.
f. The Contributor is not entitled to any Intellectual Property (IP) rights for discoveries made using these Contributions except the contribution of IP itself.
g. ICMR will not provide advice about the tax or other treatment of Contributions and the Contributors have to seek guidance from their own professional advisors to assist them in the process of making their Contributions.
h. All personal information provided by the Contributors shall remain confidential and will not be disclosed to any third party without consent of the Contributor except as required by applicable law.
i. By accepting any Contribution, ICMR does not endorse—either explicitly or implicitly—any of its Contributors, nor does it endorse those Contributors' products, services, or ideas.

The basic standards for consideration of Contributions include the following;

I. Contributions can be monetary or in-kind as provided for in this policy.
II. Contributions are considered charitable in nature and intent.
III. Contributions made to ICMR are separate from the funding that is received from Government of India.
IV. Organisational endeavours supported through the Contributions may vary from year to year depending on ICMR research priorities.
V. Acceptance of any contribution is at the discretion of ICMR
VI. ICMR will not accept any Contribution unless it can be utilised consistently with the purpose and mission of ICMR.
VII. Contributions are to be applied against the background of the applicable law.

This establishes the procedures concerning the acceptance, acknowledgment and administration of Contributions. This policy is not intended to be, and should not be interpreted as, a contract between ICMR and any Contributor or to be treated as fiduciary or other special relationship.

This policy on Contributions does not apply to Commercial and Collaborative sponsorships. They are typically sanctioned by ICMR in response to a submitted proposals and include a distinct scope of work, specific terms of payment, deliverables, sharing of resources and ownership of intellectual property discovered during the project. In addition, the agreement will normally dictate the period of time for conducting the project. They are terminable and may be even revocable. Such Projects may or may not be awarded through competitive application process.

2.2 Essential Criteria

2.2.1. Inclusion criteria

ICMR reserves independence from influences and conflicts of interest resulting from the contributions and has the discretion to utilise the contributions in furtherance of its aims and objectives. Contributions by any 'Person' shall be considered eligible if it satisfies the following criteria;

a. The Contributor has attained the age of majority i.e. eighteen (18) years
b. Contributor is a company/proprietorship or any other entity duly registered/incorporated under the laws of India or residing in India or is a foreign citizen /national residing in India or a foreign national residing outside India.

   For the purpose of this Terms and Conditions , "Indian Nationality Contributors" shall mean and include Indian citizens residing in India and other entities and bodies incorporated/registered/set-up in India and "Foreign Nationality Contributors" shall mean and include Foreign citizens residing outside India , foreign corporations and other registered bodies, Indian subsidiaries of foreign entities and non-resident Indians residing outside India at the time of making the Contribution ("NRIs").For avoidance of doubt Indian Nationality Contributors and Foreign Nationality Contributors shall hereinafter be collectively referred to as "Contributors"

c. Does not belong to any of the excluded category listed below.

ICMR reserves all rights to make amendments to the existing Terms and Conditions including the manner or conduits of making Contributions without giving prior notice. Contributions made to ICMR are immediate and irrevocable which means ICMR cannot cancel any Contribution effected upon. No refund can be made of the Contribution; nor can the end purpose be changed.

2.2.2 Exclusion Criteria

ICMR shall not accept any contribution from:

1. Political parties
2. Religious entities
3. Tobacco firms or those mainly known for tobacco related products
4. Arms manufacturer or dealer
5. Organisations involved in pornography
6. Alcoholic drinks manufacturers and suppliers.
7. Entities involved in activities promoting Gambling
8. Banned Terrorist Organisations under section 35 of Unlawful Activities (Prevention) Act, 1967**http://www.mha.nic.in/BO**
9. Organisations banned by various countries and International Communities (like UN, EU etc)

10. Any quality of Contribution unacceptable in the Contributor's country shall also be unacceptable to ICMR
11. Contribution by a convict and the Contribution comprises the proceeds of crime

2.3 Category of Contributions

2.3.1 Category A- Untied Contributions (UC)

An unbound Contribution is free from any fixed or generally stated objectives and Scope of work. It gives ICMR the freedom to utilize the funds as per the organisational requirement and priorities. Any amount of Contributions less than or equal to Rupees ten Lakhs shall be considered only under the **Category A** as untied Contribution that is to be handled on case to case basis or according to ICMR discretion. Proposal should be made as per the **Form 1.** Contributions in the form of cash will not be accepted by ICMR.

A contribution can be made by way of;

- Cheque
- Demand Draft
- NEFT
- RTGS

Negotiable instruments shall be made payable to ICMR, New Delhi unless otherwise specified. In no event Contribution shall be made payable to any individual who claims to represent ICMR.

2.3.2 Category B- Purposive Contributions

"Purposive Contribution" (PC) means the Contribution in-term of value i.e it can be either in monetary form or in-kind ("kind" means any Contribution/donation /transfer in form of technology, device, equipment, operating values etc.).

PC in kind towards mutually agreed upon objectives under this Category B can be tangible or intangible. Either the ICMR can call for Purposive Contribution or the prospective Contributor can propose the PC in a particular manner. Proposal can be made through the **Form 2** appended herein.

Purposive Contribution can be in connection with any one or more of the following domains that form the organisational mandate–

a) Communicable Diseases;

b) Non-communicable Diseases;

c) Basic Medicine Sciences;

d) Traditional Medicine;

e) Problems of urban health;

f) Nutritional problems;

g) Reproductive and Child health issues;

h) Public health system;

i) Bio-informatics;

j) Bio-medical Ethics,

k) Any other related areas of medical care

PC in turn can be-

1. A contribution in response to or to address a disease outbreak and shall be termed as –"Crisis Contribution". Such 'Call for Contribution' shall provide the particulars related to the scope and time expectations related to the specific circumstance.

Or

2. A Contribution in response to a program need or to be utilized in a particular domain and shall be termed as- "Categorical Contribution"

Categorical Contributions include;

a. **Monetary Contribution**- Contribution can be made in any manner as provided above.

b. **Technology Know-how and IP rights:** Contribution that grants any right or interest in any Technology Know-how or Intellectual Property developed and owned by the Contributor. The grant of right to ICMR can be full or partial rights, royalty-free licenses (whether exclusive or nonexclusive) with or without further right to sub-license. A sample or guidance template is appended herein as **Form 3.** IP means any right to intangible property, including trade secret, trade mark, patent, design, and plant variety as defined under the Copyright Act, 1957, the Patents Act, 1970, the Designs Act, 2000, the Semiconductor Integrated Circuits Layout-Design Act, 2000, and the Protection of Plant Varieties and Farmers' Rights Act, 2001;

c. **Software:** Perpetual or time bound licenses for any programmes or operating information can be considered by ICMR for taking forward the

ICMR activities. The grant of right to ICMR can be full or partial rights, royalty-free licenses (whether exclusive or nonexclusive) with or without further right to sub-license.

d. **Medical devices, equipment and spare parts, medicines etc.:** Based on the following considerations, Contributions in the form of Medical devices, equipment and spare parts can be called for by ICMR-

- non-availability based on actual local requirements
- the level of technical expertise of available maintenance personnel
- reception, storage and distribution of the Contribution
- recurrent costs implications
- disposal of condemned Contributions
- Assurance and readiness report the contributions are fully operational/ of optimal standard
- Availability of all essential accessories and supplies
- Simplicity of operation
- Non-use of environmentally hazardous substances

e. **Other forms of financial benefit:** Any other direct financial benefits as required by ICMR such as discounted courses, training etc.

f. **Other forms of non-financial contribution**- including technical advisory or manpower.

Purposive Contributions (PC) can be considered for certain time duration for pursuing the common objectives as agreed upon by ICMR and the Proponent based on the relevant Committee's recommendations in the manner stated below. Once the corresponding MOU/ Agreement is duly executed, the designated ICMR Scientist shall administer the Purposive Contribution Project with a specific Project Review Committee (PRC) put in place. The PC may have nominal consideration of 1 INR or single unit monetary value in any currency in order to enable execution of the necessary documents. It will be appropriate for ICMR to summarise Categorical Contribution terms in separate written agreements.

2.3.3 Category C- Foreign Contributions

"Foreign contribution" (FC) means the donation of any currency, whether Indian or foreign from a foreign source. Foreign Contribution (FC) shall be received from legitimate foreign sources. Contributions made by a citizen of India living in another country (i.e., Non - Resident Indian), from his personal savings, through the normal banking channels, is not treated as foreign contribution. However,

while accepting any donations from such NRI, the passport details to ascertain that he/she is an Indian passport holder shall be obtained. Donation from an Indian who has acquired foreign citizenship is treated as FC. This will apply to PIO card holders and to Overseas Citizens of India.

Foreign source, as defined in Section 2(1) (j) of Foreign Contribution (Regulation) Act (FCRA), 2010 includes:-

(i) the Government of any foreign country or territory and any agency of such Government;

(ii) any international agency, not being the United Nations or any of its specialized agencies, the World Bank, International Monetary Fund or such other agency as the Central Government may, by notification, specify in this behalf;

(iii) a foreign company;

(iv) a corporation, not being a foreign company, incorporated in a foreign country or territory;

(v) a multi-national corporation referred to in sub-clause (iv) of clause (g);

(vi) a company within the meaning of the Companies Act, 1956, and more than one- half of the nominal value of its share capital is held, either singly or in the aggregate, by one or more of the following, namely:-

a. the Government of a foreign country or territory;
b. the citizens of a foreign country or territory;
c. corporations incorporated in a foreign country or territory;
d. trusts, societies or other associations of individuals (whether incorporated or not), formed or registered in a foreign country or territory;
e. Foreign company;

(vii) a trade union in any foreign country or territory, whether or not registered in such foreign country or territory;

(viii) a foreign trust or a foreign foundation, by whatever name called, or such trust or foundation mainly financed by a foreign country or territory;

(ix) a society, club or other association or individuals formed or registered outside India;

(x) a citizen of a foreign country;

List of agencies of the United Nations, World Bank and some other International agencies/multilateral organisations, which are not treated as 'foreign source', are available on the website http://mha.nic.in/fcra/intro/FCRA-exemptedAgenciesUN.pdf

2.4 Confidentiality

Truly anonymous Contributions, where there is no information as to its origin and Contributors who opt out of public recognition can be considered by ICMR. For those Contributors who wish to remain anonymous, ICMR will have procedures in place that address how anonymous donors will be coded in the database, how their contributions will be included in ICMR reports.

Confidential information in oral form or on electronic, magnetic or print media will be protected so that the information is not available for anyone except ICMR personnel and statutory authorities to see.

Contribution through any means may result in certain instances of sharing of certain personal information including but not limited to phone number, name, PAN, credit and/or debit card ("Personal Information"). By participating in the Contribution process, the Contributor is consenting to the use of such information, as governed by this Terms and Conditions, by ICMR.

For the purposes of clarity, any information which is publically available and on the public domain will not be deemed as Personal Information. Proof of age, if requested, of the Contributor(s), must be submitted to ICMR (i.e., Birth Certificate, 10th Class leaving Certificate/ School certificate/ passport/ an affidavit signed by a magistrate). The Contributor(s) should additionally declare that the Contributor(s) is duly authorized to make Contributions as understood under these Terms and Conditions under applicable laws. The declaration should affirm that there are no legal incapacities that would render the contribution illegal or invalid in the format provided by ICMR.

The Contributor(s) shall do any and all acts and execute any and all documents in such manner and at such location as may be required by ICMR in its sole and absolute discretion to protect, perfect or enforce any of the proposed contribution.

Contributor acknowledges that in case any portion/clause of these Terms and Conditions is deemed invalid or becomes unenforceable or prohibited by the law of the country, such portions shall be considered divisible and shall not be part of the consideration, and the remainder of these Terms and Conditions shall be valid and binding and of like effect as though such provision was not included herein.

These Terms and Conditions shall be construed and governed in accordance with the laws of India and in case of any dispute or other matter arising in reference to the Contributions shall be referred to a sole arbitrator appointed by Department of Health Research (DHR) and shall be governed by the Arbitration and Conciliation Act, 1996, amended from time to time. The venue for arbitration shall be New Delhi, and the proceedings shall be conducted in English language. All the costs, charges and expenses in connection to the Arbitration shall be solely borne by the Contributor(s) who has raised the dispute. The arbitrator's award shall be substantiated in writing and shall be binding on the Parties.

2.5. Process

2.5.1 Proposal process

Proposals for Contributions (**Form 1or 2**) should be sent/submitted directly to

Dr/Mr/Ms_____, Contributions-in-charge

ICMR

Email-

Any prospective contributor shall fill in the Proposal Form and provide the required details as applicable for different Category.

ICMR shall consider and respond only to such proposals that provide all the required documentation including verification of the Contributor's legal status, purpose of the Contribution, the mandatory declaration and other particulars asked for in the Proposal Form.

Any proposed monetary contribution less than or equal to Rupees ten lakhs shall be considered only under Category A. Any Proposal to Contribute beyond Rupees ten lakhs shall clearly spell about the nature of the Contribution either by way of being untied or tied to the specific field of use stated by ICMR.

Any proposal for Contribution if accepted by ICMR and where Payment has been made shall be treated as irrevocable contribution for all purposes and there shall not be refund of any sort to the Contributor.

In accordance with the prevailing law, any person who makes an eligible Contribution is entitled to get tax deductions subject to conditions without any restriction as individuals, companies or any specific category of taxpayer. If aggregate of the sums donated exceed 10% of the adjusted gross total income, the amount in excess of 10% ceases to be entitled for tax benefit. Monetary contributions either through Cheque, DD or through other digital payment systems will be eligible for a tax deduction. Any contributions made in kind, like equipment, medicines etc., cannot be claimed as donation for tax exemption.

ICMR shall provide a Stamped receipt that states the name of the Contributor, the amount, the Registration number issued by the Income Tax Department under Section 80G and validity on the date of Contribution.

General policy such as this cannot cover in detail the complexity of all possible Contribution scenarios and hence can be supplemented in future with specific context based on periodical review. Contributors will be acknowledged on the ICMR website regarding their Contributions if the same is not restricted in the proposal form. Contributors shall not refer to or use the name ICMR in activities without prior written permission.

2.5.2 Review and Approval Process

Any contribution proposal for a specific activity as submitted by any entity shall be reviewed by the Committee constituted by the Governing Council of ICMR, according with the terms of the present Policy to be termed as "Contributions and Partnerships Committee" (CPC). The terms of Reference for the Committee shall include the following;

- Proposal examination
- Recommendation for rejection or acceptance
- Determination of utilisation based on the specific demands of ICMR
- Fiscal management based on project specifics
- Consider the proposed construction of Research and Development Partnerships
- Review Contributions utilisation on quarterly basis
  And-
- Consider the semi-annual report on the Contributions and Partnerships activities

The Suggested Composition of CPC is provided below*-

1. Additional DG/Sr. DDG- Chairman
2. JS DHR- Member
3. Senior FA, ICMR- Member
4. Head of International Health Division of ICMR- Member
5. Representative of MHA- Member
6. Representative of MCA-Member
7. Civil Society representative- Member
8. One domain expert Member nominated by ICMR
9. One relevant expert Member nominated by ICMR
10. Legal Expert/Consultant
11. Head of ITR Division, ICMR- Member Secretary

*Proper gender balance should be kept in mind while considering the constitution.

The quorum shall be complete with at least 06 members present at any meeting.

The filled in Proposal Forms having the required details as applicable for different Category shall undergo a preliminary scrutiny by the "Internal Contributions Group (ICG)" constituted by the CPC. Additional charge shall be given to any of the Head of the Division and a Scientist to deal with the Contribution till such time a

distinct Unit/Division is put in place. An Administrative Officer/Asst. Administrative Officer shall be delegated to handle the processes related to Contributions. ICG, the initial scrutinising Authority of ICMR shall examine the Proposals and revert within seven (07) working days on the acceptability of the Proposal.

The ICG shall communicate to such Proponents whose Proposals have been considered appropriate for further processing with the CPC with additional documents or particulars. CPC can recommend a Proposal with any suggestions or modifications deemed necessary in the interest of the organisation and the mandate of Contributions under applicable Category.

The approval based on the recommendations of the CPC can be sanctioned by the DG or such Delegated ICMR Authority. Thereafter, the acceptance of the Proposal shall be communicated for processing of the payment of Contributions.

The CPC shall have scrutiny meeting as and when required and shall review the Contributions activity on quarterly basis. The CPC report summary shall become part of the organisation's Annual report. Sub-Committee will report regularly to the GC, including tabling of meeting minutes at GC meetings.

Conflict –of-interest shall mean an interest that a decision maker or any member of the CPC has in connection with a matter for decision or discussion where the decision maker, or a person or entity with whom or which the decision maker is associated, is reasonably likely to receive a benefit or a loss able to be measured in financial terms if the matter is decided in a particular way. A decision maker includes a member of a deliberative body such as a committee. Intention is not relevant to assessing the existence of a pecuniary interest. ICMR shall put in place a due process to address issues of Conflict-of-interest.

Whenever a decision is taken to refuse a donation, it is for ICMR to decide how much detail it gives to the Contributor or other third parties about the reasons for the refusal. Internally it is important to be able to demonstrate that a clearly defined process has been followed and that a decision has been made on this basis.

There will be no appeal process for Contributors who have had a Contribution refused.

2.5.3 Accounting Process

Contributions will be maintained in a separate bank account of ICMR. ICMR shall maintain a separate register of Contributions amenable to audits as per norms.

Inland contributions will be housed in a separate interest bearing account and foreign contributions shall be received in the FCRA account.

Usual basis of accounting will be followed for contributions by which revenue, expenses, assets and liabilities are reflected in the accounts in the period in which they accrue. The basis of accounting includes considerations relating to accrual of income, provisioning of expenses, deferral, allocations like depreciation and amortisation under different heads.

Contribution based accounting books shall be maintained in the following manner;

a. A separate set of books and records will be maintained for foreign and Indian contributions, as per the requirements of the Foreign Contribution (Regulation) Act.
b. Similarly, separate sets of books and records will be maintained for the various projects, departments for implementing its programmes and interventions.
c. Separate ledgers, accounts and records will also be maintained with regard to the various funds representing the various contributions received from various sources and if it was received with or without stipulations and restrictions.
d. ICMR shall submit an annual return, duly certified by a Chartered Accountant, giving details of the receipt and purpose-wise utilisation of the foreign contribution. The return is to be filed for every financial year (1st April to 31stMarch) within a period of nine months from the closure of the year i.e. by 31st December each year. Submission of a 'Nil' return, even if there is no receipt/utilization of foreign contribution during the year, is mandatory. The return is to be submitted, in prescribed Form.

ICMR may hold reserves depending on the type of activity undertaken, how it operates and funds its operations. A reserve is an appropriation of profits for a specific purpose and hence ICMR can carry reserves for future needs- for both short and longer term purposes. Authority for use of Reserves is delegated to the DG in consultation with the SFA of ICMR. The use of Reserves will be reported to the GC at the next scheduled meeting, accompanied by a description of the analysis and determination of the use of the Contribution funds. The Reserves Policy will be implemented in concert with the other governance and financial polices of ICMR and is intended to support the goals and strategies contained in these related policies. In general, reasons to hold reserves can be summarised as follows:

- To fund unexpected expenditure, for example when projects overrun or Un-planned events occur;
- To fund shortfalls in income, when income does not reach expected levels
- To accumulate funds for a major project or mission

Form FC-6 requires the following information to be recorded in case of receipt that will be issued by ICMR:

(i) Date

(ii) Name and Address of the Contributor

(iii) Mode of receipt

(iv) Purpose of receipt

(v) Quantity received

(vi) Approximate value

(vii) Date of intimation sent to Central Government

In case of contributions received in kind, the approximate value is required to be mentioned in Form 6 and is also required to be reported in Form FC-3.

ICMR shall 'red-flag' potentially unacceptable Contributors and automatically reject any proposal from them.

Repeat Contributors need not go through a review each time they give a proposal till two years from the date of the last Contribution.

2.5.4 Utilization guidelines

(A) Utilization of Grant-in-aid received from GOI shall be strictly as per the government norms as issued from time to time.

(B) Utilization of funds received in form of Contribution by ICMR can have certain flexibilities in accordance with the corresponding PC terms or other separating Agreements. Flexibilities in utilisation may include spending on travel, procurement of goods and services and other contingency.

Process of flexibility consideration can be approved by DG, ICMR based on the recommendations of the CPC. Certain flexibilities can also be referred to under the Program Implementation Unit Establishment Chapter of this Policy.

2.5.5 Record -Keeping Process:

A full and accurate record of ICMR Contributions will be created, captured and maintained in systems with appropriate recordkeeping functionality and controls. ICMR is obliged to create, maintain, preserve and dispose off records to comply with Right to Information and regulations related to public records, privacy and evidence. Contribution records will be destroyed in accordance with ICMR weeding and record disposal policies, procedures and guidelines issued by the Government of India. Records will not be destroyed if they are required, or are reasonably likely to be required in current or future litigation.

3. Policy for Partnerships

3.1 Principles and scope of the Policy on Partnerships

The fundamental principles that govern the Partnerships with ICMR are;

a. ICMR is uniquely positioned to collaborate as enabling Partner to various national, international and interdisciplinary entities
b. Collaborative approach is recognized as an essential component of knowledge development and is vital to promotion of scientific solutions for issues of social relevance
c. Dissemination of research findings is best made possible through fostering the creation of partnerships and collaborative relationships
d. Exchange of organisational best practices by facilitating access through new Partners
e. Build the Project specific fund utilisation guidelines

Partnership with ICMR in the Health Sector can address any of the following:

a) Undertaking basic and applied research and development activities

b) Therapeutic agents

i. Development of single molecule based drugs for diseases of National and International interest [entirely new or me-too kind]
ii. Development of biologicals as therapeutic agents
iii. Development of vaccines
iv. Development of herbals [botanicals] as therapeutic agents
v. Development of combination therapies
vi. Development of new targets for each disease
vii. Development of existing off patent targets

c) Drug delivery systems including special formulations

d) Diagnostics

i) New targets for each disease

ii) Existing off patent targets

iii) Diagnostic kits

e) Medical Devices

f) Medical technologies

i) Instruments

ii) Stem cell based technologies

iii) Tissue Engineering

g) Elucidation of drug mechanisms

h) Exploitation of Bioinformatics

i) Bio repository

j) Big data analytics

k) **Processes-** New / modified chemical and biochemical manufacturing processes, downstream processing particularly separation and purification of bio-molecules

l) **Support activities**

m) In vitro and in vivo testing [including knock-out animals, etc.]

i. Conducting clinical trials

ii. Biosafety and Toxicological Investigations

iii. Validation of diagnostic kits

n) Creating awareness, capacity building and community interventions

o) Alternate/ indigenous systems of medicine

p) Health systems Management and Research

q) Preventive and promotive aspects

r) Any other related areas

Each component of this vast spectrum of activities as stated above offers an opportunity of collaboration and partnership. The ICMR has enormous pool of expertise and infrastructural facilities, which provide various possible mechanisms for ICMR interactions. The pre requisites for enabling partnerships primarily include-

- Matching of interests
- Professional dealings to define the problems to be addressed, commitment of the work on each side. timelines and the deliverables
- Proactive management approach in order to encourage wide angle interaction and fund utilization based on project specifics

- Long term relationship for larger public interest and towards access of the Project results
- Generation of empowering, flexible and rewarding research environment

Based on the spectrum of Interactions and the issues involved there can be-

i) Transfer of existing IP, know-hows, technology developed by ICMR using its own resources (fully or partially developed)

ii) Validation of the IP, know-hows, technology developed by the partnering entity by ICMR using its own resources

iii) Joint development by ICMR and the Partner entity/entities

iv) Consortia establishment for developmental agenda

v) Any other mode of Partnership

This policy shall apply to all partnerships proposed by any likeminded organisation or invited by ICMR to undertake an overarching collaborative Research or Consultancy that will either pool the mutual resources and share the responsibilities or utilize the ICMR resources and expertise respectively. The partnerships can be of any category;

1. 'Research and Development Partnership or
2. 'Consultancy' or
3. 'Government Owned and Company Operated Facility Partnership (GOCO)' or
4. 'Program Implementation Unit (PIU) establishment' or
5. 'Incubator/Accelerator Partnership'

The policy is for development and implementation of organisational partnerships in any domain to pursue the ever-increasing opportunities of comprehensive research at all phases as provided below;

Phase I. Initiating the Partnership

Phase II. Determining the general Memorandum of Understanding terms

Phase III. Specific Agreements execution conditions between the Partners

Phase IV. Implementing the Partnership Project

Phase V. Monitoring and evaluation of the Project

3.2 Process

ICMR consistently encourages team spirit among Scientists of the organization in the mode of collaborative and value added partnerships wherever possible. ICMR can identify any potential partnership through internal discussion and extend invitation in potential research topics of interest to leaders of involved organizations. Individual Departments through the initiating Scientist can submit the proposed thrust areas and the mode of expected Partnership to the Partnership Assessment Group (PAG). The PAG shall be constituted by the DG, ICMR at HQ. Institutions and the Centres of ICMR can identify a Partner in the areas of their operations and submit the Proposal to the PAG. The resultant invite can be open or limited.

ICMR can also consider any proposals received from other organisations or Companies with specific strategies and activities that are in line with the ICMR mandate. ICMR and the potential Partner will determine the aims/purpose/goals, fund utilisation guidelines and desired outcomes of the proposed Project considering the perspectives of each partnering entity thereafter and then implement the Project Components.

Any Partnership proposal shall undergo the initial feasibility analysis by the PAG along with the initiating department based on the proposal or response to ICMR invitation. Such proposal for a specific partnership activity as invited by ICMR or submitted by any entity along with the feasibility report shall be considered further by the "Contributions and Partnerships Committee" (CPC) as specified under the policy for Contributions. The terms of Reference for the Committee shall include the following;

- Proposal examination
- Recommendation for rejection or acceptance
- Determination of utilisation based on the specific demands of ICMR
- Consider the proposed construction of Partnership arrangements
- Review Contributions utilisation on quarterly basis

And-

- consider the semi-annual report on the Contributions and Partnerships activities

The CPC will consider the following aspects;

- Significance of the research problem in line with organisational mandate
- Scientific and strategic benefits of the proposed Partnership
- Determine what contributions the outcomes will make to practice and knowledge of the proposed arena
- Determine presence of conflict-of-interest if any between the interests of the ICMR and the Partnering entity and address the same
- Assessment of the regulatory requirements for all aspects of the proposed project

- Identify and assess technical, financial and personnel resources needed and available to complete the research project-in-partnership
- Definitive roles and responsibilities of the Partnering entities
- Establish a process for intellectual property governance, publications, product distribution, pricing of healthcare product or services
- Provide for the Joint monitoring of the objectives and milestones of the proposed Project
- Outlined timetable for the project
- Adaptation and flexibility related to the project or changes that may be required for fund utilisation.
- Determine mechanism for pre-term exit scenarios
- Dispute Resolution mechanism

Based on the recommendation of CPC, ICMR will enter into a Memorandum of Understanding (MOU) with the Partnering Entity. The MOU is usually non-binding in nature unless specified otherwise and shall provide for the general scope of the proposed Partnership model and shall pave way for further separating agreements on mutually agreed upon terms and conditions. A model MOU is provided herewith as guidance and can be tailor made to reflect the partnership's specific minutia there under the corresponding headings (**FORM 4**).

Foreign Source as defined earlier shall abide by the statutory requirements while entering into any Partnership with ICMR.

3.2.1. 'Research and Development Partnership' (RADP)

'Research and Development Partnership', (RADP) may be for joint development by ICMR and the Partner entity/entities or for Consortia establishment.

PRINCIPLES

Basic principles for consideration of RADP shall include;

a. Joint role in addressing the underlying problem

b. Joint contribution in the Project developments

c. Pooling of resources

d. Mutually agreed upon fund utilization guidelines and IP governance

e. Sharing of the benefits

f. Societal access to the results of the research

The Partnership can be proposed at any stage-before proof of concept (POC) or after the POC. Any novel, fundamental research discoveries at early stage, technologies in early

clinical studies and research tools developed by ICMR can be taken for further development by any relevant third Party (public or private) OR *Vice-versa* under this category. The prime aim of such Partnership includes;

1. Exploration of new knowledge in the domain of public health
2. Identification, evaluation, protection. Licensing and marketing of ICMR/Partner developed technologies
3. Effectively administer benefit sharing and related progress
4. Steering of R&D funds from different sources

The governance of the results of the RADP Project accordingly will depend on the extent of intellectual contributions and sharing of resources by the Partners thereto and the same shall be agreed upon before initiating the execution of Project components. The following are the points that will guide the governing strategy;

1. Products should be developed for public health
2. Appropriate return on public investment should be ensured
3. Only specific and necessary rights are to be granted to the Partner for ensuring use of technology in any field of use
4. The obligations of the Parties should have enforceable milestones

ICMR can provide for any one or more of the following options based on a case to case evaluation of the underlying factors and national interest;

a. Royalty free licenses for further research by ICMR and its Institutes/Centres
b. Commercialisation condition in India at differential pricing
c. Preferential consideration for integration with the relevant national/global health care programmes in consultation with Health Ministry
d. Supply commitment for Project related goals even beyond the Project duration, technology transfer and training as required under the RADP mandate
e. Subsidy of any sort
f. Joint ownership of the Project IP, IP generated during the RADP Project implementation excluding the background IP
g. First right of refusal
h. March-in-rights
i. Preferential supply commitment in cases for national public health emergency
j. Any other benefit sharing terms based on Project specifics

The effective period of the RADP Project shall have both the Project duration component and the validity component. The end of the timeline for executing the Project activities shall be considered as the Project duration and the period till which any sort of governance including that of the IP or unutilised funds shall be considered for validity period. The Effective date of the Project shall usually be the date of execution by the last of the Party thereto unless specified otherwise.

Every RADP implementation agreement shall be individually examined to determine the Clauses and the underlying conditions well before the execution in order to avoid ambiguity and potential conflict. Taking the time to think through and discuss the terms of the RADP Agreement helps foster communication between Partners and sets the project on a path for success and attainment of ICMR mandate.

In case of commercialization of the products developed by ICMR should consider distinct acknowledgement that the underlying technology is a joint development with ICMR with the disclaimer that there is no implied or express liability for the product.

3.2.2. Consultancy

Consultancy can be for-

A. Engagement of any third Party for further research/development/validation of the IP, know-how, technology developed by ICMR or its Institutes and centres

B. Provision of ICMR resources for further research/development/validation of the IP, know-how, technology developed by any third Party

C. Provision of Expert Advisory by ICMR

ICMR scientists, while working on their own, may obtain results which are commercially exploitable and can be passed on to Industry either for immediate commercialization or for further development. The know-how to be transferred may be protected (through patents) or proprietary in nature. For transferring such partially or fully completed know-how to Industry, the following may be the guiding principles –

i. The project is developmental and ICMR, on its own cannot complete the value chain due to the necessity for additional infrastructure and/or expertise.
ii. The Industrial Partner or any third Party has the necessary facilities and expertise which the ICMR lacks pertaining to the developmental work.
iii. The Licenses/transfers should be based on “non-exclusivity”, though, there should be flexibility to give exclusive rights under justifiable circumstances.
iv. The terms for grant of rights can be negotiated as a lump-sum amount and/or Royalty based on the foreground costing as per the table given below and the market reach.
v. The Sharing of the resultant net benefits through the grant of rights can be as per the governing agreement or as per the prevailing ICMR IPR Policy

TABLE-1

Calculation of foreground costing for Existing Know-How/technology/IP of ICMR shall be based on the aspects as given hereunder:

1	Cost of man-days of various contributors based on man-day charges
2	Cost of Consumables used
3	Cost of Services
4	Equipment usage cost, if the use of an equipment has been heavy
5	Expenses incurred on outsourcing, if any
6	Cost of IP protection & maintenance

The above guiding principles are indicative and any deviation therefrom can be based on justifiable case specific facts and circumstances. A template for Royalty Agreement is appended hereto this Policy.

Sometimes the third Party may have developed anIP, know-how or technology which requires further testing and analysis, validation and other services to be carried out using the resources and expertise of ICMR and its Institutes and Centres. The general principles in such Consultancy Research arrangements include:

I. ICMR has the necessary facilities and expertise pertaining to the developmental work proposed in terms of recurring and non-recurring budget specifications
II. The cost for the scope of ICMR work is adequately covered by the Partner proposing the Consultancy Research
III. If there is any scope for new IP generated during the Project implementation due to the ICMR intellectual contribution, then, such Project specific 'New IP' shall be on joint ownership basis and terms accordingly can be determined through a separate Agreement
IV. ICMR's right to publication shall be preserved subject to IP protection
V. Periodic payment arrangements shall be based on the mutually agreed upon milestones
VI. Limit on the time spent by a scientist- No scientist can spend more than fifty two working days in a year on Consultancy. Should the work require more than fifty two man-days, another scientist having requisite expertise may be assigned as a joint consultant
VII. The charges for Consultancy should be at least three times the man-day salary of the scientists involved
VIII. The sharing ratio of the earnings and the benefits due to Consultancy shall be determined on case to case basis by the CPC.

3.2.3. Government Owned and Company Operated (GOCO) Facility Partnership

A GOCO partnership allows each partner to perform distinct implementation components for which it is uniquely suited.

Examples:

1. The Government establishes mission areas, and the private sector Partner implements the missions, using best business practices.

2. Government owns the laboratory site, the buildings, and the equipment; the Partner provides the employees and managers.

The GOCO Contract/ Partnership allows fixed budget, defined production and pre agreed processes. Operating Partners can be of any number.

3.2.4. Program Implementation Unit (PIU) establishment

Mission oriented projects ideal for handling specific problems, which require facilities and expertise scattered all over the country in different Institutions belonging to different organisations and vast networking, generates, in essence, a Virtual Organization, which may receive funds from a single or multiple government agencies. In some cases, it may receive funds even from Industry. Such long term project governance structure can necessitate establishment of Program Implementation Cell at ICMR (alternate reference terms include- Mission Implementation Cell, Network Developmental Unit, Consortia Establishment, Program Management Unit).

PIU establishment thus involves;

- Identification of proposed mission/ program/ focus area

- Selection of different partners

-Generation of a joint proposal by ICMR CPC

- Application and sanction of funding

- Determination of Implementation Framework

- Nodal Officer and Monitoring and reporting mechanism

- Realizing the deliverables and making them accessible to public

Anyone making a suggestion for PIU Establishment can send a one to two page note explaining why he/she considers the idea to be important. Only such ideas need be suggested which if successful, lead to entirely new products which could make a national/international impact. The note should identify the various gross components and work elements involved in the project/program and also identify the potential participants

having requisite expertise and infrastructure. It is examined by the CPC. The PIU proposal after incorporation of the required particulars thereafter can be processed for funding applications. The Governance Framework for every PIU shall be clearly stated in the proposal. The underlying Letters of Intent (LOI), Memorandum of Understanding (MoU), Acceptance Term Sheets (ATS) or Expression of Interest (EOI) shall become integral part of the finalized PIU proposal. The funds for the PIU after due sanction may be received by ICMR on behalf of all participants. These funds are then disbursed to all participating institutions or implementers. One of the ICMR authorized personnel will be the 'Nodal Officer' who will be the link between the PIU and the ICMR governance structure. The Primary structure for PIU governance shall be a 'Secretariat' housed at ICMR or such approved location. The operational head of the PIU shall be the Mission Director/ Team Leader (Senior Consultant Level). The two cardinal components of implementation- Technical & Finance shall be administered by a Program Core Committee (PCC).

PCC may have the following constitution;

- DG, ICMR - Chairperson (ex-officio)
- Additional DG, ICMR -*Member ex-officio*
- JS, DHR- *Member ex-officio*
- Sr. FA (ICMR) - *Member ex-officio*
- Representative from DBT - *Member ex-officio*
- Representative from DST - *Member ex-officio*
- Representative from M/o H&FW – *Member ex-officio*
- Representative from CSIR - *Member ex-officio*
- Representative from DRDO - *Member ex-officio*
- Head of the ECD Division, ICMR
- -ITRC officer
- Chair of TECs for Vaccine, Diagnostics, Therapeutics, Implementation Research
- Nodal officer from ICMR - *Member ex-officio (Member Secretary)*

A High Level Advisory Board shall be the primary Advisory Body having all the expertise (National and International) required for the program. Some of the work in such PIU establishment would be done in an independent mode whereas the rest would have been conducted in an interactive mode. The nature of IPR will therefore be varied. Some patents may have inventors from only one organisation whereas the others may have multi-organisational inventors. All decisions regarding the technical, IP, progress, pre-exit etc. shall be taken by the Programme Core Committee and the decisions made by the committee are to be forwarded through the nodal officer of ICMR for necessary action.

3.2.5. Incubation or Acceleration Facility for enabling Innovations

Incubation or Acceleration facility for enabling Innovations will be established by ICMR. ICMR will put in place the requisite physical infrastructure (shared/specific) such as laboratory and workshop facilities, utilities, support services, pre-incubation services, networking, mentoring, other facilities and will put in place a core team/supporting staff for its successful operations.

The Facility will be established after due execution of a Joint Effort Agreement between the stakeholders and will provide for a transparent policy for selection, housing and exit of Incubatees and start-ups.

The translational model can be any of the following models provided for hereunder-

a. Setting up of ICMR Technology Incubation Center to implement the Scientific Entrepreneurship Scheme

ICMR may consider commercialisation of inventions and innovations in terms of the Scientific Entrepreneurship Scheme brought forth vide. Office Memorandum dated May 25, 2009 bearing file no. 3/3/2009-TU/V/Knowledge-to-equity issued by Department of Scientific and Industrial Research, Government of India. The OM is Place as Annexure II to this policy for reference and for broad guidelines for implementing the scheme. ICMR in due course can establish a Special Purpose Vehicle (SPV) for translational functions of ICMR innovations on specific governance terms and after due approval either in collaboration with other Public funded institutions or Private sector funded institutions or in Public Private Partnership (PPP) mode.

b. Shared core facilities in ICMR institutes and centres

Each of the ICMR Institutes and Centres can identify such Central and core facilities that can be pooled for common innovation enablement purpose and can be termed as 'Innovation Incubation Cells' under the existing Research Section of the entity. Facilities and space of these Cells shall be shared among the incubated scientific personnel of all/other ICMR Institutes and Centers

c. Model where Third Party Incubator will house ICMR as the Umbrella Incubatee

ICMR can enter into an umbrella arrangement with any other Government funded or not-for-profit Incubator in order to enable any of the ICMR Institutes and Centres in the vicinity to become Incubatees. Required facility/ services/ space can be availed on the prevailing/ negotiated terms of incubation or early stage acceleration.

3.3 Terms and Conditions for Partnerships

The ICMR can either use institutional formats or the Partners' proposed standard formats for the purpose of entering into the initial MOU or the definitive agreements thereafter in order to enable partnership implementation.

The cardinal principles while scouting for Partners/collaborators/ licensees include;

I. Reservation of the right to "NON-COMMERCIAL RESEARCH PURPOSES" in favour of ICMR and its Institutes at all occasions.
Note: "NON-COMMERCIAL RESEARCH PURPOSES" means: Use or practice of Licensed Patent Rights (LPR) for academic research and other not-for-profit or scholarly purposes which are undertaken at a non-profit or governmental institution that does not involve the production or manufacture of products for sale or the performance of services for a fee.

II. Exclusive licenses if required, should be structured in a manner that encourages technology development and use.

III. Licensing of "future improvements" where the background IP is with ICMR should be minimized.

IV. Conflicts of interest related to Partners should be effectively managed.

V. Enforcement action and legal remedies should be carefully considered while entering into Partnerships

VI. Provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for the developing nations should be considered for incorporation wherever possible.

VII. The prime aim of a partnership implementation Agreement is to also establish a harmonious relationship among the participating stakeholder entities and will have the essential sections on: (1) statement of objectives, (2) Research Plan, (3) General provisions, (4) Budget, and (5) Specific terms for governance and boilerplates. Partnerships grow and change; this invariably leads to the need for amendments. Even best collaborative research agreements need numerous amendments in order to reflect the evolving needs of the parties involved. Hence any amendments can be brought on record through supplementation to the original implementation agreement. ICMR and the partnering entity can also have specific governance frameworks on governance related to IP, Commercialisation and other benefit sharing for the results of the Project in addition to the main Agreement for bringing more clarity and to determine the mutually agreeable process.

Note: Research plan should have the partner specific activities and team construct, implementation site, built-in indicators, quantifiable deliverables, timelines and communication strategy, list of materials exchanged along with the details of the background intellectual property brought on board by each and every Partner.

VIII. A specific clause on confidentiality should be considered as integral part of the governing agreement. It is important for the collaborative research agreement to differentiate between two types: (1) confidential information that a party brings into the project and that predates the agreement, and (2) confidential information that is generated under the agreement and that the parties generated while working together and conducting project experiments.

IX. Boilerplate and eventuality Clauses can include the indemnification, foreclosure, force majeure and the termination clauses. The term 'boilerplate' refers to the foreseen and unforeseen risks due to which the interests of ICMR as enabling entity of Government of India should be protected and such conditions due to which any of the Parties can pre-exit the Agreement.

X. Acknowledgement Clause-If the third Party engages ICMR under CRV, it shall acknowledge the ICMR assistance while publishing, marketing the resultant Product or presenting in any manner the details of the Project, its progress or its success along with the "Disclaimer" that reference therein to any specific commercial product, process, views or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or assuming liability of any sort by ICMR.

XI. Governing law and Dispute Resolution mechanism for Partnership Arrangements:

If all the Parties are Indian entities, then the substantial and procedural law shall be the Laws of India subject to the exclusive jurisdiction of the courts at Delhi. If the Partners are multinational entities, effort may be made to retain the Indian governing law and the jurisdiction. If the foreign governing law or the jurisdiction cannot be negotiated, then an Alternate Dispute Resolution mechanism through an Institution of International repute can be incorporated into the agreement along with the standard governing law clause of such international partner.

Even the foreign jurisdiction clause can be accepted by ICMR provided that the interests of the organisation is adequately protected in the terms therein. Arbitration Clause having vague terms should be avoided. To the extent possible the standard arbitration clause prescribed by the proposed institution should be followed in its entirety.

Agreements having all Indian Partners can consider inclusion of the Arbitration provision as given below by the International Center for Alternate Dispute Resolution (ICADR), an autonomous organization working under the aegis of the Ministry of Law & Justice, Department of Legal Affairs, Government of India;

Note: STANDARD CLAUSE ON DISPUTE RESOLUTION AND ARBITRATION

"In the event of any dispute or difference between the Parties hereto upon or in relation to or in connection with this Agreement, such dispute or difference, shall be resolved amicably and in good faith by mutual consultation.

If such resolution is not possible, then the unresolved dispute or difference whatsoever arising between the Parties out of or relation to the construction, meaning, scope, operation or effect of this Agreement or the validity the breach thereof or in respect of any defined legal relationship associated therewith or derived there from dispute shall be submitted for arbitration to International Center for Alternate Dispute Resolution (ICADR), an autonomous organization working under the aegis of the Ministry of Law & Justice, Department of Legal Affairs, Government of India. The Authority to appoint the arbitrator(s) shall be the ICADR. The Arbitration under this Clause and provision of administrative services by ICADR shall be in accordance with the ICADR Arbitration Rules, 1996. The award made in pursuance thereof shall be binding on the Parties. The venue of arbitration shall be New Delhi and the arbitration proceedings shall be conducted in English Language. The provision of this Clause shall not become inoperative notwithstanding the Agreement expiring or ceasing to exist or being terminated or foreclosed".

XII. IPR provisions

Research/internal use of the technology, its commercial application, biological material which forms the subject matter, any inter-institutional arrangements to consider, interests of the Government and the general public, proposed commercialization plan and any other relevant factors shall determine the mode of licensing , whether exclusive or non-exclusive.

Associated with the transfer of know how are finance related issues like lump sum charges, quantum and period of Royalty payment as well as the period of exclusivity, if any. Though all these are eventually decided through the process of negotiation, it is useful to have this policy, which can be helpful to those who negotiate on behalf of ICMR. Non-exclusive licensing will be the general norm. Exclusive licensing as a strategy can be considered in situations where desired practical application of technology has not been achieved and may not be achieved under a nonexclusive license, where competition in market place will not be substantial, where there is core-Competency and commitment to bring Product and/or Service to Market by a specific licensee, or any other justification pertinent to the peculiar facts and circumstances and have win-win result. Auction as a method may also be explored exclusive transfers by ICMR. For unprotected knowledge, it may be reasonable not to always expect Royalty, instead a high Lump sum amount may be charged as is feasible during the negotiations. If Royalty is

agreed to in such cases, it can be low and for a relatively short period of around five years. On the other hand, if the know-how involves considerable novelty and is supported by appropriate IPR protection, not only Lump sum payment, but also Royalty be charged at a relatively high percentage. Further, the Royalty in such a case should be for the life time of the patent, as far as possible. Milestone lumpsum payments should be agreed to, if the invention needs to pass through further regulatory procedures as well as possible further development. Here again, decisions have to be taken on the merits of each case.

3.4 Delegation of Power (DOP) for Translational Partnerships

RACI model–Detailed as Annexure III

- R=Responsible personnel/ initiator and recommendatory body
- A= Approving Authority
- C=Concurring Authority (Finance/legal)
- I= Information if any to be provided to such Authorities after due approval/sanction

4. Policy for Data Sharing and Public Disclosure

Research outcomes developed with ICMR funding should be made available to the research community for furthering research and to the public for broad access. Data sharing plan for the Projects and Programmes may vary depending on the nature of the data being generated and collected and in consideration of essential information as to:

(1) What is the description of the data that will be shared?

(2) Who will have access to the data including storage and edits?

(3) Where will the data to be shared be located and the custodian obligations?

(4) When will the data be shared and retrieved?

(5) How will the stakeholders access the data?

To optimize the benefits of public access and media dissemination, any ICMR Official may issue press release, make public statements regarding Contribution or Partnership or responses to queries from the news media and other third Party or channelize research results. Such outreach measures shall bein accordance with the Media and Publication Policy of ICMR.

5. **Annexure**(s)

5.1 Guidelines on Fund Utilization From Non-Government/ Partner Sources

a. Hiring of technical/expert and ad-hoc Consultants- The criteria and mode of expert and ad-hoc Consultant selection shall be determined based on the specific Program requirements and skill sets for specified time period. The recommendations shall be further considered by ICMR.
b. Any technology acquisition will be determined on the basis of expected utility, the ability to deliver and support the solution, platform infrastructure, application integration, implementation processes and resources, training and knowledge transfer approaches essential to attain mission objectives. Technology for the mission can be considered either through call for Proposal or from proposals submitted through willing Partners on their own. Based on the specific recommendation for a technical Partner pertaining to specific mission objective, ICMR can consider due sanctioning.
c. Procurement of equipment and services shall be considered in the following manner;

   -Procurement may be undertaken internally through ICMR as per prevailing norms.

   -The Collaborating Partners may also procure the required equipment/ services/ expertise and contribute the same for a Program/ Project after due approval of the relevant Committee.

d. The travel of the experts for any relevant Committee may be in accordance with the co-funding/partnering agreement if any having specific governing Clause that is mutually agreed upon. In case of the funds generated from Non-Government/International partners, the travel of the experts will be undertaken by the cheapest airlines including non-Air India in view to expedite convening the meetings even at shorter notice.
e. Travel class of invited International experts to attend meetings in India to be decided by the relevant Committee.

5.2 OM of 2009 – Scientific Entrepreneurship Scheme

Annexure II (Separate PDF file)

5.3 Delegation of Powers - Partnerships

Annexure III

S No	Activities	R	A	C	I	Timeline
1.	**IP generation /Lead generation** • Identifying type of IP, • Conducting prior art search, • Reporting the outcome	Inventors with IP &Tech Coordinator	Director of concerned institute (Submission of report)	Head Quarter (for filing write to ITR division and then send to DG for approval)	• Internal Finance • Project file • Report to the GC • ICMR main file	Minimum one and half month or on case to case basis
2.	**Scouting for Market potential and Partners** • Commercial value, • Market size, • Potential players, • Draft a report for submission • Identified Partner	Inventors/ By IP& Tech Coordinator	Director of concerned institute (Submission of report)	Head Quarter (submit to ITR division)		Over 3 months in each case
3.	**Technology validation** • Send the tech to R&D divisions of other labs on case to case basis	Inventor initiated third party validation	Director of concerned institute (Submission of report)	Head Quarter (submit to ITR division)		Few months to over a year depending upon the technology.
4.	**Evaluation of scouted partners and EOI** • Determination of EOI terms	IP& Tech Coordinator shall send approved reports of market potential and technology validation to the ITR Division Hqrs.	Committee at Hqrs. (placed before committee)	Final approval by DG ICMR		one and half month or on case to case basis

5.	**Dossier preparation** To evaluate the appropriateness and completeness of the sensitive information to be given to Company as SOP for manufacturing.	Inventor& IP& Tech Coordinator representative along with the identified Partner	Finalized and checked by Director and its committee	Committee at Hqrs. &Final approval by DG ICMR		one and half month or on case to case basis
6.	**Pre exit issues such as foreclosure or termination of an arrangement**	Identified by the dealing Division	Final approval by DG ICMR	Committee at Hqrs.		15 days from Committee reference
7.	**Receipt of benefits including Royalty**	Project or Programme Framework based evaluation	Final approval by DG ICMR	Committee at Hqrs.		one and half month or on case to case basis
8.	**Projection of innovation/Technology/Partners/ products/showcase**	In line with media or Public access policy	Final approval by DG ICMR	Committee at Hqrs.		15 days from Committee reference or on case specifics

5.4 Formats, Forms and Standard Templates

FORM- 1

Proposal Form

(Unbound Contribution)

Contributor (please print or type)

Name _____

Address _____

Zip Code _____

Phone 1 | Phone 2 _____

Fax | Email _____

Contributor Information (documentary proof to be attached as pdf file with the proposal form)

Nature of legal entity (individual/company/LLP/organization/Society/Trust)-

PAN card details-

Age proof for individuals -

Contribution Information

It is proposed to contribute a total of _____ to be paid to ICMR as unbound contribution after having read and understood the nature of such contribution.

This contribution will be made in the form of: ☐DD ☐cheque☐NEFT/RTGS ☐other form of digital transaction.

Statement of Purpose for the contribution: _____

_____

Acknowledgement Information

Please use the following name(s) in all acknowledgements (Please specify)-

☐I wish to have the Contribution remain anonymous.

DECLARATION	
It is hereby declared that the statements made above are true and the Contribution as proposed herein does not suffer from any legal incapacity that will render the same invalid under the prevailing laws of the land. The source of the Contribution s lawful and is not as a result of any criminal act. It is confirmed that there exists an entitlement with the Proposer to make the present Contribution in accordance with the policy for Contributions. Nothing material has been concealed therefrom. I indemnify ICMR in the event of all legal consequences that may arise from the present contribution proposal.	
Signature(s)	Date

FORM 2

Proposal Form

(Purposive Contribution)

Contributor (please print or type)

Name _____

Address _____

Zip Code _____

Phone 1 | Phone 2 _____

Fax | Email _____

Contributor Information (documentary proof to be attached as pdf file with the proposal form)

Nature of legal entity (individual/company/LLP/organization/Society/Trust)-

PAN card details-

Age proof for individuals -

Contribution Information

It is proposed to contribute a total of _____ to be paid to be to ICMR as unbound contribution after having read and understood the nature of such contribution.

This contribution will be made in the form of: ☐DD ☐cheque☐NEFT/RTGS ☐other form of digital transaction.

Statement of Purpose for the contribution: _____

_____

_____

Area of Purposive Contribution _____ (Please specify from any of the below mentioned areas)

a) Communicable Diseases;

b) Non-communicable Diseases;

c) Basic Medicine Sciences;

d) Traditional Medicine;

e) Problems of urban health;

f) Nutritional problems;

g) Reproductive and Child health issues;

h) Public health system;

i) Bio-informatics;

j) Bio-medical Ethics,

Acknowledgement Information

Please use the following name(s) in all acknowledgements: ___

DECLARATION It is hereby declared that the statements made above are true and the Contribution as proposed herein does not suffer from any legal incapacity that will render the same invalid under the prevailing laws of the land. The source of the Contribution is lawful andis not as a result of any criminal act. It is confirmed that there exists an entitlement with the Proposer to make the present Contribution in accordance with the policy for Contributions. Nothing material has been concealed therefrom. I indemnify ICMR in the event of all legal consequences that may arise from the present contribution proposal.		
Signature(s)		Date

FORM 3

Proposal Form

(IP/ software - Categorical Contribution)

Contributor (please print or type)

Name

Address

Zip Code

Phone 1 | Phone 2

Fax | Email

Contributor Information (documentary proof to be attached as pdf file with the proposal form)

Nature of legal entity (individual/company/LLP/organization/Society/Trust)-

PAN card details-

Age proof for individuals -

Contribution Information

Statement of Purpose for the contribution:

A description of the qualified intellectual property (IP) /software in sufficient detail to identify the property

The scope of the contribution in terms of the rights and interests including the proposed effective date and the governing terms

The documentation requirements that ICMR should undertake in order to formalize the Categorical Contribution

Acknowledgement Information

Please use the following name(s) in all acknowledgements: ___

DECLARATION It is hereby declared that there is no legal incapacity that will render the present contribution illegal. The source of the Contribution is lawful and is not as a result of any criminal act. It is confirmed that there exists an entitlement to make the present Contribution in accordance with the policy for Contributions and that the particulars stated above are true to the best of my knowledge.	
Signature(s)	Date

Form 4

Memorandum of Understanding model Concerning the establishment of a Research and Development Partnership between Indian Council of Medical Research (ICMR) and ++++++++++++++++++ (Partner)

This Memorandum of Understanding (MOU) is made on this _____ day of _____2017 (Effective Date) BETWEEN _____(hereinafter called ICMR which expression shall include its successors-in-interest and assigns) of the One Part.

AND

_____having its Registered Office at ++++++++++++++++++++++++++++ (Hereinafter called 'PARTNER' which expression shall include its successors-in-interest, liquidators, administrators and permitted assigns) of the Other Part.

WHEREAS ICMR has been charged with the mandate to promote research in health care sector and further to provide all other policy and institutional support for all contributing stakeholders.

WHEREAS PARTNER is ==========.

WHEREAS both ICMR AND PARTNER shall be collectively referred to as Parties

WHEREAS The Partner is desirous to undertake a Research and Development Partnership Contribution (RADP) to the Project/ program/ mission in association with ICMR that has the objective to support;

1. medical scientific research in India and to promote and assist institutions for the study of diseases, their prevention, causation and remedy.

2. bio-medical research, the propagation of knowledge and experimental measures in connection with –

a) Causation, mode of spread and prevention of Communicable Diseases;

b) Non-communicable Diseases;

c) Basic Medicine Sciences;

d) Traditional Medicine;

e) Problems of urban health;

f) Nutritional problems;

g) Reproductive and Child health issues;

h) Public health;

i) Bio-informatics;

j) Bio-medical Ethics, and

k) Other relevant biomedical aspects.

AND WHEREAS the Parties hereby express their wish to mutually benefit, develop and structure their cooperation in areas of common concern and decide to work together towards the shared goal of eradicating the tuberculosis through the areas covered by the MOU.

NOW THEREFORE IT IS AGREED BY AND BETWEEN THE PARTIES AS FOLLOWS:

1. OBJECTIVE OF THE MOU

The prime objective of the MOU is for PARTNER to ==========.

2. PERIOD OF THE MOU

This MOU would become effective from _____ and shall be valid initially for a period of three years from the date of this MOU. The MOU may be renewed for further periods by mutual consent.

3. ROLE OF ICMR

i. Provide necessary support to PARTNER to undertake the activities and tasks in furtherance of realizing the objective of this MOU.
ii. To review and add more activities or increase the scope of the engagement in consultation with PARTNER.
iii. Closely liaise with PARTNER for developing the health research capabilities

4. ROLE OF PARTNER

In order to facilitate the delivery of ICMR's mandate, PARTNER would undertake the following roles, activities and tasks;

i. to
ii. to
iii.

5. INTELLECTUAL PROPERTY

The Intellectual Property (IP) including copyright of the resulting data and the Market Report that shall be generated if any during the implementation shall be governed in accordance with the consequent and separating Agreement entered into between the Parties.

6. CONFIDENTIALITY

It shall be the responsibility of both the Parties to ensure maintenance of confidentiality of such information identified as 'confidential' in respect of their behalf and on behalf of their employees, representatives and associates.

7. FURTHER AGREEMENTS AND ASSURANCES

The Parties will make, do and execute, or cause to be made, done and executed, all such further acts, deeds, agreements, transfers, assurances, instruments or documents as may be reasonably required by either of them in order to document or implement or evidence the RADP components and transactions contemplated herein.

8. JOINT REVIEW

Review and decisions shall be made by consensus of the Joint ICMR-PARTNER Committee (JC) that will be constituted jointly by the Parties.

9. NON EXCLUSIVITY

Nothing herein is intended nor shall be construed as creating any exclusive arrangement between ICMR and PARTNER. This Contract shall not restrict either ICMR or PARTNER from acquiring or providing similar, equal or like services from or to other entities or sources.

10. EFFECT OF THE MOU

i. This MoU takes effect upon its execution, and shall remain in effect until ++++++++++++ year thereafter.
ii. Before the completion of the valid duration of this MOU either party can withdraw by giving three months' notice in writing to the other Party, if any of them no longer desires to be part of the Partnership.
iii. This MOU may be executed in counterparts each of which when so executed and delivered shall be an original hereof.
iv. The MOU represents the entire agreement between the parties.

11. GOVERNING LAW

This MOU shall be governed and interpreted in accordance with the laws of India.

IN WITNESS WHEREOF ICMR and PARTNER have executed these presents the day and year first above written.

For and on behalf of ++++++++++++++	**For and on behalf of** ++++++++++++++++++++++

Witness

1	2