

Department of Health Research
Ministry of Health and family Welfare
Government of India

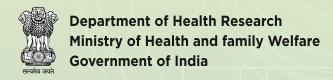


ICMR GUIDELINES FOR UTILIZATION OF CORPORATE SOCIAL RESPONSIBILITY FUNDS











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Foreword



In April 2014, India became the first country in the world to have statutorily mandated Corporate Social Responsibility (CSR) for certain companies to comply with the provisions relevant to CSR. India, with its comprehensive CSR framework, has established a standard for achieving sustainability objectives and promoting stakeholder engagement for societal impact.

ICMR, being the apex body in India for formulation and coordination of biomedical research through Intramural and Extramural research activities, is mandated to foster the development and acceleration of medical countermeasures to address public health challenges as per national health priorities. In alignment with the mandate that CSR funds should be allocated for activities with widespread public benefits through public-private partnerships, ICMR has been instrumental in advancing this initiative with the utmost intent and spirit.

The "ICMR Guidelines for Utilization of Corporate Social Responsibility" will ensure the effective utilization of CSR funds in accordance with the CSR objectives as outlined in Schedule VII of the Companies Act, 2013. These funds, generated from industry donations, will be directed towards supporting the research of national health importance not provisioned under the Intramural and Extramural Grants of ICMR, thereby fostering innovative research to address critical health challenges. Key areas include the development and delivery of vital health technologies such as vaccines, therapeutics, devices, and diagnostics. By backing pre-clinical and clinical evaluations, ICMR strives to accelerate the delivery of advanced healthcare solutions to the public. The guidelines also highlight mechanisms to support the validation of promising technologies and impart training in medical and biomedical research to ensure the development of a skilled workforce capable of addressing emerging health needs. Additionally, these guidelines provide flexibility to address other national health priorities as may be realized due to evolving healthcare needs, ensuring that CSR contributions adapt to evolving health needs.

These Guidelines are forward looking and are based on experiential learnings. I would like to express my commendation for the dedication demonstrated by the ICMR team, particularly the Medical Device and Diagnostics Mission Secretariat (MDMS) under the Division of Development Research, for their diligent efforts in developing these guidelines that will foster the culture of innovation through public-private partnerships leading to improved public health outcomes.

Dr. Rajiv Bahl

Secretary to Government of India, Department of Health Research and Director General, Indian Council of Medical Research (ICMR)

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List of Abbreviations

Abbreviations	Full Form	
AICTE	All India Council for Technical Education	
ICMR	Indian Council of Medical Research	
CAG	Comptroller and Auditor General	
CD	Communicable Diseases	
CSR	Corporate Social Responsibility	
CSIR	Council of Scientific & Industrial Research	
DAE	Department of Atomic Energy	
DHR	Department of Health Research	
DPE	Department of Public Enterprises	
DRDO	Defence Research and Development Organisation	
DST	Department of Science and Technology	
GFR	General Financial Rules	
Gol	Government of India	
Hqrs.	Headquarters	
ICAR	Indian Council of Agricultural Research	
ICADR	International Centre for Alternative Dispute Resolution	
IP	Intellectual Property	
IIT	Indian Institute of Technology	
LLP	Limited Liability Partnership	
MCMs	Monitoring, Control, and Management System	
MeitY	Ministry of Electronics and Information Technology	
MoHFW	Ministry of Health and Family Welfare	
NCD	Non Communicable Diseases	
NDIAC	New Delhi International Arbitration Centre	
NMC	National Medical Commission	
PCI	Pharmacy Council of India	
R&D	Research and Development	
RCN	Reproductive, Child Health & Nutrition	
SAB	Scientific Advisory Board	
SDG	Sustainable Development Goals	
SMEs	Small and Medium Scale Enterprises	
TAC	Technical Advisory Committee	
UGC	University Grants Commission	





About ICMR & DHR

The Department of Health Research (DHR) was created as a separate Department under the Ministry of Health & Family Welfare on 17th September 2007. DHR aims to bring modern health technologies to the people through research and innovations related to diagnosis, treatment methods and vaccines for prevention; to translate them into products and processes and, in synergy with concerned organizations, introduce these innovations into the public health system. DHR also has the mandate of promoting inter-sectoral coordination and promotion of public-private partnership in medical, biomedical and health research-related areas.

The Indian Council of Medical Research (ICMR), is an autonomous organization under DHR for the planning, promoting, coordinating and conducting biomedical research in India. The objectives of ICMR are in consonance with the National Health policy and aim towards improving the health of the people of India through biomedical research. ICMR (established in 1911) is one of the oldest medical research organizations in the world, with a broad mandate to generate new knowledge through the conduct and support of biomedical research in all areas that would have a bearing on improving the health of Indian people. The Council carries out its mandate through its network of institutes/centres, extramural research support to investigators at various institutes and medical colleges in India, and through active international collaborations. Further, ICMR and DHR are mandated to respond to public health needs by undertaking focused Research and Development (R&D) for developing Medical Counter Measures (MCMs) through industry engagement.

ICMR has been notified to receive Corporate Social Responsibility (CSR) funds as per notification G.S.R. 525(E), dated 24th August, 2020 published by the Ministry of Corporate Affairs read with Companies (Corporate Social Responsibility Policy) Rules, 2014 and the Companies Act, 2013. ICMR endeavours to create a suitable framework for ensuring effective utilization of the funds generated from industry donations. These funds are aimed at supporting the development of diagnostics, therapeutics, vaccines, and devices by funding critical activities, carrying out implementation research to achieve Sustainable Development Goals (SDGs) and promoting the 'Make in India' initiative within the realm of public health.











ICMR GUIDELINES FOR UTILIZATION OF CORPORATE SOCIAL RESPONSIBILITY FUNDS















Background

1.1 The Indian Council of Medical Research (ICMR) is the apex body in India for the formulation and coordination of biomedical research. It is an autonomous body under the Department of Health Research (DHR), Ministry of Health and Family Welfare (MoHFW), Government of India. Its research priorities align with the national health priorities focusing on the prevention of communicable diseases and non-communicable diseases, improving reproductive and child health and nutrition, and promoting basic medical sciences and drug research, including traditional medicines. ICMR promotes biomedical research in the country through intramural and extramural research. Further, ICMR/DHR is mandated to respond to public health needs by undertaking focused Research and Development (R&D) for developing Medical Counter Measures (MCMs) through industry engagement. ICMR has been notified to receive Corporate Social Responsibility (CSR) funds as per notification G.S.R. 525(E), dated 24th August, 2020 published by the Ministry of Corporate Affairs read with Companies (Corporate Social Responsibility Policy) Rules, 2014 and the Companies Act, 2013.

1.2 Corporate Social Responsibility (CSR) Funds

- 1.2.1 The Ministry of Corporate Affairs, Government of India notified Section 135 of the Companies Act, 2013 along with Companies (Corporate Social Responsibility Policy) Rules, 2014. The 'CSR Rules' and other notifications related there to make it mandatory (with effect from 1st April, 2014) for certain companies to comply with the provisions relevant to Corporate Social Responsibility.
- 1.2.2 The term 'Corporate Social Responsibility (CSR) refers to a corporate initiative to assess and take responsibility for the company's effects on the environment and impact on social welfare. The term generally applies to a company's efforts that go beyond what may be required by regulators or environmental protection groups. The



Ministry of Corporate Affairs, Government of India notified the Section 135 of the Companies Act, 2013 along with Companies (Corporate Social Responsibility Policy) Rules, 2014. The 'CSR Rules' and other notifications related thereto make it mandatory (with effect from 1st April, 2014) for certain companies to comply with the provisions relevant to Corporate Social Responsibility.

- 1.2.3 The soul of CSR is that it should be utilized for activities that provide larger public benefits, especially to those who need the corporate handholding the most.
- 1.2.4 The Ministry of Corporate Affairs vide notification G.S.R. 525(E), dated 24th August, 2020 amended specific portions of Schedule VII [3] of the Act to include "Contribution to incubators funded by Central Government or State Government or any agency or Public Sector Undertaking of Central Government or State Government, and contributions to public funded Universities, Indian Institute of Technology (IITs), National Laboratories and Autonomous Bodies (established under the auspices of Indian Council of Agricultural Research (ICAR), Indian Council of Medical Research (ICMR), Council of Scientific and Industrial Research (CSIR), Department of Atomic Energy (DAE), Defence Research and Development Organization (DRDO), Department of Science and Technology (DST), Ministry of Electronics and Information Technology (Meity) engaged in conducting research in science, technology, engineering and medicine aimed at promoting Sustainable Development Goals (SDGs) as eligible for approved CSR funding modes mandated under Section 135 of the Act.
- 1.2.5 ICMR shall follow the provisions of the CSR Rules laid down by the Ministry of Corporate Affairs, Government of India from time-to-time under the Companies Act, 2013 and its amendments.
- 1.2.6 Funds received in the form of contribution/donation under CSR reflect voluntary contribution and contributor(s) cannot prescribe any particular deliverable benefit or item, nor impose their area of interest in exchange for contributions from ICMR.
- 1.2.7 Any point not covered by these Guidelines will be interpreted in accordance with the Companies Act, 2013 read with the Companies (Corporate Social Responsibility Policy) Rules, 2014 and the Department of Public Enterprises (DPE) Guidelines, with the former taking precedence over the latter in case of any conflict, as well as any subsequent amendments, notifications or guidelines laid down by the Government of India from time-to-time.



Vision

- 2.1 To ensure the effective utilization of funds generated from industry donations to help develop diagnostics, therapeutics, vaccines and devices by funding critical activities such as the development of products for lab, pre-clinical and clinical evaluation by Indian industry.
- 2.2 To carry out implementation research to achieve Sustainable Development Goals (SDG) by promoting equity in health through increased coverage and access to quality healthcare for economically and socially marginalized populations.
- 2.3 To serve the needs of our citizens and to promote 'Make in India' in the area of public health.







Admissible Activities of ICMR with CSR Funds

The CSR related funds may be considered for utilization under the following activities by ICMR in consonance with the CSR objectives provided in Schedule VII of the Companies Act, 2013:

- 3.1 To support research activities not provisioned under intra-mural or extra-mural grants of ICMR.
- 3.2 To support the development and/or delivery of technologies of national health importance, including vaccine(s), therapeutic(s), device(s) or diagnostic(s) required for pre-clinical and clinical evaluation.
- 3.3 To support the validation of technologies of national interest, including lab-based studies, pre-clinical and clinical research that cannot be supported under regular budget heads of ICMR.
- 3.4 To support activities such as training and teaching related to medical/biomedical research.
- 3.5 Any other health-related issue of national importance as approved by the Competent Authority.





Corporate Funding Acknowledgement

All publications, products, processes, activities and technologies developed through corporate support under CSR may include the name of the company along with ICMR to acknowledge the corporate contribution.







CSR Fund Management & Governance

In order to monitor and ensure transparency for the proper utilization of CSR funds, ICMR shall constitute various Committees responsible for reviewing proposals, fund allocation and its management.

5.1 Eligible Entities for Fund Receipt

The following legal entities are eligible to receive funds under these Guidelines:

- 5.1.1 Indian Industry, Limited Liability Partnership (LLP) firms, Companies including Startups, Small and Medium Scale Enterprises (SMSEs) and other legal entities established as per Indian laws (Companies Act, 2013 and Limited Liability Partnership (LLP) Act, 2008) that have the capacity to produce high-quality products with requisite quality certification.
- 5.1.2 Research Institutes, Universities, Research Foundations, Medical Colleges and Institutions both public and private with valid affiliations from UGC/AICTE/PCI or approval from NMC.

5.2 Fund Management

- 5.2.1 The ICMR Finance Department, led by the Senior Financial Advisor, will be responsible for handling the CSR fund(s).
- 5.2.2 A separate interest-bearing bank account in a nationalized/scheduled bank will be maintained to keep a record of all CSR fund receipts.
- 5.2.3 Any earnings from this fund, such as interest earned or revenue generated, will be ploughed back to this fund. The fund will be spent based on the process laid out by ICMR from time-to-time.
- 5.2.4 All receipts and payments related to CSR activities will be undertaken strictly as per provisions of GFR, 2017 as amended from time-to-time, and the same will be subjected to internal audit, CAG audit, or audit by a recognized Chartered

- Accountant. A separate expenditure statement for CSR related activities shall also be maintained.
- 5.2.5 ICMR will accept CSR contributions from companies that comply with CSR norms/guidelines of the Ministry of Corporate Affairs, Government of India.
- 5.2.6 ICMR shall ensure that there is no conflict of interest with the donor organization, ensuring that individuals or organizations do not derive personal benefit from actions or decisions made in their official capacity.
- 5.2.7 Accrual basis of accounting will be followed for contributions, which will reflect revenue, expenses, assets and liabilities in the period in which they accrue.
- 5.2.8 Approval by the Competent Authority of ICMR should be ensured at all the stages concerned.
- 5.2.9 The CSR Fund(s) allocated and approved must strictly be used for their intended purpose and in no way be diverted for any other purpose.

5.3 Composition and Functions of Committee(s) involved in Fund Management and Governance

5.3.1 **Screening Committee:**

- A. The Screening Committee shall be responsible for screening of proposals based on essential eligibility criteria for the requisite proposal as defined by ICMR from time-to-time.
- B. This Committee shall consist of the following members:
 - a. The Committee shall be co-chaired by heads of ICMR Intramural Research Divisions [Communicable Disease (CD), Non Communicable Diseases (NCD) and Reproductive, Child Health & Nutrition (RCN)].
 - b. Administrative representative [Assistant Director General (Asst. DG, Admin) or Senior Administrative Officer (Sr. AO)].
 - c. Finance representative [(Assistant DG, Finance or Senior Accounts Officer (Sr. ACO)].
 - d. Program Officer of the concerned division, ICMR Hqrs. (Member Secretary).
 - e. Director/Concerned Scientist (ICMR-Institute).

5.3.2 **Technical Advisory Committee**

- A. The Technical Advisory Committee (TAC) shall act as a CSR fund Steering Committee and shall be responsible for the technical review of proposals for the evaluation of its robustness, feasibility and achievability.
- B. The Committee shall consist of 5 to 7 members, including the Chairperson, as nominated by the Director General (DG), ICMR.
- C. The Technical Advisory Committee will be chaired by a member of the Scientific

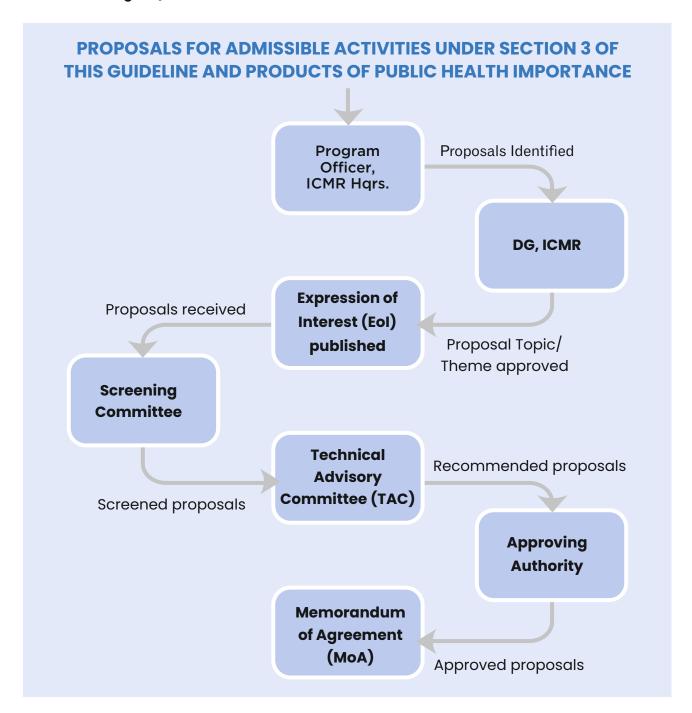


Advisory Board (SAB), nominated by the Director General (DG), ICMR and cochaired by the Additional Director General (Addl. DG), ICMR (Intramural research).

5.3.3 **Approving Authority**

All project proposals shall be approved by the Competent Authority as per the General Financial Rules, 2017(GFR). All the proposals for the utilization of funds shall be placed before the Competent Authority for consideration and approval, as per Section 5.3.4 below.

5.3.4 Regime/Governance





General Provisions

While entering into or implementing any CSR fund supported research activity, any intellectual property generated (IP rights), data rights, publication rights, press releases, confidentiality, March-in rights shall be dealt by the set provisions under ICMR Guidelines for Technology Development Collaboration. In addition, ICMR shall reserve the right to require that the Product must be sold at a differential affordable price to the government's procurement for addressing public health needs.







7

Jurisdiction & Dispute Resolution Mechanism

- 7.1 These Guidelines shall be governed and interpreted in accordance with the laws of India, subject to the exclusive jurisdiction of the Courts at New Delhi.
- 7.2 Disputes arising under these Guidelines shall be resolved amicably and in good faith by mutual consultation. If no resolution is reached within 30 (thirty) days following the date on which one party first notifies the other in writing of its request that such a meeting be held, then the dispute shall be resolved by arbitration under the provisions of the Arbitration and Conciliation Act, 1996 and the Rules thereunder, as amended from time-to-time.
- 7.3 Any unresolved dispute or difference whatsoever arising between the Parties out of or in relation to the construction, meaning, scope, operation or effect of these Guidelines or the validity of the breach of agreements executed thereof or in respect of any defined legal relationship associated therewith or derived therefrom dispute shall be submitted for arbitration to International Centre 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 with the ICADR. The Arbitration under this clause and provision of administrative services by ICADR shall be in accordance with the ICADR Arbitration Rules, 1996 read with the New Delhi International Arbitration Centre (NDIAC) Act, 2019 and as per the Indian Arbitration & Conciliation Act, 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 Guidelines expiring or ceasing to exist or any agreement being terminated or foreclosed there under.



Review of Guidelines

Based on the revision needs recognized during the implementation of these Guidelines, required changes shall be made with the approval of the DG, ICMR with financial concurrence by the Senior Financial Advisor, ICMR.







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