Guidance document for Licensing ICMR supported Technologies:

1. Scope of Work

i. ICMR is willing to collaborate with eligible organizations, companies, and manufacturers for undertaking Transfer of technology or further Joint development and commercialization of ……..…… (1)

ii. The Company would be granted rights to undertake further development, manufacture, sell, and commercialize the Technology/Product ……. (Details of technology/Product) or undertake further R&D and commercialize the end product(s) /technology.

iii. An Agreement (in case of joint development or licensing) following EoI is proposed to be executed on a "Exclusive/Non-Exclusive" basis with single/multiple companies to enable wider outreach of the ……. (Technology/Product) for societal benefit and public health use. All the related issues shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority.

iv. ICMR-XXX Institute has expertise in various techniques, methods and information relating to aforesaid technology which could be used for the production of …… (1)

Role of ICMR:

i. ICMR-XXX Institute will provide expert guidance & technical support for the production of……. (1), in all phases. Such technical oversight by ICMR-XXX Institute would accelerate the development of the Product and its commercialization.

ii. ICMR would provide technical support through its team of experienced scientists in study planning, product development, development of study protocol, results/data analysis, outcome assessment, safety & efficacy assessment, product improvement, etc., if deemed fit upon the mutual understanding between ICMR and collaborative company.

iii. ICMR through its Institutes would provide support and facilitation to conduct the R&D/clinical study of new technology/ product in India through its Affiliates/ Institutes, in collaboration with the company/institutions in a professional and mutually agreed-upon manner and timelines, which will be decided later under the Agreement.

iv. ICMR would provide technical support in development of technology/ product and will also facilitate the validation, if required, as per the terms & conditions of the Agreement.

v. ICMR shall have no financial implications unless otherwise specified.

Role of Company

i. The Company shall have valid provisions to provide all necessary infrastructure/ material/ manpower required for product development/ validation/ scale-up either directly or otherwise.

ii. The Company shall have provisions to undertake the scale-up as required, manufacturing and commercialization of the …….. (1), in a set milestone.

iii. The Company agrees to share the technical data with ICMR and participate in all discussions in a professional and mutually agreed-upon manner.

iv. The Company agrees to allow authorized personnel/scientist/team of ICMR to visit the designated lab/ production facility as and when required, as envisaged under this EoI and subsequent Agreement.

v. The Company shall be responsible for obtaining all the regulatory approvals required for commercialization or starting from R&D for product development to its commercialization

2. Intellectual Property Rights

It is submitted that in case of transfer of Technology, ICMR is the sole owner of the said Technology, including any underlying Intellectual Property(ies) and commercialization rights.

Intellectual Property (IP) shall mean patents, rights to inventions, copyright and related rights, moral rights, rights in designs, rights in trademarks, rights to preserve the confidentiality of information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply for and be granted), divisional, continuations, continuations-in-part, reissues, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world regarding subject matter disclosed in Licensed patents.

ICMR legally possess the rights and authority to retain full or part of the 'Technology' by itself or to assign at its discretion full or part of the Technology including any patent(s) or intellectual property rights(s) or the invention(s), and/or ICMR is lawfully entitled to enter into any form of non-exclusive License Agreements with selected companies including transfer of the Technology through suitable Agreement(s).

In case of collaboration between ICMR and the Company for the Joint development of the Technology/ Product, Background Intellectual Property ("BGIP") shall always remain the sole and exclusive property of the Party generating the BGIP. Any IP, if generated during the course of collaboration, including any improvement thereof, shall be jointly owned by ICMR and the Company. All such provisions related to intellectual property rights shall be governed by ICMR IP Policy, as revised and approved by the Competent Authority.

3. Process involved in Partnership/Collaboration/Technology Transfer

Interested companies/manufacturers are invited to join hands with ICMR for co-development/ further development & commercialization of the Technology/ Product(s). Under this EoI, the manufacturers/companies who are responsive and fulfilling all the technical need will be shortlisted based on their R&D plan, facilities and capabilities. Qualified companies/manufacturers will only be contacted for execution of MoA/MoU/Agreement for partnership/collaboration/technology transfer, etc. Subsequent to the execution of the Agreement such companies/manufacturers shall be responsible to pay the Royalty @ 1% or 2% on Net sales, as applicable, according to the ICMR Guidelines for Technology Development Collaboration.

4. Publication

i. In case of Co-development, the Parties shall have equal rights on the manuscripts/scientific publications (joint publication/acknowledgment /other credits as applicable) and in accordance with guidelines of International Committee of Medical Journal Editors (ICMJE.org).
ii. Support of ICMR must be duly acknowledged in all publications by the Company.
iii. ICMR Scientists can be given due to advantage of authorships in the publications arising out of Licensing/co-development.

5. Data Rights

i. Data Rights will be exclusively with ICMR, if ICMR provide 100% funding.
ii. Data rights shall be jointly owned by ICMR and Licensee/Co-developer, in case of joint funding.
iii. Data rights in cases where Artificial Intelligence is involved shall be dealt separately.
iv. Licensee/ Company to ensure that data is anonymized, kept confidential and strictly abide by the provisions of Information Technology Act, 2000 while dealing with such data

6. Details of documents to be furnished

Proponents are requested to go through all pre-qualification requirements, scope of work for execution & requirements with respect to technical capabilities for submission of interest, subject for verification by ICMR.
Documents to be furnished are as follows:

i. Declaration - Expression of Interest (Format – 1)
ii. Authorization Letter (Format – 2)
iii. Undertaking with regard to Blacklisting (Format-3)
iv. Undertaking with regard to Non-Conviction (Format – 4)
v. EoI document with each page duly stamped and signed by the Authorized signatory.
vi. Undertaking with regard to laboratory facility (Format – 5)
vii. Production Capacity Undertaking (Format-6)
viii. Supporting documents, as mentioned in Format-1
ix. MSME Certificate (if applicable)
x. Concept note on business plan- A brief concept note on R&D, clinical studies, planning & execution, production, marketing etc. with timeline (not more than 5 pages)
xi. Any other information which proponent may wish to provide to support the EoI.

ICMR reserves the right to call for any clarifications confined in the broad scope, wherever such a clarification become necessary for proper judgement in evaluation.

7. Rejection Criteria

The application is liable to be rejected if:

i. The proposal is not submitted as per the requirements indicated in the EoI.
ii. Not in the prescribed format.
iii. Not properly stamped and signed.
iv. Received after the expiry of due date and time.
v. All relevant supporting documents are not furnished with the Pre-Qualification Criteria (PQC).
vi. The proposal shall be substantially responsive without any material deviation, failing which the proposal shall be summarily rejected.
vii. Applications not fulfilling the terms of the document will be summarily rejected.
viii. Any other non-compliance.

8. Evaluation Methodology

Screening of EoIs shall be carried out as per Pre-Qualification criteria mentioned in the EoI document and based on verification of documents submitted.

9. Pre-Qualification Criteria (PQC)

The following will be the minimum Pre-Qualification Criteria (PQC). Responses not meeting the minimum PQC will be summarily rejected and will not be evaluated further:

Sl. No.	**Pre-Qualification Criteria (General)**	**Supporting copy of documents required** (All documents must be self-attested by the authorized person of the proponent)
General Criteria		
1	The proponent shall be a legal entity, registered as Institution/Company/ LLP/ Society/ partnership firm/ proprietorship firm under respective acts in India and shall have more than 51% of Company stakes by promoters from India.	Registration of firm/ organization/Company Incorporation Certificate from Registrar of Companies (ROC) /Partnership deed etc. whichever is applicable
2	The proponent must be registered in India with taxation and other administrative authorities.	GST Registration or GST exemption certificate/ PAN Card
3	The proponent should have proven prior experience of manufacturing and/or R&D with manufacturing during the last three years, either in-house or through agreed collaboration and must have marketed same/similar products in the	Research paper/Pamphlet / brochure of the product/DCGI License for existing product. Supporting documents for collaboration, if any.

	past with a good track record.	
4	The proponent has to be profitable and should not have incurred overall loss in past three (3) years. (applicable on commercial firms/organizations only)	Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for last three financial years or Income Tax return.
5	The proponent should have good track record and currently not black-listed/ barred by any Central / State Government / Public Sector Undertaking, Govt. of India, (applicable on commercial firms/organizations only).	Undertaking on the Letter Head of the Proponent duly signed & Stamped by Authorized Signatory (As per format – 3).
6	The proponent should have a manufacturing unit in India.	Registration copies/ factory license/ DSIR certificate, if have any.
7	The proponent and its promoters should not have been convicted for any offence in India by any competent court or judicial body during the past 3 years.	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 4)
8	GMP/ quality certification (ISO or approved Indian certification) of manufacturing facility and GLP/ necessary certifications for R & D	Copies of Certificates
Specific Criteria (Based on the nature of the Proposal)		
9.	The proponent should have functional laboratory to carryout R&D for the product development	Undertaking on Proponent's Letter Head, duly signed and stamped by the Authorized Signatory (As per format – 5)
10.	Capacity to produce at least……(quantity) per week	Undertaking (As per format – 6)

NOTE- For MSMEs and Start-ups, Start-Up-India, Make-in-India and other relevant guidelines of Government of India shall be applicable

10. Disclaimer

i. ICMR shall not be responsible for any late receipt of applications for any reasons whatsoever.
ii. ICMR reserves the right to cancel the call for EoI without assigning any reasons thereof.
iii. ICMR may relax or waive any of the conditions stipulated in this document as deemed necessary in the best interest of the ICMR without assigning any reasons thereof.
iv. To include any other item in the Scope of work at any time after consultation with proponents or otherwise.

v. For International Clients, please note that EoI and other necessary correspondences shall be submitted in English only.

11. Arbitration

That any dispute and/ or any part of the dispute which couldn't be resolved through mutual consultation, the same shall be referred to the sole arbitrator as per the Arbitration & Conciliation Act, 1996 and any amendment thereafter. The Venue and Seat of the arbitration proceedings shall be New Delhi and the courts at New Delhi will have exclusive jurisdiction.