स्वास्थ्य अनुसंधान विभाग
DEPARTMENT OF HEALTH RESEARCH
सत्यमेव जयते

icmr
INDIAN COUNCIL OF MEDICAL RESEARCH
Serving the nation since 1911

Indian Council of Medical Research (ICMR)

GUIDELINES FOR

TECHNOLOGY DEVELOPMENT COLLABORATION

Guidelines For Technology Development Collaboration

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Government of India

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डॉ. राजीव बहल, एमडी, पीएचडी

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सचिव, भारत सरकार

स्वास्थ्य अनुसंधान विभाग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं

महानिदेशक

भारतीय आयुर्विज्ञान अनुसंधान परिषद

Secretary, Government of India

Department of Health Research

Ministry of Health & Family Welfare

Director-General

Indian Council of Medical Research

FOREWORD

The Indian Council of Medical Research (ICMR), as the premier biomedical research institution in India, has always strived to advance medical science and technology to address the nation's evolving health challenges. With a steadfast commitment to fostering excellence in health research, ICMR has continually sought innovative and collaborative approaches to drive progress.

ICMR plays a pivotal role in technology transfer by bridging the gap between cutting-edge biomedical research and practical healthcare solutions. As a leader in fostering biomedical research in the country, ICMR facilitates the commercialization of research discoveries, ensuring they are transformed into accessible and impactful medical technologies. During the COVID-19 pandemic, ICMR provided crucial validation support, ensuring rapid and accurate assessment of diagnostics and treatments. This proactive approach facilitated the swift deployment of effective medical solutions, significantly contributing to India's pandemic response efforts.

By establishing the guidelines and frameworks for technology transfer, joint development, validation and material transfer, ICMR promotes effective collaborations between researchers, industry partners, and other stakeholders. This ensures that novel medical advancements are efficiently developed, validated, and brought to market, ultimately enhancing public health outcomes and positioning India at the forefront of global healthcare innovation.

The inclusion of standard agreement templates in these guidelines will provide greater transparency and clarity to all stakeholders, ensuring smoother and more efficient collaborations. To better reflect the emphasis on collaboration for strengthening the ecosystem, the guidelines are named as the "ICMR Guidelines for Technology Development Collaboration." These guidelines align with our Hon'ble Prime Minister Narendra Modi's vision of Viksit Bharat by 2047 in the area of Innovation, Research and Development. They emphasize creating an industry-friendly environment that fosters public-private partnerships for the development and commercialization of technologies, as per the National Health Research Policy.

I commend the dedication of researchers and experts, particularly the Medical Device and Diagnostic Mission Secretariat (MDMS) unit of ICMR for their diligent efforts in revising these guidelines. Their commitment to excellence in research and innovation is evident in the thoroughness and clarity of this document. I am confident that these revised guidelines will serve as a crucial tool in fostering a culture of innovation and collaboration, ultimately leading to significant advancements in medical technology and improved public health outcomes.

Rajiv Bahl

(Dr. Rajiv Bahl)

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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. The DHR aims to bring modern health technologies to the people through research and innovations related to diagnosis, treatment methods, therapeutics 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 the 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.

There is a well-recognized need in India to strongly promote healthcare innovations. ICMR endeavours to encourage and promote new intellectual property development and technology transfer and is unveiling a suitable framework to disseminate technologies developed with its support by ensuring the seamless transfer of technologies to industries to boost the growth and capabilities of the manufacturing sector of the country, leading to the development of “Make in India” products for the envisioned Atmanirbhar Bharat. Additionally, ICMR is establishing a suitable framework for material transfer, joint development, technology transfer and validation of technologies with an objective to bring utmost transparency and provide equitable opportunity to all industries/stakeholders.

SECTION - I
BACKGROUND

BACKGROUND

Indian Council of Medical Research (ICMR), established in 1911, is a premier organization of the Department of Health Research, Government of India with the mandate of planning, promoting, coordinating, and conducting biomedical research in the country. As a part of its mandate, ICMR is actively involved in innovation and translation research activities. Many of the scientific technologies under research and development by ICMR Institutes or through ICMR funding support are commercially viable and are transferred to companies for further development and commercialization.

This policy document incorporates ICMR-guidelines for material transfer, joint development, technology transfer and validation of technology with an objective to bring utmost transparency and provide equitable opportunity to all Industries/ stakeholders. These policy guidelines endeavour to disseminate ICMR technologies through a framework that ensures seamless transfer of technology(ies) to industry, leading to indigenous product development and commercialization as per the "Make in India" initiative of the Government.

The policy also includes a basic framework for royalty determination, its reporting and monitoring structure to ensure uniformity & transparency.

OBJECTIVE

The objective of the 'ICMR Guidelines for Technology Development Collaboration' is to disseminate Technologies developed by ICMR support through a framework that ensures seamless transfer/joint development/material transfer/ facilitate validation of technology(ies) to boost the growth and capabilities of manufacturing sector of the country leading to development of "Make in India" products for the envisioned Atmanirbhar Bharat.

SECTION - II

SCOPE OF WORK

SCOPE OF WORK

These guidelines would cover different channels like Material Transfer, Collaboration for joint development, Licensing of technologies developed by ICMR and Validation for Drugs/Devices/Diagnostics/ Vaccines, for which ICMR collaborates with Industry/Institutes for development and commercialization of health technologies.

1. Material Transfer

1.1. ICMR transfers material(s) such as biological materials, molecules, reagents, antibodies etc. to various Government and Private institutes/ organizations for research and development purposes. ICMR also provides gold standard data to aid in the development of AI tools. The materials so transferred generally play an important role in technology development and commercialization.

1.2. Such material transfer to the eligible candidates will be governed by a detailed Material Transfer Agreement (MTA) signed between ICMR and the industry partner/Institutes. MTA to be executed between the Parties for Material Transfer is palced at Annexure - I

1.3. In the event of Material Transfer leading to product development and commercialization, revenue sharing in the form of royalty at the rate of 1% of the net-sales will be applicable with a sunset period of 10 years from the date of commercialization.

1.4. Further details of this revenue sharing will be as elaborated under the Section III of this policy detailing revenue sharing modules.

2. Collaboration for Joint Development

2.1. Collaboration for joint development of technologies/products of public health importance wherein end-to-end support is provided by ICMR, including lead identification, R&D, pre-clinical and /or clinical studies as per requirements of the product.

2.2. Before initiating any type of collaboration with another Party (Institute/Industry), it is essential to execute a Memorandum of Agreement (MoA) to define the scope and purpose of the collaboration, roles and responsibilities of the parties including specific terms and conditions with respect to Intellectual Property (IP) Rights, Data Rights, Publication Rights etc. MoA to be executed between the Parties for Joint Development is placed at Annexure - II

2.3. In the event of collaboration leading to product development and commercialization, revenue sharing in the form of royalty at the rate of 2% of the net-sales will be applicable with a sunset period of 10 years from the date of commercialization.

2.4. Further terms and conditions of revenue sharing will be as elaborated

under Section III of this policy detailing Revenue Sharing Modules.

3. Technology Transfer and Licensing

3.1. The technologies developed by ICMR institutes through intra-mural research or by grantees through extra-mural funding support are licensed by ICMR to interested Industry partners following Expression of Interest (EoI) by ICMR.

3.2. Any Technology to be licensed by ICMR must meet the following eligibility criteria.

i. Intellectual Property (IP) has been filed for the technology to be licensed, &

ii. Independent validation of the technology has been successfully undertaken*

**However, in exceptional circumstances, wherein there are no specialized institute(s) available for undertaking independent validation of the technology(ies), validation data generated by the Institute/Inventor may be evaluated for inviting EoI, by the Licensing and Collaborations Committee, having subject matter experts.*

3.3. All technologies developed through ICMR support shall be transferred on a 'non-exclusive' basis to ensure maximum public access. However, an Exclusive License may be considered in exceptional circumstances and shall be evaluated by the Licensing and Collaboration Committee, followed by approval by the Competent Authority of ICMR.

3.4. **Eligibility of Applicants for Technology Transfer:** Applicants meeting the following eligibility criteria shall be eligible to apply for licensing:

i. Companies including start-ups, incorporated under the Companies Act 2013 having a minimum of 51% of the shares of the Company held by Indian citizens. (Start-up should furnish a DPIIT recognized certificate)

ii. Limited Liability Partnership (LLP) incorporated under the Limited Liability Partnership Act, 2008 having a minimum of half of the persons who have subscribed their names to the LLP document as its Partner should be Indian citizens. (NOTE: The applicant Company/ LLP should have adequate in-house facility to address the project implementation and manufacturing of the product as per cGMP/regulatory requirements) The Company should have a DSIR (Department of Scientific and Industrial Research) certificate or should be incubated with any of the recognized incubation facility with suitable tie-ups for product manufacturing.

iii. Any other legal entity established under the statutory Act in India.

iv. Technology transfer to Foreign Entity or to an Entity with Foreign Equity shall be subject to due approval by the Competent Authority, ICMR, Government of India.

v. The applicant should have proven prior experience in manufacturing and/or R&D with manufacturing either in-house or through agreed collaboration.

vi. The Company should have been

in existence for the last 3 years working in the area of Technology to be licensed.

Note: Such provisions (v and vi above) may be waived off for start-up companies.

3.5. Prior to taking a decision regarding licensing of technology from ICMR, the prospective licensee may desire to conduct a 'due diligence' for comprehensive understanding of the technology. Thus, in order to safeguard the Intellectual Property of ICMR, it is essential to enter into NDA with the prospective licensee as a pre-requisite for permitting the prospective licensee to carry out the 'due diligence' for validating the claims about the technology.

3.6. License Agreement (LA) for transfer of technology will be entered between ICMR and the Licensee for enabling transfer of technology.

The License Agreement to be executed between the Parties is placed at Annexure - III

3.7. In the event of licensing leading to product development and commercialization, revenue sharing in the form of royalty at the rate of 2% of the net-sales will be applicable with a sunset period of 10 years from the date of commercialization.

3.8. Further terms and conditions of revenue sharing will be as elaborated under the Section III of this policy detailing Revenue Sharing Modules.

4. Validation /Pre-clinical/ Laboratory/ Field / Clinical Studies by ICMR

4.1. ICMR facilitates validation of technologies/products at various stages of the technology development cycle, including at early stages to establish the proof-of-concept and also at advanced stages of technology readiness for validating the sensitivity and specificity, safety and efficacy claims prior to commercialization.

4.2. Validation is usually facilitated on an 'Application' basis in the research priority areas, as identified by ICMR. However, in certain cases, validation in health priority areas is taken up on the advice by the Government. Similarly, some validations are undertaken on the basis of the mandate from Drug Controller General of India (DCGI).

4.3. In the event of validation leading to commercialization, revenue sharing in the form of royalty at the rate of 1% of the net-sales will be applicable with a sunset period of 10 years from the date of commercialization.

4.4. However, in case of validation requested by the Government or mandated by DCGI, no royalty will be applicable. In such cases, a 'Cost-Recovery' approach will be adopted for which ICMR will notify costs.

4.5. Further terms and conditions of revenue sharing will be as elaborated under Section III of this policy detailing Revenue Sharing Modules

4.6. Before initiating validation, it is essential to execute a Memorandum of Agreement (MoA) so as to define the roles and responsibilities of the ICMR and the industry partner/ Institute including specific terms and conditions with respect to IP Rights, Data Rights, Publication Rights etc.

The MoA to be executed between the Parties for validation is placed at Annexure - IV

SECTION - III

REVENUE SHARING MODULE

REVENUE SHARING MODULE

The revenue sharing arrangements between ICMR and the Industry partner/Institute for different collaborative activities, as elaborated under Section II, will follow either of the following two revenue sharing modules: -

- **Royalty Model, or**
- **Cost Recovery Model**

5. ROYALTY MODEL

5.1. **Applicable Rate:** The royalty, applicable in different categories, is a function of the extent of support provided by ICMR to the Industry/ Collaborator. Accordingly, the following Royalty-percentages on net sales will be applicable in distinct categories: -

Categories	*Royalty on net sales	Remarks
Material Transfer for the Development of Product	1%	
Joint Development and Commercialization	2%	
Licensing for Technology Transfer and Product Commercialization	2%	
Validation of Product		
Validation/Pre-clinical/Laboratory/ Field/Clinical studies by ICMR	1%	
Government Referred	0	Cost Recovery only
DCGI Mandated	0	Cost Recovery only
Post-DCGI Approved Technology	0	Cost Recovery only

**Royalty waiver may be granted in exceptional circumstances only with 2/3rd majority recommendation by Licensing & Collaborations Committee followed by approval of EC and GC.*

5.2. **Basis of Royalty calculation:** Royalty calculation will be based on 'Net Sales' made by the Grantee/Licensee, Sub-licensee, or other associates in India and foreign countries. For this purpose, 'Net Sale' would have a definition as defined by the Cost Accounting Standards – 24, as provided in the Annexure -V.

5.3. **Sunset Clause:** Royalty shall be payable to ICMR from the net sales for a period of 10 years from the date of commercialization of the product which shall be notified to ICMR by the concerned collaborator.

5.4. **Cases where Royalty will not be applicable: -** No Royalty will be levied in the following categories: -

i. **Validation support, post DCGI approval:** In case of products/ technologies for which validation is requested by the grantee/ collaborator post DCGI approval and such study is undertaken by ICMR, no royalty shall be levied by ICMR.

ii. **DCGI mandated validation:** Where ICMR has been listed as one of the identified institutes by DCGI/CIB (Central Insecticide Board) to provide the services for Validation/Performance Evaluation for ensuring regulatory compliance, no royalty shall be levied by ICMR.

iii. **Government referred validation:** If ICMR is requested by any State/ Central Government for validation of technology in the health priority areas, no royalty shall be levied by ICMR in such cases, in the interest of public health.

NOTE: In cases where no royalty is applicable, Cost Recovery model shall be applicable.

5.5. **Royalty Reporting**

i. Grantee/Licensee shall pay the royalties on half yearly basis. Royalty due up to 31st March must be paid before the last working day of April, and for royalty due up to 30th September by the last working day of October.

ii. Grantee/Licensee must submit to ICMR a Chartered Accountant (CA) Certified account statement for the Royalty Period in the following format:

Product Name	
Unit Sale Price	
Total Quantity Sold	
Gross Sales Value (INR)	
Net Sales value (INR)	
% of Royalty Payable	
*Royalty Amount (INR)	

**Goods and Services Tax (as applicable) shall be paid additionally on Royalties due.*

5.6. **Mode of Payment of Royalty to ICMR:** The Royalty on the net sales shall be paid by the Grantee/Licensee by way of account payee crossed cheque or Demand Draft drawn in favour of "Director General - Indian Council of Medical Research" payable at "New Delhi" or by electronic mode in favour of ICMR.

5.7. **Delay in Payment of Royalty and Non-Payment**

i. In case of delay in payment of Royalty, the Grantee/Licensee shall be liable to pay simple interest at the rate of 12 (twelve) per cent per annum on the amount of default in payment of royalty for the period of delay.

ii. In cases where three consecutive Royalty payments have not been made by the Licensee/Grantee, it will result in the automatic termination of the License Agreement with prior notice of 30 days to remedy the breach and make the payment.

5.8. **Royalty Monitoring & Audit Rights**

i. Grantee/Licensee must keep, and must ensure that Grantee/Licensee itself and each of its Sub-Licensee

keep true and accurate accounts and records of the quantities of the product manufactured, sold, and in stock, gross sales price and net sales of the products in relation to each of the sub-territories comprising the territory, all other accounting, stock, ordering, purchasing invoicing, and delivery records in relation to the Products as are required by good accounting practice.

ii. The Grantee/Licensee must ensure to strictly abide/comply with the Termination Clause mentioned in the Agreements, which shall include strict compliance with the royalty remittance obligation, non-compliance of the same by the Licensee/Grantee shall result in the Termination of the License.

5.9. Inspection of Accounts by ICMR

i. ICMR may at any time, appoint a person or reputed auditing firm to inspect the Licensee's/Grantee's and sub-licensee's books and records so maintained for ensuring royalty compliance.

ii. Cost of such audit shall be borne by the Grantee/Licensee.

6. COST RECOVERY MODEL

In cases where no royalty is applicable, Cost Recovery model shall be applicable, considering the nature of the support provided by ICMR. Applicable cost recovery amount for different activities will be as per notification issued by ICMR from time-to-time keeping in account the operational costs such as man-hours and resources etc. being used for the said activity. Such rates would be determined in consultation with a third party, such as Institute of Chartered Accountants of India (ICAI), Institute of Cost and Works Accountants of India (ICWAI) etc.

SECTION - IV

MANDATORY PROVISIONS OF APPLICABLE AGREEMENTS

MANDATORY PROVISIONS OF APPLICABLE AGREEMENTS

7. Branding and Acknowledgement

7.1. Support of ICMR must be suitably acknowledged in the publications (papers, reports, advertisements, brochures, websites, flyers etc.) and products (labels, leaflets, package inserts etc.) by the Grantee/Licensee.

7.2. Use of ICMR Logo on Product packages:

i. The name/logo of ICMR shall suitably be displayed on each and every product by the Grantee/ Licensee.

ii. The Grantee/Licensee shall be permitted to use the ICMR Logo following approval by the Competent Authority of ICMR and as per the Brand Guidelines of ICMR.

8. Press Release and Public Announcements

8.1. Prior written permission must be taken by the Grantee/Licensee from ICMR prior to any press releases, public announcements, or media statement with respect to the technology that has been given grant-in-aid assistance by ICMR or licensed by ICMR for commercialization.

8.2. ICMR reserves the right to make any modifications for incorporation by the Grantee/Licensee in the Proposed Publication/Press Release.

9. Intellectual Property (IP) Rights

9.1. Background Intellectual Property ("BGIP") shall remain the sole and exclusive property of the respective Parties generating the BGIP.

9.2. Foreground Intellectual Property ("FGIP") or IP generated during the course of the Licensing/Co-development shall be jointly owned by ICMR and the Licensee/Co-developer.

10. Data Rights

10.1. Data rights shall be jointly owned by ICMR and Licensee/Co-developer

10.2. Data rights in cases where Artificial Intelligence is involved shall be dealt with separately.

10.3. Licensee/collaborator to ensure that data is anonymized, kept confidential and strictly abides by the provisions of the IT Act, 2000 and The Digital Personal Data Protection Act, 2023 while dealing with such data.

11. Publication

11.1. 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).

11.2. Support of ICMR must be duly acknowledged in all publications.

11.3. ICMR Scientists may be given due advantage of authorship in the publications arising out of Licensing/ co-development.

12. Responsibility of Grantee/ Licensee

12.1. **Regulatory Approvals**: Grantee/ Licensee shall be responsible to apply for the required certifications and approvals necessary for commercialization of the technology nationally and internationally and have them in order at their own cost.

12.2. **Commercialization for Societal Impact**: It shall be the responsibility of Grantee/Licensee to make every effort to commercialize the technology at a reasonable price.

12.3. **March-in-Rights:** ICMR shall retain a Royalty-free, non-exclusive, irrevocable license to the Product, after taking into consideration the Grantee/Licensee requirement for reasonable expansion and the demand-supply gap at the appropriate time, shall have the right to require the Grantee/Licensee to transfer the technical know-how of the Product developed under the Project to other entrepreneur(s)/Person and train them, on such terms and conditions as may be mutually agreed among ICMR, Grantee/Licensee, and such other entrepreneur(s)/Person.

12.4. **Mandatory GeM Registration and Discounted Pricing for Government**

i. Grantee/Licensee is required to register its novel product derived from the Patents licensed by ICMR/co-developed with ICMR on GeM portal of the Ministry of Commerce and Industry, Government of India.

ii. It shall be the responsibility of the Grantee/Licensee to make every effort to commercialize the Product at a discounted price to the Government of India as declared in National Interest and the final decision will be that of the Government of India.

13. Saving Provisions for ICMR

13.1. **Release**

i. Grantee/Licensee shall unconditionally release ICMR and its officers, employees, sub-contractors and agents absolutely from and against all actions, claims, proceedings or demands and in respect of any loss, death, injury, illness or damage (whether personal or property, and whether special, direct, indirect or consequential, including consequential financial loss) suffered by the Grantee/ Licensee, its affiliates, any sub-licensee(s) or any third party arising out of such party's Commercialization or use of the Intellectual Property, or the Products.

ii. To the full extent permitted by law, ICMR and its officers, employees, sub-contractors and agents will not be liable to the other Party/Licensee for any special, indirect or consequential damages, including consequential financial loss arising out of the Commercialization or use of

the Intellectual Property, by the Grantee/Licensee, its affiliates, or any sub-licensee(s), or the Products derived from the Intellectual Property, by the Grantee/Licensee, its affiliates, or any sub-licensee(s).

13.2. **Indemnification:** Grantee/Licensee shall indemnify and shall agree to keep the ICMR and its officers, employees, sub-contractors and agents indemnified from and against: (i) all actions, claims, proceedings or demands (including those brought by third parties) which may be brought against any of them, whether on their own or jointly, in respect of any loss, death, injury, illness or damage (whether personal or property, and whether special, direct, indirect or consequential, including consequential financial loss) arising out of the Commercialization or use of the Intellectual Property, or any Products; (ii) any breach of any provisions, including of the representations and warranties, any and all misrepresentation, liabilities, obligations, commitments; and/or (iii) any violation of the applicable laws.

13.3. **No-warranty Clause**

i. ICMR shall make no warranty, express or implied, about the workability of the technology/ IPR/Data/Records being transferred by ICMR. The same shall be transferred by ICMR on an "as is where is" basis.

ii. ICMR will not have any liability to the Grantee/Licensee or any other person resulting from the use of the Records, or any other information supplied or for any opinions expressed by any of them or for any errors, omissions, or misstatements.

iii. Among other things, ICMR shall disclaim any express or implied warranty of merchantability, of fitness for a particular purpose (i) of non-infringement or (ii) arising out of any course of dealing.

14. ICMR Rights (Societal Benefit)

ICMR shall retain rights, on behalf of itself and all other ICMR-supported non-profit research institutions/centres,

i. To use the technology and associated inventions or technology for educational and research purposes.

ii. Non-exclusive license to commercialize in Public Interest, notified by the Government of India.

iii. March-in-Rights where demand-supply gap is not being met at a reasonable price, or the technology has not been commercialized by the Grantee/Licensee within 2 (two) years from Licensing.

iv. ICMR and Institutes/Centres of ICMR shall have equal rights on IP and on data sharing.

15. Non-performance by Grantee/Licensee

i. In the event the Grantee/Licensee is unable to commercialize the Product within 2 (Two) years from the date of completion of the grant-in-aid project or licensing of the technology, ICMR shall have the March-in-Rights and the Grantee/ Licensee shall be obligated to

transfer the know-how to as many third parties as ICMR may advise.

ii. In the event the Grantee/Licensee is unable to commercialize the Product within the stipulated period, due to unavoidable circumstances and causes beyond the control of the Grantee/Licensee, the Grantee/ Licensee shall make a request in writing for an extension of the time limit before the expiry of the date giving detailed reasons. This request will be carefully examined and considered on merit by the ICMR.

iii. Upon expiration or termination of the Agreement for any reason, the rights granted to Licensee shall terminate immediately. The Licensee may, however, be allowed to use the know-how for a period not exceeding more than 30 (thirty) days to complete such orders that are in production at the time of termination and existing stock lying on the date of termination shall be allowed to be liquidated.

SECTION - V

OTHER PROVISIONS

OTHER PROVISIONS

16. Confidentiality

The Grantee/Licensee to protect the 'Confidential Information' owned by ICMR.

17. Dispute Resolution Mechanism

17.1. To be resolved amicably and in good faith by mutual consultation.

17.2. If no resolution is reached within 30 (thirty) days following the date on which one party first notifies in writing to the other of its request that such a meeting be held, then the Dispute shall be resolved by arbitration as per the provisions of the Arbitration and Conciliation Act, 1996 and the Rules thereunder, as amended from time to time.

17.3. 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 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 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 Act 2019 (NDIAC) therewith 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 Agreement expiring or ceasing to exist or being terminated or foreclosed.

17.4. The venue of arbitration shall be New Delhi.

18. Foreclosure and Termination

18.1. Automatic Termination: Automatic termination for default in payment of amounts due and non-payment of royalties due for payment for three consecutive Royalty reporting periods.

18.2. Termination by ICMR: ICMR shall notify the Grantee/Licensee regarding the breach of provisions under which grant-in-aid assistance/license was given, thereby invoking the provisions of termination, giving 1 (one) month notice to remedy the breach. ICMR

shall have the right to foreclose and terminate if the default prevails even after serving notice under the following circumstances:

i. For failure to achieve milestones within the timelines agreed between ICMR and the Grantee/ Licensee.

ii. On account of submission of false reports or misrepresentations by the Grantee/Licensee.

iii. For non-compliance with the Royalty remittance obligation.

iv. Failure to submit CA audited documents (upon royalty remittance) certifying the actual sales made by the Company.

v. For non-fulfilment of obligations pursuant to the Grant-in-assistance or license.

vi. If the Grantee/Licensee suspends or discontinues manufacture of the Product for a period exceeding 1 year without obtaining prior written permission or extension in this regard from the ICMR, except for reasons beyond the control of the Grantee/Licensee and that are agreed by the ICMR.

18.3. Termination by Grantee/Licensee: Grantee/Licensee may at any point of time choose to terminate the applicable agreements after giving reasons, by giving prior notice of at least three months.

Under such circumstances, the Grantee/Licensee shall:

I. Meet all the financial liabilities, including Royalty payments due till that point in time,

II. Submit a confidential report detailing the status of technology development till that point in time, and;

III. Cooperate with ICMR in transferring the technology to third party.

19. Survivability

Not with standing the termination or foreclosure, Grantee/Licensee shall continue to be bound by the following provisions:

19.1. Royalty reporting (Section III (5.5))

19.2. Branding and Acknowledgement (Section IV (7))

19.3. Press release and public announcements (Section IV (8))

19.4. Intellectual Property Rights (Section IV (9))

19.5. Data Rights (Section IV (10))

19.6. Publication (Section IV (11))

19.7. Saving Provisions for ICMR (Section IV (13))

19.8. ICMR Rights (Societal Benefit) (Section IV (14))

19.9. Non-Performance by Grantee/ Licensee (Section IV (15))

19.10. Confidentiality (Section V (16))

19.11. Dispute Resolution Mechanism (Section V (17))

20. Definitions

(Please refer Annexure V- for Definitions)

LIST OF ABBREVIATIONS

Abbreviations	Full Form
AI	Artificial Intelligence
BGIP	Background Intellectual Property
CA	Chartered Accountant
CIB	Central Insecticide Board
CSIR	Council of Scientific & Industrial Research
CGMP	Current Good Manufacturing Practice
DBT	Department of Biotechnology
DCGI	Drugs Controller General of India
DG	Director General
DPIIT	Department for Promotion of Industry and Internal Trade
DRDO	Defence Research & Development Organisation
DSIR	Department of Scientific & Industrial Research
DST	Department of Science & Technology
EC	Executive Council
EoI	Expression of Interest
FGIP	Foreground Intellectual Property
GC	Governing Council
GeM	Government-e-Marketplace
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GST	Goods and Services Tax
ICADR	International Centre for Alternative Dispute Resolution
ICAI	Institute of Chartered Accountants of India
ICAR	Indian Council of Agricultural Research
ICMJE	International Committee of Medical Journal Editors

ICMR	Indian Council of Medical Research
ICMR-Hqrs.	ICMR Headquarters, New Delhi
ICWAI	Institute of Cost and Works Accountants of India
IPR	Intellectual Property Rights
IT Act	Information Technology Act
IVD	In-Vitro Diagnostics
LA	License Agreement
LLP	Limited Liability Partnership
MDMS	Medical Device and Diagnostics Mission Secretariat
MoA	Memorandum of Agreement
MTA	Material Transfer Agreement
NDA	Non-Disclosure Agreement
NDIAC	New Delhi International Arbitration Centre
PI	Principal Investigator
Sr. FA	Senior Financial Advisor
TAC	Technical Advisory Committee

MEMBERS OF THE DRAFTING COMMITTEE

- Dr. Rajiv Bahl, Secretary DHR & DG, ICMR (Chairperson)
- Dr. Anil Wali, Former MD, FITT, IIT- Delhi (Co-Chair)
- Prof. (Dr.) Balram Bhargava, Former Secretary DHR & DG, ICMR, New Delhi
- Dr. Bharati Kulkarni, Scientist 'G', ICMR, New Delhi
- Dr. Deepankar Singh, Joint Director, ER & IPR, DRDO, New Delhi
- Shri Jagdish Rajesh, ADG (A), ICMR, New Delhi
- Dr. K.P Singh, Associate Director, ER &IPR, DRDO, New Delhi
- Dr. K.S. Kardam, Former-Joint Controller of Patents & Designs, Indian Patent Office
- Dr. Kamini Walia, Scientist 'G', ICMR, New Delhi
- Smt. Manisha Saxena, Sr. DDG (A), ICMR, New Delhi
- Dr. Nabendu Chatterjee, Scientist 'G', ICMR, New Delhi
- Ms. Nidhi Jain, Project Research Scientist, ICMR, New Delhi
- Dr. Nivedita Gupta, Scientist 'G', ICMR, New Delhi
- Dr. R Lakshminarayanan, DDG (Admn), ICMR, New Delhi
- Dr. R S Dhaliwal, Scientist 'G', ICMR, New Delhi
- Dr. Raj Hirwani, Former Director, CSIR-URDIP, Pune
- Shri. R. Ramakrishnan, Former Sr. DDG (A), ICMR, New Delhi
- Dr. Sadhana Srivastava, Former Scientist 'G, ICMR, New Delhi
- Dr. Samiran Panda, Former Scientist 'G', ICMR, New Delhi
- Dr. Shiv Kumar, Former Director, DRDO, New Delhi
- Dr. Suchita Markan, Scientist-E, MDMS Unit, ICMR, New Delhi (Member Secretary)
- Ms. Sugandhika Mehta, Former Consultant, ICMR, New Delhi
- Dr. T. Velpandian, Prof & Incharge of Ocular Pharmacology & Pharmacy, AIIMS, New Delhi
- Shri Udai Kumar, ACO, Finance Division, ICMR, New Delhi
- Ms. Varsha Padhi, Former Consultant, ICMR, New Delhi

ANNEXURE - I

MATERIAL TRANSFER AGREEMENT (MTA)

MATERIAL TRANSFER AGREEMENT

Between

INDIAN COUNCIL OF MEDICAL RESEARCH

And

XYZ University/Research Organisation/Private entity

Ministry of Health & Family Welfare,
Government of India

This Material Transfer Agreement (hereinafter the "Agreement") is made and entered into as of the _____day of _____, 202X (the "Effective Date")

BETWEEN

Indian Council of Medical Research an apex body in India for formulation, coordination and promotion of biomedical research under the Department of Health Research, Ministry of Health & Family Welfare, Government of India, registered as a Society under the Societies Registration Act, 1860 having its registered office at V. Ramalingaswami Bhawan, Ansari Nagar, Post Box 4911, New Delhi- 110029, India (**"ICMR"**) represented by **ICMR-XXXX Institute**, an ICMR organization and having its registered office at_____India (hereinafter referred to as **"ICMR-XXX"**, the **'Provider'** for this Agreement, on the one part;

AND

XYZ University/Research Organization/Private entity, existing under the laws of India/ a company registered under the Companies Act, 2013 and having a place of business/registered office at_____**India** (hereinafter referred to as **XYZ**), the **'Recipient'** for this Agreement, on the other part.

ICMR and **XYZ** each may be referred to herein individually as a **"Party"** or collectively as the **"Parties."** NOW, THEREFORE, in consideration of the mutual covenants, Terms and Conditions and understanding set forth in this agreement, the Parties, with the intent to be legally bound, hereby agree as follows:

1. PURPOSE

The Recipient wishes to receive/obtain _____(also referred to as the 'Material') from the ICMR-XXX (the Provider) for undertaking academic research/medical research work/development of the technology/due diligence of the technology _____ (Details of the Project).

2. DEFINITIONS

2.1. **Agreement** means this "Material Transfer Agreement" for the aforesaid purpose between the parties.

2.2. **Confidential Information** shall mean certain proprietary and/or non-public information with respect of the Materials which it has designated as confidential or which, under the circumstances surrounding its disclosure, ought to be treated as confidential ("Confidential Information"). Confidential Information shall also include (a) any information disclosed by the Provider to Recipient pursuant to this Agreement in written, graphic, machine readable or other tangible form (including without limitation documents, biological materials, prototypes, samples, data sets, and plant and equipment), and is marked "Confidential," "Proprietary" to indicate its confidential nature, (b) oral information disclosed by Provider to Recipient pursuant to this Agreement, provided that such information is designated as confidential at the time of disclosure, and (c) information otherwise reasonably expected to be treated in a confidential manner under the circumstances of disclosure under this Agreement whether expressly marked Confidential or not, as long as it is being disclosed under and for the purpose of this Agreement. Confidential Information shall not include information:

i. That is already or subsequently becomes public knowledge without the Recipient having failed in its obligations,

ii. That is publicly known or which is brought to the public domain through no fault of the Recipient,

iii. That is known to the Recipient prior to its communication by the Provider, as demonstrated by the Recipient's previous records.

2.3. **Data** means a representation of information, facts, concepts, opinions or instructions in a manner suitable for communication, interpretation or processing by human beings or by automated means (as defined under The Digital Personal Data Protection Act, 2023).

2.4. **Discloser** shall mean a party to this Agreement which discloses Confidential Information to any other party.

2.5. **Effective Date** shall mean the date of execution of this Agreement by all Parties. In the event Parties to this Agreement affix their signatures on different dates, the Effective Date shall mean the date on which the last of the executing Parties affixes its signatures to the Agreement.

2.6. **Improvements** shall mean, in connection with the Licensed Patent(s), any and all improvements, enhancements, variations, or modifications of the Technology described in the Licensed Patent(s) and all inventions, designs, information, know-how, specifications, formulae, data, processes, methods, techniques arising in connection with the development, manufacture and production of any Products used in, generated or otherwise created using the Licensed Patents encompassing the Technology;

2.7. **Intellectual Property Rights** or **IP** shall mean patents, rights to inventions, copyright and related rights, moral rights, designs, any other rights to preserve the confidentiality of information (including know-how and trade secrets) and any IP, 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 the Technology.

2.8. **Material** in this Agreement shall mean biological/chemical/any research material, data (electronic/hard copies), protocol etc. which are specified in Schedule I, and forms a part of this Agreement.

2.9. **Non-Commercial Use** means the use of the original Material for purposes not constituting commercial use.

2.10. **Net Sales** shall mean Revenue from sales of goods or services by all ICMR Grantees/ Licensees based on the net sales realization from operations, net of discounts and indirect taxes, as defined by the Cost Accounting Standards - 24 and certified by the Chartered Accountant.

2.11. **Royalty Period** shall mean each consecutive period ending up to 30th September and up to 31st March respectively every year.

2.12. **Royalty Term** shall mean Royalty payable by the recipient from the Net Sales for a period of 10 years from the date of commercialization of product.

2.13. **Provider** means ICMR or any of its institutes providing the original Material.

2.14. **Recipient** means any University or Research Organization or Industry to which the original Material is provided by the Provider.

2.15. **Technology** shall mean any and all discoveries, inventions, processes, methods, techniques, product and/or process or know-how, Intellectual Property and proprietary rights, expressed in whatever form including technical information, processes, procedures, material for trials, methods, formulae, protocols, software, specifications, instructions, data, documents, drawings, images, prototypes and materials encompassing for "_____".

3. TERMS OF USE OF MATERIAL

The Recipient shall ensure that the Material:

3.1. Shall be used solely by the Recipient for the purposes of the project (for evaluation and discussions concerning the Technology) during the term of this Agreement. All the Materials shall be used in compliance with this Agreement and all applicable laws/ regulations of India.

3.2. Shall not give, sell, share, release, convey, or otherwise distribute the Material and/ or any accompanying Confidential Information to any third party without the prior written permission of Provider.

3.3. The Recipient acknowledges that Provider may withhold its consent for any reason it deems necessary and is not obliged to give the reason thereof.

3.4. Agrees that any remaining Material upon verification will be destroyed (unless requested by Provider to return remaining Material) upon termination of this Agreement or completion of Evaluation.

3.5. Handling of the Material (storage, dissolution, application) shall be in accordance with best practice, published scientific information and prescribed by Regulatory Guidelines and other rules, law enacted and prevailing from time-to-time.

3.6. In no event shall the Material and/or Modifications be used in human beings unless necessary regulatory approvals have been obtained.

3.7. The Materials shall be used in compliance with the guideline issued by the Ministry of Health and Family Welfare (MoHFW), Government of India (GoI) vide O.M. No. L-190155397-IH (Pt) dated 19th Nov., 1997 for proposals involving the transfer of human biological material for biomedical research purposes.

4. OBLIGATIONS OF PROVIDER

The Provider shall transfer the Material immediately upon receipt of duly signed copy of this Agreement by the Recipient. The Provider shall transfer the Material after ensuring all safety norms and ethical guidelines. The Provider agrees to hire the services of a reputed courier agency and certified packaging agency as per the requirements of the Project. The Provider's and Recipient's laboratories will confirm dispatches and receipt of Materials.

5. OBLIGATIONS OF RECIPIENT

The Recipient agrees to ensure that the original Material received from the Provider will be handled in appropriate safe research environment following good laboratory practices and must ensure to strictly abide/comply with the obligations provided under the "ICMR Guidelines for Technology Development Collaboration" (as amended from time to time).

6. COST AND PAYMENT ARRANGEMENTS

The Material shall be provided for free of cost/charge to the Recipient. However, in certain circumstances, the Recipient agrees to bear the cost of shipping of the said Material, if requested by the Provider.

7. LEGAL TITLE AND INTELLECTUAL PROPERTY RIGHTS

Nothing in this Agreement shall operate to transfer to the Recipient any Intellectual Property rights (all patents, copyrights, trade secrets or any other form of IP) of ICMR, nor shall this Agreement grant any Party any rights in or to the Confidential Information of the other Party except as expressly set forth herein. It is understood that this Agreement in no way grants to Recipient (i) a license to make, use, or sell the Material or product made from the Material, under any patent or Technology owned by ICMR or (ii) a sublicense under any license held by ICMR. Any IP created/generated by the Recipient through the Material transferred shall be jointly owned by ICMR and the Recipient. Parties shall employ the best possible efforts for suitable protection including filing and prosecution of IP owned, if so generated with mutual consensus followed by approval by the Competent Authority, ICMR.

8. NATIONAL BIODIVERSITY AUTHORITY AND BENEFIT SHARING

The Parties agree to obtain the necessary approval of National Biodiversity Authority, Chennai (NBA) for research/ commercial utilization/ bio-survey or bio-utilization purpose, as part of the mandatory requirements of Statutory Compliance to the National Laws. (as and when applicable).

9. RETURN OF MATERIAL

After the completion of the studies (Project___) according to the purpose of the Material or at the expiry of this MTA whichever occurs first, the Recipient shall at the discretion of the Provider, either destroy or return to the (ICMR-XXXX) Institute the remaining Material and modification incorporating the Material, complying all safety norms and the ethical guidelines.

10. PRODUCT DEVELOPMENT AND ROYALTY

10.1. If the Recipient's project/research results in an invention, a new use, or a product based on the utilization of the said Material, the Recipient agrees to disclose the same to the ICMR immediately, on a confidential basis. Also, in such cases, the royalty applicable shall be governed by the ICMR's 'ICMR Guidelines for Technology Development Collaboration' (as amended from time to time).

10.2. The Recipient shall pay the royalty @1% to the Provider from the Net sales for the Royalty term as per the 'ICMR Guidelines for Technology Development Collaboration,' as amended from time- to- time. Payment of royalty shall fall due beginning with the first sale of the product(s). Royalty for each financial year shall be payable to the Provider on half yearly basis. Royalty due up to 31st March must be paid before the last working day of April and for royalty due up to 30th September by last working day of October.

10.3. Further, if there arises a situation wherein commercialization of product based on the Material is undertaken, prior approval from ICMR must be sought. In such cases, a separate License Agreement shall have to be executed with conditions between the Parties.

11. MAINTENANCE OF CONFIDENTIALITY

Recipient shall take reasonable measures to protect the secrecy of and avoid disclosure and unauthorized use of the Confidential Information of Disclosure/Provider with respect to the Material. Without limiting the foregoing, Recipient shall take at least those measures that it employs to protect its own confidential information of a similar nature. The Recipient shall not make any copies of the Confidential Information of Discloser/Provider unless the same are previously approved in writing by Discloser/Provider. The Recipient must use the Confidential Information solely for the purpose for which it was disclosed and for no other purpose whatsoever, without the prior written consent of the Discloser, which the

Discloser shall be at liberty to give or to decline to give in its unfettered and uncontrolled discretion. The Recipient shall reproduce Discloser's/Provider's proprietary rights notices on any such authorized copies, in the same manner in which such notices were set forth in or on the original. It shall be the responsibility of the Recipient to ensure maintenance of such confidentiality including on behalf of their employees, representatives and associates involved in the Project. The Recipient shall promptly notify the Discloser/Provider of any unauthorized use or disclosure, or suspected unauthorized use or disclosure, of Discloser's/ Provider's Confidential Information of which Recipient becomes aware. The report and the results and conclusions of the Material / Tests shall not be disclosed by Recipient to any third parties without the prior written consent of the Discloser/Provider, and the Recipient shall take such measures to protect the report including the results and conclusions as it uses to protect its own proprietary information.

12. DATA RIGHTS AND DATA PRIVACY

12.1. ICMR shall have equal rights on all the data generated under the course of the Project. ICMR shall be free to use the Data so generated from the Project under this Agreement for any purpose including for further research and teaching purposes. The Recipient shall take reasonable steps to prevent ICMR Data, documents or other ICMR confidential and proprietary information from unauthorized usage or falling into unauthorized hands. The Recipient shall ensure that its personnel working on such assignment shall sign appropriate agreements (acceptable to ICMR) to prevent unauthorized usage and disclosure of specific data, documents or other ICMR confidential and proprietary information.

12.2. Data rights in cases where Artificial Intelligence is involved shall be dealt separately.

12.3. Recipient to ensure that data is anonymized, kept confidential and strictly abide by the provisions of IT Act, 2000 and The Digital Personal Data Protection Act, 2023 while dealing with such data.

13. NO WARRANTY

The Material is provided "AS-IS-WHERE-IS BASIS." ICMR-XXX or ICMR makes no warranties, express, implied, or otherwise, regarding its accuracy, safety, completeness, or performance.

14. BRANDING AND ACKNOWLEGMENT

14.1. Support of ICMR must be suitably acknowledged in the publications (papers, reports, advertisements, brochures, websites, flyers etc.) and products (labels, leaflets, package inserts etc.) arising out of the Material used by the Recipient.

14.2. In case any Product is developed from the Material provided by the Provider the logo of ICMR shall suitably be displayed on each product by the Recipient.

14.3. Recipient shall be permitted to use the ICMR Logo only post approval by the Competent Authority, ICMR and as per the Brand Guidelines of ICMR.

15. PRESS RELEASE AND PUBLIC ANNOUNCEMENTS

15.1. Prior written permission must be taken by the Recipient from ICMR prior to any press releases, public announcements, or media statement with respect to the source of the Material that has been given by ICMR or transferred by the ICMR for commercialization.

15.2. ICMR reserves the rights to make any modifications for incorporation by the Recipient in the proposed Publication/Press Release with respect to the Technology or Product coming out of the Material being transferred.

16. PUBLICATION

16.1. 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).

16.2. Support of ICMR must be duly acknowledged in all publications.

16.3. ICMR Scientists may be given due advantage of authorships in the publications arising out of material transfer/co-development.

17. NO LIABILITY

Recipient assumes all liability for damages that may arise from its use, storage, or disposal of the Materials. Provider will not be liable to Recipient for any loss, claim or demand made by Recipient, or made against Recipient by any other party, due to or arising from the use, storage, or disposal of the Materials by Recipient, and Recipient agrees, to the extent allowed under applicable law, to defend, indemnify and hold Provider harmless from and against any such losses, claims or demands.

18. TERM AND TERMINATION

This Agreement shall remain effective for a period of _____ (months/years) (herein referred to as **"Term"**) from the date of execution unless terminated by either Party by giving thirty (30) days prior written notice to the other Party. The requirement to protect Confidential Information disclosed under this Agreement shall survive for a period of 10 years from the date of expiration of this Agreement. This MTA may be renewed upon the mutual consent of the Parties either by means of a new MTA or by amendments hereto expressed in writing. The Recipient must ensure to strictly abide/comply with obligations provided under the "ICMR Guidelines for Technology Development Collaboration" (as amended from time to time), non-compliance of the same by the Recipient shall result in the Termination of this Agreement.

19. NOTICES

All notices required to be served should be mailed postage prepaid and addressed to the respective Parties, as follows:

To PROVIDER	To RECIPIENT
Name	**Name**
Designation	**Designation**
Address	**Address**
Email	**Email**
Phone No.	**Phone No.**

20. ENTIRE AGREEMENT

This Agreement constitutes the final agreement between the Parties, and it supersedes all prior verbal understandings, and other correspondence/ communications between the Parties with respect to the subject matter hereof.

21. NO AMENDMENTS

No amendment, modification, or waiver of any provision of this Agreement shall be effective unless in writing and signed by duly authorized signatories of both Parties. The waiver by either Party of a default under any provision of this Agreement shall not be construed as a waiver of any subsequent default under the same or any other provision of this Agreement, nor shall any delay or omission on the part of either Party to exercise or avail itself of any right or remedy that it has or may have hereunder operate as a waiver of any right or remedy.

22. RELEASE AND INDEMNIFICATION

22.1. **Release**

22.1.1. The Recipient unconditionally releases ICMR including its Institutes, study sites, officers, employees, sub-contractors, and agents absolutely from and against all actions, claims, proceedings or demands and in respect of any loss, death, injury, illness or damage (whether personal or property, and whether special, direct, indirect or consequential, including consequential financial loss) suffered by the Recipients, its affiliates, any sub-licensee(s) or any third party arising out of such party's Commercialization or use of the Material, Products, or the Intellectual Property.

22.1.2. To the full extent permitted by law, ICMR, its Institutes, study sites, and its officers, employees, sub-contractors, and agents will not be liable to the other for any special, indirect or

22.1.3. Consequential damages, including consequential financial loss arising out of the Commercialization or use of the Material, Products, or the Intellectual Property, by the Recipient, its affiliates.

22.2. **Indemnification -** The Recipient hereby indemnifies and agrees to keep ICMR, its Institutes, study sites, and their officers, employees, sub-contractors, and agents

indemnified from and against: (i) all actions, claims, proceedings or demands (including those brought by third parties) which may be brought against any of them, whether on their own or jointly, in respect of any loss, death, injury, illness or damage (whether personal or property, and whether special, direct, indirect or consequential, including consequential financial loss) arising out of the Commercialization or use of the Intellectual Property, or product, on or after the date of this Agreement; and/or (ii) any breach of any provisions of this Agreement, including of the representations and warranties contained herein, any and all misrepresentation, liabilities, obligations, commitment to make any payment, covenants, or agreement of the Recipient contained in this Agreement; and/or (iii) any violation of the applicable laws.

23. GOVERNING LAW, JURISDICTION AND DISPUTE RESOLUTION

23.1. This Agreement and the associated undertaking shall be governed and interpreted in accordance with the laws of India subject to the exclusive jurisdiction of the Courts at New Delhi.

23.2. 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 no resolution is reached within 30 (Thirty) days following the date on which one Party first notifies in writing to the other of its request that such a meeting be held, 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 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 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 New Delhi International Arbitration Centre (NDIAC) Act, 2019 and as per 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 Agreement expiring or ceasing to exist or being terminated or foreclosed.

24. FORCE MAJEURE

Neither Party shall be liable for any failure to perform under this Agreement to the extent such failure to perform was caused in whole or in part due to any act of God, natural calamities, act of terrorism, biological or chemical contamination, war, governmental regulations, riots or labour strike. Provided that, to be excused from its failure to perform, an affected party must act diligently and use reasonable efforts to continue to perform, provide appropriate notices to the other party and/or resume performance as soon as possible. If a force majeure event continues for a continuous period of more than 90 days, either Party may choose to terminate the Agreement.

25. SURVIVABILITY

If at any point one or more terms and conditions within this Agreement are deemed to be unenforceable or void, the Parties agree to substitute a similar term or condition to replace the defective one.

26. SURVIVAL

Notwithstanding the foreclosure or termination, or completion of the term of this agreement. Recipient shall continue to be bound by the following provisions:

26.1. Clause 7, (Legal Title and Intellectual Property Rights)

26.2. Clause 11, (Maintenance of Confidentiality)

26.3. Clause 12, (Data Rights and Data Privacy)

26.4. Clause 14, (Branding and Acknowledgement)

26.5. Clause 15, (Press Release and Public Announcements)

26.6. Clause 16, (Publication)

26.7. Clause 22, (Release & Indemnification)

26.8. Clause 23, (Governing Law, Jurisdiction & Dispute Resolution)

27. MISCELLANEOUS

27.1. This Agreement and the rights and obligations hereunder may not be assigned or delegated by Recipient, in whole or part, whether voluntarily, by operation of law, change of control or otherwise, without the prior written consent of Provider.

27.2. This Agreement may not be changed, modified, or released, discharged, abandoned, or otherwise terminated in whole or in part, except by an instrument in writing signed by each Party.

27.3. This Material Transfer Agreement is non-assignable and non-transferable.

27.4. The Material would not be used for any future commercial purposes other than those stated above.

27.5. The Material would not be transferred to any other person/agency in any circumstances.

27.6. The Recipient indemnifies the Provider from all damages that may occur due to improper handling of the Material.

27.7. Upon request, the Recipient shall provide the ICMR with a yearly report on the use of Material.

27.8. No variation of or amendment to this Agreement shall bind either Party unless made in writing and signed by a duly authorized representative of each Party.

27.9. Any other required compliances of Government, as amended from time-to-time.

The version of this MTA applicable to any Material shall be the version in effect at the time of raising a request for transfer of Material.

Agreed and Accepted
(To be signed in duplicate)

For and on behalf of the ICMR (PROVIDER)	For and on behalf of UNIVERSITY/ ORGANIZATION/COMPANY (RECIPIENT)
Name:	Name:
Designation:	Designation:
Signature:	Signature:
Date:	Date:
Witness	**Witness**
Name:	Name:
Designation:	Designation:
Witness	**Witness**
Name:	Name:
Designation:	Designation:

Schedule I

Details of the Materials to be transferred under this MTA

DETAILS PROVIDED BY RECIPIENT
• *Type of Material (Biological/chemical/molecules/research material/protocols/data etc.):*
• *Quantity required (please specify):*
• *Purpose (Please specify):*
DETAILS BY PROVIDER
• *Type of Material (Biological/chemical/molecules/research material/protocols/data etc.):*
• *Quantity provided:*
• *Purpose:*

Recipient Signature:

Date:

ANNEXURE - II

MEMORANDUM OF AGREEMENT

(FOR JOINT DEVELOPMENT/ COLLABORATION)

MEMORANDUM OF AGREEMENT (MOA)

Between

INDIAN COUNCIL OF MEDICAL RESEARCH

And

ICMR-XXX / XYXY- .....

And

YYY

Ministry of Health & Family Welfare,
Government of India

FOR JOINT DEVELOPMENT OF DRUGS/ VACCINES/ DEVICES/ DIAGNOSTICS (COLLABORATION AGREEMENT)

MEMORANDUM OF AGREEMENT

THIS MEMORANDUM OF AGREEMENT (hereinafter referred to as 'MoA' or 'Agreement') is made and entered into on this_____day of_____, 202_ by and between the "Effective Date"

By and Between

The INDIAN COUNCIL OF MEDICAL RESEARCH, an apex body in India for formulation, coordination and promotion of biomedical research under the Department of Health Research, Ministry of Health & Family Welfare, Government of India, registered as Society under the Societies Registration Act, 1860, having its registered office at V. Ramalingaswami Bhawan, Ansari Nagar, Post Box 4911, New Delhi – 110029, India (hereinafter referred to as **"ICMR"** which expression shall wherever the context so admits include its successors and permitted assignees) the **PARTY OF THE FIRST PART (FIRST PARTY)**

AND

ICMR-XXX (XXX) with_____, as the designated Project Investigator (PI), a constituent laboratory/institute of Indian Council of Medical Research (ICMR), Department of Health Research, Ministry of Health & Family Welfare, Government of India having its Registered office at _____(hereinafter referred to as ICMR-XXX) the **PARTY OF THE SECOND PART (SECOND PARTY)**

OR

_____ XYXY, an institute/laboratory established under_____Act of Parliament/society registered under the Societies Registration Act, 1980/ Trust registered under Indian Trusts Act, 1882, having its registered office at _____ (hereinafter referred to as XYXY which expression shall wherever the context so admits include its successors and permitted assignees) the **PARTY 1, PARTY 2, PARTY 3 _____ OF THE SECOND PART (as applicable) (SECOND PARTY);**

AND

YYY, a company registered and incorporated under the Companies Act 1956, (or Companies Act 2013) and having its registered office at _____ (hereinafter referred to as 'COMPANY' which expression shall wherever the context so admits include its successors in interest, liquidators, administrators and permitted assignees)/ _____(Mention the name of Society/ University/ Research Institute/ College wherein the Research/development is being conducted) _____ (hereinafter referred to as "INSTITUTE") the **PARTY OF THE THIRD PART (THIRD PARTY**)

The FIRST PARTY, SECOND PARTY and THIRD PARTY are hereinafter collectively referred to as the "Parties".

WHEREAS

I. The SECOND PARTY has developed a ..... (hereinafter referred to as the "PRODUCT") with potential for .....

II. The THIRD PARTY shall extend its support to co-develop .....

III. FIRST PARTY shall extend support to the SECOND PARTY and THIRD PARTY for "..... Study" hereinafter referred to as the "Project" as mentioned in Clause 3 below.

IV. FIRST PARTY, SECOND PARTY and THIRD PARTY herewith have decided to cooperate and collaborate with each other for joint development of the ".....".

V. The overall objective of the collaboration from the perspective of the Parties is to contribute towards jointly undertaking ..... development by the Parties and bringing the PRODUCT to the market for societal impact by providing required resources and expert opinions/ materials as per terms of this MoA.

NOW THEREFORE, FIRST PARTY, SECOND PARTY and THIRD PARTY, each in consideration of the covenants and agreements of the other and intending to be legally bound, agree as follows:

1. REPRESENTATIONS AND WARRANTIES OF THE FIRST PARTY, SECOND PARTY AND THE THIRD PARTY

The FIRST PARTY represents and warrants the following:

1.1. The FIRST PARTY represents and warrants as of the Effective Date that: (i) it has the legal power, authority and right to enter into this MoA and to fully perform all of its obligations hereunder; (ii) this MoA is a legal and valid obligation binding upon it and enforceable in accordance with its terms and (iii) the performance of its obligations hereunder do not conflict with, violate or breach or constitute a default or require any consent under, any contractual obligations, of the FIRST PARTY.

The SECOND PARTY and THIRD PARTY represent and warrant the following:

1.2. The SECOND PARTY and THIRD PARTY has all requisite authority to enter into this Agreement and to perform and fulfill its obligations under this Agreement;

1.3. The execution and delivery of this Agreement and the performance or fulfilment of the THIRD PARTY's obligations under this Agreement will not conflict with, or result in breach of, or constitute a default under, or require the consent of any third party under any applicable laws, or instrument to which the THIRD PARTY is bound;

1.4. There are no pending or threatened lawsuits, actions, or any other legal or administrative proceedings against the THIRD PARTY, its promoters, or directors, or dean/heads which, if adversely determined against them, would have a material adverse effect on the ability of the THIRD PARTY to perform its obligations under this Agreement.

2. DEFINITIONS

2.1. **Background Intellectual Property** (**BGIP**) shall mean any Intellectual Property/IP that is created or owned by the Party prior to the Effective Date of this Agreement between the Parties.

2.2. **Disclosing Party** shall mean the Party to the MoA, or its employees, agents and other authorized representatives disclosing the CONFIDENTIAL INFORMATION to the other Party to the MoA, or its employees, agents and other authorized representatives.

2.3. **Effective Date** shall mean the date of signing of this MoA or the date of issuance of Sanction Order by ICMR (as applicable). In the event the Parties affix their signatures to this Agreement on separate dates, the Agreement shall be effective from the date on which the last set of signatures is affixed thereto. Three copies of the Agreement shall be signed by each of the Parties and one copy each shall remain in the custody of each Party.

2.4. **Intellectual Property** shall mean and include the following (a) Invention (as defined herein) or discovery (whether patentable or not); manner, method or process of manufacture; method or principle of construction; chemical composition or formulation; biological material; product; computer program; integrated circuit, circuit layout or semiconductor chip layout or design; plan, drawing; or scientific, technical or engineering information or document; (b) Invention(s), improvement, modification or development of any of the foregoing; (c)patent, application for grant of a patent, right to apply for grant of a patent or similar rights for or in respect of any subject matter referred to in sub-paragraphs (a) or (b) above; (d) trade secret, know-how, or right of secrecy or confidentiality in respect of any information or document or other Intellectual Property referred to in sub-paragraphs (a) or (b) above; (e) copyright or other rights in the nature of copyright subsisting in any works or other subject matter referred to in sub-paragraphs (a) or (b) above; (f) circuit layout rights.

2.5. **Invention(s)** shall mean any inventions, design, techniques, process, observations, data, information, results, ideas, concepts, discoveries, developments, know-how, trade secrets, methodologies, modifications, innovations, derivatives, improvements, materials, products, laboratories formulations or other discoveries whether or not patentable.

2.6. **Net Sales** shall mean Revenue from sales of goods or services by all ICMR Grantees/ Licensees/ Sub-licensee(s) based on the net sales realization from operations, net of discounts and indirect taxes, as defined by the Cost Accounting Standards - 24 and certified by the Chartered Accountant.

2.7. **PRODUCT** shall mean each product under development/ expected to be developed under this Project or .....

2.8. **Project** shall mean the research proposal entitled ".....".

2.9. **Project Review Committee (PRC)** shall mean a monitoring Committee comprising of eminent experts from the relevant field(s) which will be constituted by FIRST PARTY to monitor the progress of the objective(s) of the Project.

2.10. **Receiving Party** shall mean the Party, its employees, agents, or other authorized representatives, receiving Confidential Information from the other Party, its employees,

agents or other authorized representatives.

2.11. **Royalty Term** shall mean Royalty shall be payable to the FIRST PARTY from the Net sales for a period of 10 years from the date of commercialization of PRODUCT.

2.12. **Scope of Work** shall mean, in respect to the Project, the scope as detailed in this MoA, including any document or agreement executed pursuant to this MoA or as mutually agreed and executed between the Parties.

2.13. **Technology** shall mean any and all discoveries, inventions, processes, methods, techniques, know-how, Intellectual Property and proprietary rights, expressed in whatever form including technical information, processes, procedures, material for trials, methods, formulae, protocols, software, specifications, instructions, data, documents, drawings, images, prototypes and materials encompassing the Licensed Patents and Improvements there upon developed for the purpose of this Project.

2.14. **Term** shall mean the term or duration of this MoA commencing from the Effective Date and continuing for ..... () years thereafter, unless terminated earlier in accordance with Clause 13 (Termination) or extended with the agreement of both Parties in writing.

3. SCOPE OF THE PROJECT

The scope of the Project will include the following:

3.1. To work closely for enabling joint development of the PRODUCT under the Project.

3.2. To liaise and discuss the plan of action for designing final experiments and other requirements, required for effective implementation of the Project.

3.3. Obtaining required approvals for execution of the planned work.

3.4. To support the study including laboratory testing and .....

3.5. To develop work plans, standard operating procedures and manual of procedures in consultation with each other for implementation of the planned work.

3.6. To carry out the assignment in accordance with the highest standard of professional and ethical competence and integrity, having due regards to the nature and purpose of the assignment.

3.7. The Parties agree and understand that the collaborative Project will progress to the ..... only after successful completion of ..... and that the Agreement will automatically terminate, if the study results are not satisfactory, upto the satisfaction of the Parties.

4. ROLES & RESPONSIBILITIES OF THE PARTIES

4.1. THE FIRST PARTY

In consideration of the mutual covenants hereunder, the FIRST PARTY hereby agrees that:

4.1.1. It shall only be the nodal agency for coordination of the Project.

4.1.2. It will provide logistic support (monitoring/administrative) or financial support as approved by the Project Review Committee (PRC)/Competent Authority. It

reserves the right to extend the Project as and when required and the approval for the Project is placed at **Schedule-1**.

4.1.3. There will be no financial or other obligation(s) to the FIRST PARTY after the proposed duration of the Agreement (as defined thereunder).

4.1.4. It shall constitute a Project Review Committee (PRC) approved by the Competent Authority, ICMR, HQ, which will track, assess, or monitor the progress of the Project with a view to assist in troubleshooting the problems faced by SECOND PARTY and THIRD PARTY in conducting pre-clinical & clinical studies for the ..... candidate for facilitating its commercialization for societal benefit. The PRC shall monitor progress with respect to developmental phases of the .... in pursuance of the present Agreement, with the FIRST PARTY detailing all or any of the actions, efforts, endeavors, arrangements, appointments, engagements etc. undertaken by the SECOND PARTY and THIRD PARTY.

4.1.5. The FIRST PARTY agrees to abide by the confidentiality obligations as per Clause 11, defined hereafter.

4.2. THE SECOND PARTY

In consideration of the mutual covenants hereunder, the SECOND PARTY hereby agrees that:

4.2.1. It shall nominate a Project Investigator (PI) who shall be responsible for coordination of this Project and interaction with the FIRST PARTY and the THIRD PARTY for complying with the terms and conditions of this Agreement.

4.2.2. The PI shall ensure that the activities for this Project are executed in timely manner for successful completion of the Project within the stipulated Term of this Agreement.

4.2.3. The PI of the SECOND PARTY shall ensure the use of the PRODUCT is strictly for the intended purpose of the PRODUCT for which the Agreement is being made and not for any other purposes.

4.2.4. It will conduct the validation study, if applicable, as per the agreed protocol and will share the anonymized findings with the THIRD PARTY.

4.2.5. It shall maintain and provide complete and accurate records and all supporting documentation as sufficient and necessary by the requirements as may be provided under this Agreement in such connection to the scope of the Project.

4.2.6. It shall notify the FIRST PARTY of any material change in its entity status, Project Investigator, implementation site or any other such change that would impact the performance of its obligations under this Project and this Agreement.

4.2.7. It shall abide by the confidentiality obligations as per Clause 11, defined hereafter.

4.3. THE THIRD PARTY

In consideration of the mutual covenants hereunder, the THIRD PARTY hereby agrees that:

4.3.1. It shall undertake the Project in collaboration with FIRST PARTY and the SECOND

PARTY under this MoA.

4.3.2. It shall participate in all discussions and shall be responsible for drafting protocols and providing necessary information to the FIRST PARTY in a professional and mutually agreed manner.

4.3.3. It shall ensure submission of ..... samples of claim and providing required information/help for execution of planned work for conducting the ..... study and technical assistance for PRODUCT development, as per requirement of the Project.

4.3.4. It shall have provisions to undertake the scale-up as required, manufacturing and commercialization of the ....., in a set milestone.

4.3.5. It will return the devices/materials/documents/Data after the tenure of the Agreement if/whenever asked by the "SECOND PARTY" and/or by the FIRST PARTY. There is no obligation on any of the Parties to enter into a purchase process after the Agreement is over.

4.3.6. It shall adhere to the guidelines and directions of the Competent Authority, ICMR Headquarter, New Delhi or his nominee during the conduct of the proposed study under the Project.

4.3.7. It shall, subject to its norms, permit personnel designated by the FIRST PARTY and SECOND PARTY to participate in Project including regular visits to the sites, designated labs and to conduct other specific Project activities envisaged under this MoA.

4.3.8. It shall maintain and provide complete and accurate records and all supporting documentation as sufficient and necessary by the requirements as maybe provided under this Agreement in such connection to the scope of the Project.

4.3.9. It shall be responsible for the proper and intended usage of the PRODUCT(s) provided by the SECOND PARTY under this Agreement.

4.3.10. It shall extend the required support for implementation of the proposed study/ Project for the benefit of public health.

4.3.11. Any other roles & responsibilities as may be directed by the Competent Authority, ICMR shall be undertaken by the THIRD PARTY.

4.3.12. It shall notify the FIRST PARTY of any material change in its incorporation status, shareholding, entity status, Project Investigator/ Coordinator, implementation site or any such change that would impact the performance of its obligations under the Project and this Agreement.

4.3.13. It shall not assign or transfer the PRODUCT/Project interests/ rights to any third party directly or indirectly without prior written consent from the FIRST PARTY till full and final settlement of all dues as mutually agreed by the Parties.

4.3.14. It shall be responsible to apply for the required certifications and necessary approvals required for commercialization of the technology or starting from R&D for product development to its commercialization, nationally and internationally and have them in order at their own cost.

4.3.15. It shall be responsible to make every effort to commercialize the technology at a reasonable price.

4.3.16. The THIRD PARTY is required to register its novel PRODUCT co-developed with the FIRST PARTY and SECOND PARTY under this Agreement, on the GeM portal of the Ministry of Commerce and Industry, Government of India.

4.3.17. The THIRD PARTY must ensure to strictly abide/comply with all the obligations provided under the "ICMR Guidelines for Technology Development Collaboration" (as amended from time to time).

4.3.18. To obtain necessary approvals, sanctions, adhere and comply with any other required compliances of Government of India, as amended from time-to-time.

4.3.19. It shall abide by the confidentiality obligations as per Clause 11, defined hereafter.

5. INTELLECTUAL PROPERTY (IP) RIGHTS:

5.1. Background Intellectual Property (**BGIP**) of the Parties shall always remain the sole and exclusive property of the Party possessing the BGIP. Furthermore, when either Party receives any BGIP from the other Party, necessary and reasonable care will be taken by such Party while using the same for the implementation of the research components. BGIP shall include trade secrets, materials, and confidential data of the respective Parties.

5.2. Any Intellectual Property resulting under the scope of this MoA, shall be protected using the appropriate IP.

5.3. All IP generated during collaborative development under the Project shall be jointly owned by ICMR and the THIRD PARTY. ICMR shall be responsible for IP filing, Protection and Management of Jointly developed Technologies/ IP under this MoA. **Intellectual Property** or **I.P.** shall mean as defined in this Agreement therein.

5.4. The FIRST PARTY shall grant THIRD PARTY a non-exclusive world-wide license to commercialize the "....." developed under the Project and the underlying I.P. generated under this Agreement. However, in case an exclusive license is granted to the THIRD PARTY, the THIRD PARTY agrees that if they fail to Commercialize the "PRODUCT" and make it available to the country at scale and volumes it is required for public health benefit, the exclusive license may get converted into a Non-exclusive license and the FIRST PARTY shall then be free to transfer the I.P. to any other Company for meeting public health objectives.

5.5. Any Improvement which claims priority from or which are obvious modifications (as evidenced by potential application of Improvements w.r.t. the Field of Use) and improvements to the inventions, it is agreed that ICMR and THIRD PARTY shall jointly own all Intellectual Property in such Improvements throughout the Territory and in perpetuity and any I.P. Rights in such Improvements shall be deemed to fall within the scope of this Agreement. In case of modifications and improvements which do not claim priority from and are substantially different (with application beyond the Field of Use) from the inventions, the party conceptualizing shall exclusively and absolutely own all Intellectual Property in such Improvements, throughout the Territory and in perpetuity,

wherein 'Improvements' shall mean, any and all improvements, enhancements, variations, or modifications of the Technology and all inventions, designs, information, know-how, specifications, formulae, data, processes, methods, techniques arising in connection with the development, manufacture, and production of any Products used in, generated or otherwise created using the Technology.

6. ROYALTY PAYOUTS

6.1. From the date of the first commercialization of the PRODUCT, THIRD PARTY shall pay 2% Royalty on "**Net Sales**" on half yearly basis after March and September every year to the FIRST PARTY.

6.2. Submit audited Annual reports along with the certified audited balance sheets and profit & loss accounts to the FIRST PARTY within 30 days after submission of the balance sheet to the Registrar of Companies ("ROC") till full and final settlement of all Royalty dues to the satisfaction of the FIRST PARTY. However, such audited books of accounts shall be submitted only once a year on financial year closing and mid-year payment of 30th September will be based on provisional statement of accounts duly certified by accounts department of the THIRD PARTY.

6.3. THIRD PARTY shall pay the royalties on half yearly basis. Royalty due up to 31st March must be paid before the last working day of April and for royalty due up to 30th September by last working day of October.

6.4. To pay royalty under and in terms of this sub-clause shall accrue upon the commencement of the commercial sale of the PRODUCT ("Royalty"). These reports shall show for the period in question based on Net Sales made by the THIRD PARTY and its Affiliates, if any, of the PRODUCT(S), details of the quantities of the PRODUCT sold, Net Sales made by the THIRD PARTY and the royalty due to the FIRST PARTY from both Government and Non-Government sales.

6.5. **Royalty Reporting**

Product Name	Unit Sale Price	Total Quantity Sold	Gross Sales Value (INR)	Net Sales value (INR)	% of Royalty Payable	*Royalty Amount (INR)

*Goods and Services Tax (as applicable) shall be paid additionally on Royalties due.

6.5.1. The THIRD PARTY shall pay the royalties on half yearly basis. Royalty due up to 31st March must be paid before the last working day of April and for royalty due up to 30th September by last working day of October.

6.5.2. THIRD PARTY must submit to the FIRST PARTY a CA Certified account statement for the Royalty Period in the following format:

6.6. **Mode of Payment of Royalty to the FIRST PARTY**

The Royalty on the Net sales shall be paid by the THIRD PARTY by way of account payee crossed cheque OR Demand Draft drawn in favour of "Director General-Indian Council of Medical Research" payable at "New Delhi" or by electronic mode in favour of ICMR.

6.7. Delay in Payment of Royalty and Non-Payment

6.7.1. In case of delay in payment of Royalty, the THIRD PARTY shall be liable to pay simple interest at the rate of 12 (twelve) per cent per annum, on the amount of default in payment of Royalty for the period of delay.

6.7.2. In cases where three consecutive Royalty payments have not been made by the THIRD PARTY, it will result in Automatic termination of License/ Agreement with prior notice of 30 days to remedy the breach and make the payment.

6.8. Royalty Monitoring & Audit Rights

6.8.1. The THIRD PARTY must keep, and must ensure that THIRD PARTY itself and each of its Sub-Licensee (if any) keeps true and accurate accounts and records of the quantities of the PRODUCT manufactured, sold, and in stock, Gross Sales Price and Net Sales of the PRODUCT(s) in relation to each of the sub-territories comprising the Territory, all other accounting, stock, ordering, purchasing invoicing, and delivery records in relation to the PRODUCT(s) as are required by good accounting practice.

6.8.2. The THIRD PARTY must ensure to strictly abide/comply with the Termination Clause mentioned in this Agreement, which shall include strict compliance with the Royalty remittance obligations provided under the "ICMR Guidelines for Technology Development Collaboration," non-compliance of the same by the THIRD PARTY shall result in the Termination of this Agreement.

6.9. Inspection of Accounts by the FIRST PARTY

6.9.1. The FIRST PARTY may at any time, appoint a person or reputed auditing firm to inspect the THIRD PARTY's and sub-licensee's books and records so maintained for ensuring Royalty compliance.

6.9.2. Cost of such Audit shall be borne by the THIRD PARTY.

6.10. The Project will move to the next phases i.e., Phase- I, Phase- II, and Phase III only in case of drugs/vaccines and pilot or pivotal trial in case of devices, if the results of previous Phase are found to be acceptable and sufficient for extension to the next Phase. If the results of any of the phases of Projects are found unacceptable/ unsatisfactory, the Parties shall mutually decide to terminate this MoA and any related agreement(s) immediately.

7. ICMR RIGHTS

7.1. ICMR shall retain rights, on behalf of itself and all other FIRST PARTY supported non-profit academic research institutions/centres:

7.1.1. To use the Project outcomes and associated inventions or I.P. for educational and research purposes.

7.1.2. Non-exclusive, sub-licensable license for the PRODUCT envisaged under this Agreement which can be exercised by the FIRST PARTY in case of public health emergency for societal benefit and in National Interest as declared by the Government of India and governed by specific Order of the FIRST PARTY.

8. PUBLICATION

8.1. 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)

8.2. Support of ICMR must be duly acknowledged in all publications.

8.3. ICMR Scientists may be given due advantage of authorships in the publications arising out of licensing/co-development.

9. BRANDING AND ACKNOWLEDGEMENT

9.1. Support of ICMR must be suitably acknowledged in the publications (papers, reports, advertisements, brochures, websites, flyers etc.) and PRODUCTS (labels, leaflets, package inserts etc.) by the THIRD PARTY.

9.2. Use of ICMR Logo on PRODUCT packages:

9.2.1. The name/logo of ICMR shall suitably be displayed on each PRODUCT by the THIRD PARTY at its own cost.

9.2.2. The THIRD PARTY shall be permitted to use the ICMR Logo following approval by the Competent Authority of ICMR and as per the Brand Guidelines of ICMR.

10. PRESS RELEASES AND PUBLIC ANNOUNCEMENTS

10.1. Prior written permission must be taken by the THIRD PARTY and the SECOND PARTY from ICMR before making any press releases, public announcements, or media statement with respect to the PRODUCT that has been given grant-in-assistance by ICMR as per this Agreement.

10.2. The FIRST PARTY reserves the rights to make any modifications for incorporation by the THIRD PARTY and/or SECOND PARTY in the proposed Publication/Press Release.

11. CONFIDENTIALITY

11.1. "Confidential Information" means all information (whether in oral, written or electronic form) relating to the minutia of research and development proposals, presentations, Intellectual Property stated in the research and development proposals, due diligence reports, in-house analysis reports and Freedom to operate reports, information on business and finances, unpublished data, organizational and individual information, proposed technology or intended inventions/ procedures, nature of research and/or plans for prioritizing research, commercialization strategy, technical validation, budgets and strategies, minutes of the meeting(s) or other agnate materials including any notes or summaries derived from those materials of the Disclosing Party and Confidential Information received by the Disclosing Party from third parties. All information under the MoA shared between the Parties shall be treated as Confidential Information and shall be subject to restrictions on disclosure other than for the purpose of this MoA.

11.2. During the Term of this Agreement, the Parties, undertake to maintain strict confidentiality and refrain from disclosure thereof, of all or any part of the information and data exchanged/generated from the Project under this Agreement for any purpose other than purposes in accordance with this Agreement. It shall be the responsibility of the Parties to ensure maintenance of such confidentiality including on behalf of their employees, representatives and associates involved in the Project.

11.3. The Parties shall not have any obligation of confidentiality with respect to any information that is provided with documentary evidence that it:

a) Is in the public domain by use and/or publication at the time of its disclosure by the Disclosing Party; or

b) Was already in possession of the recipient prior to receipt from the Disclosing Party; or

c) Is properly obtained by the recipient from a third party with a valid right to disclose such information and such third party is not under confidentiality obligation to the Disclosing Party; or

d) Was disclosed to any third party on a non-confidential basis prior to commencement of the Project; or

e) Was developed by the recipient, as established by acceptable written record, independently of the disclosure of information by the Disclosing Party; or

f) Is required by public authority, by law or decree.

11.4. Notwithstanding anything contained herein, the provisions of Confidentiality shall survive early termination or expiration of this Agreement for a period of ten (10) years from early termination or expiration, as the case may be.

12. DATA RIGHTS AND DATA PRIVACY

12.1. The Parties shall have joint and equal rights on the data generated during this collaboration under this Agreement and shall be free to use the data for any purpose including for further Research and Teaching purpose. THIRD PARTY shall take reasonable steps to prevent the FIRST PARTY and SECOND PARTY data, documents or other confidential and proprietary information from unauthorized usage or falling into unauthorized hands. The THIRD PARTY shall ensure that its personnel working on such assignment shall sign appropriate agreements (acceptable to the FIRST PARTY and SECOND PARTY) to prevent unauthorized usage and disclosure of specific data, documents, or other confidential and proprietary information thereof.

12.2. Data rights in cases where Artificial Intelligence is involved shall be dealt separately.

12.3. In case patient data is being used by the THIRD PARTY it must ensure that the data is anonymized, and it must ensure to strictly abide by the provision of Information Technology (IT) Act, 2000 and The Digital Personal Data Protection Act, 2023 while dealing with such data.

13. FORECLOSURE AND TERMINATION

13.1. Automatic Termination

Automatic termination shall take place for default in payment of amounts due and non-payment of royalties due for payment for three consecutive Royalty reporting periods.

13.2. Termination by the FIRST PARTY

The FIRST PARTY shall notify the THIRD PARTY and SECOND PARTY regarding the breach of provisions under this Agreement, thereby, invoking the provisions of termination giving one-month notice to remedy the breach. The decision of the FIRST PARTY shall be final in all respects. The THIRD PARTY and/or SECOND PARTY (applicable only when Second Party is not an ICMR Institute) shall immediately refund any amount unutilized out of the FIRST PARTY's disbursements to the FIRST PARTY. The FIRST PARTY shall have the right to foreclose and terminate if the default prevails even after serving notice, under following circumstances:

13.2.1. For failure to achieve milestones within the timelines agreed between the FIRST PARTY, SECOND PARTY and THIRD PARTY.

13.2.2. on account of submission of false reports or misrepresentations by the THIRD PARTY.

13.2.3. for non-compliance with the royalty remittance obligation.

13.2.4. failure to submit CA audited documents (upon royalty remittance) certifying the actual sales made by the THIRD PARTY.

13.2.5. for non-fulfilment of obligations pursuant to this Agreement.

13.2.6. If the THIRD PARTY suspends or discontinues manufacture of the PRODUCT for a period exceeding 1 year without obtaining prior written permission or extension in this regard from the FIRST PARTY, except for reasons beyond the control of the THIRD PARTY and that are agreed by the FIRST PARTY.

13.3. **Termination by SECOND PARTY (XYXY-not an ICMR Institute) and THIRD PARTY** SECOND PARTY (XYXY-not an ICMR Institute) / THIRD PARTY may at any point of time choose to terminate this Agreement after giving reasons, by giving prior notice of at least three months to the Parties. On serving such notice, the FIRST PARTY shall seek compliance with the following obligations from the SECOND PARTY or/and THIRD PARTY (as applicable). Accordingly, the SECOND PARTY or/and THIRD PARTY shall-

13.3.1. Meet all the financial liabilities, including Royalty payments due till that point in time.

13.3.2. Submit a confidential report detailing the status of Technology development till that point of time, and;

13.3.3. Cooperate with the FIRST PARTY in transferring the Technology to third party.

For effective Termination, the above obligations shall be subject to approvals by the Competent Authority, ICMR.

13.4. This MoA is for a period of _____months in the first instance and shall be subject to renewal thereafter on mutually agreed terms. The deliverables of the collaboration would however extend beyond the terms of this MoA till the satisfactory completion of this project and mutual acceptance by the Parties unless terminated sooner in accordance with the provisions of this MoA.

13.5. THIRD PARTY and/or SECOND PARTY (XYXY-not an ICMR Institute) shall immediately refund any amount unutilized out of ICMR's disbursements to ICMR.

14. RELEASE AND INDEMNIFICATION

14.1. Release

14.1.4. The THIRD PARTY unconditionally releases ICMR including its Institutes, study sites, officers, employees, sub-contractors, and agents absolutely from and against all actions, claims, proceedings or demands and in respect of any loss, death, injury, illness or damage (whether personal or property, and whether special, direct, indirect or consequential, including consequential financial loss) suffered by the THIRD PARTY's and/or by the INSTITUTE, its affiliates, any sub-licensee(s) or any third party arising out of such party's Commercialization or use of the PRODUCTs, or the Intellectual Property.

14.1.5. To the full extent permitted by law, ICMR, its Institutes, study sites, and its officers, employees, sub-contractors, and agents will not be liable to the other for any special, indirect or consequential damages, including consequential financial loss arising out of the Commercialization or use of the PRODUCT(s) or the Intellectual Property, by the THIRD PARTY.

14.2. Indemnification

14.2.1. THIRD PARTY shall indemnify and shall agree to keep the FIRST PARTY, SECOND PARTY, and its officers, employees, sub-contractors and agents indemnified from and against: (i) all actions, claims, proceedings or demands (including those brought by third parties) which may be brought against any of them, whether on their own or jointly, in respect of any loss, death, injury, illness or damage (whether personal or property, and whether special, direct, indirect or consequential, including consequential financial loss) arising out of the Commercialization or use of the Intellectual Property, or any PRODUCTs; (ii) any breach of any provisions, including of the representations and warranties, any and all misrepresentation, liabilities, obligations, commitments; and/or (iii) any violation of the applicable laws.

14.2.2. The THIRD PARTY shall at all times, indemnify and keep indemnified the FIRST PARTY and SECOND PARTY against all claims/damages etc. by any infringement of any Intellectual Property Rights (IPR) while carrying out their responsibilities/ work under the Project and this Agreement.

14.2.3. The provision under this Agreement does not create any liability, explicit or implicit, on the FIRST PARTY including SECOND PARTY in respect of the manpower engaged in the Project.

15. FORCE MAJEURE

Neither Party shall be liable hereunder by reason of any failure or delay in the performance of its obligations hereunder on accounts of riots, fires, flood, storm, explosions, act of God, war, governmental action, lockdown, epidemic, pandemic, labour conditions, earthquakes or any other cause which is beyond the reasonable control of such Party provided the affected Party gives the other Party prompt written notice of the occurrence of any Force Majeure Event and the nature and extent to which the affected Party will be unable to perform its obligations under this Agreement. The affected Party agrees to use commercially reasonable efforts to correct the Force Majeure Event as quickly as possible. Performance shall be excused only to the extent of and during the reasonable continuance of such Force Majeure Event, provided that either Party may terminate this Agreement if such Force Majeure Event continues for a period of 30 (thirty) days or more. Any deadline or time for performance specified in this Agreement which falls due during or subsequent to the occurrence of a Force Majeure event shall be automatically extended for a period of time equal to the period of the Force Majeure Event.

16. NO JOINT VENTURE

Nothing contained in this Agreement will be construed as creating a joint venture, agency, partnership or employment relationship between the Parties hereto, nor will any Party have the right, power or authority to create any obligation or duty, express or implied, on behalf of the other Party.

17. NOTICES

All notices, approvals, instructions and other communications given or made under this Agreement shall be in English and in writing and shall be given by personal delivery or shall be sent by the reputed courier service or pre-paid registered post addressed to the relevant Party at its address set out below. Any written communication or notice so delivered shall be deemed to have been received by the addressee at the time and date when actually delivered, or in any event within five (5) working days after posting in the manner provided herein, provided no postal disruption shall exist. Any Party may, from time to time, change its address or representative for receipt of notices provided for in this Agreement by giving all the other Parties intimation in writing.

If to **ICMR-FIRST PARTY:**

Address: Indian Council of Medical Research,

V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi-110029

ATTN: The Director General, ICMR

Designation: Director General

Phone No.:

Fax No.:

Email: secy-dg@icmr.gov.in

If to **XXX/XYXY - SECOND PARTY:**

Address: XXXXX,

.....

..... India

Designated Persons:

Name:

Designation:

Phone No.:

E-mail:

If to the **COMPANY/INSTITUTE -THIRD PARTY:**

Address: XXXXX,

.....

..... India

Designated Persons:

Name:

Designation:

Phone No.:

E-mail:

18. AMENDMENTS

No amendment or modification of this MoA shall be valid unless the same is made in writing by the Parties or their authorized representatives and specifically stating the same to be an amendment of this MoA. The modifications/charges shall be effective from the date on which they are made/ executed, unless otherwise agreed to.

19. SEVERABILITY

In case any one or more of the provisions or parts of a provision contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provision or part of a provision of this Agreement; and this Agreement shall, to the fullest extent lawful, be construed as if such invalid or illegal or unenforceable provision, or part of a provision, had never been contained herein.

20. SURVIVABILITY

If at any point one or more terms and conditions within this Agreement are deemed to be unenforceable or void, the Parties agree to substitute a similar term or condition to replace the defective one.

21. WAIVER

The failure to enforce or uphold any aspect of this Agreement shall not constitute a waiver of any other aspect of the Agreement.

22. ENTIRE AGREEMENT

This MoA constitutes the entire understanding between the Parties and supersedes all prior, promises, proposals, representations, understandings and negotiations, whether written or oral, between the Parties with respect to the subject matter hereof.

23. REGULATORY COMPLIANCE

The THIRD PARTY shall primarily be responsible for complying with all applicable laws, regulatory approvals and obtaining such regulatory approval shall be read as integral part to this Agreement.

24. GOVERNING LAW, JURISDICTION AND DISPUTE RESOLUTION

24.1. The MoA shall be considered, interpreted and governed by the laws of India and Courts at Delhi shall have exclusive jurisdiction in all such matters.

24.2. 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 no resolution is reached within 30 (Thirty) days following the date on which one Party first notifies in writing to the other of its request that such a meeting be held, then, the Dispute shall be resolved by arbitration as per the provisions of the Arbitration and Conciliation Act, 1996 and the Rules there under, as amended from time to time.

24.3. 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 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 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 New Delhi International Arbitration Centre Act, 2019 (NDIAC) and as per 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 Agreement expiring or ceasing to exist or being terminated or foreclosed.

25. SURVIVAL

Notwithstanding the foreclosure or termination or completion of the term of this Agreement, the Parties shall continue to be bound by the following provisions:

Clause 5 ('Intellectual Property (IP) Rights')

Clause 6 ('Payouts')

Clause 7 ('ICMR Rights')

Clause 8 ('Publication')

Clause 9 ('Branding &Acknowledgement')

Clause 10 ('Press Releases and Public Announcements')

Clause 11 ('Confidentiality')

Clause12 ('Data Rights & Data Privacy')

Clause 14 ('Release and Indemnification')

Clause 15 ('Force Majeure')

Clause 16 ('No Joint Venture')

Clause 19 ('Severability')

Clause 20 ('Survivability')

Clause 24 ('Governing Law, Jurisdiction and Dispute Resolution')

IN WITNESS WHEREOF, THE PARTIES HAVE EXECUTED THIS MoA ON THIS ..... DAY OF ..... 202.....

Parties

For and on behalf of ICMR – FIRST PARTY	
(Signature & Stamp)	
Name:	
Date:	
WITNESSES	
Signature:	Signature:
Name:	Name:
Date:	Date:

For and on behalf of ICMR-XXX/XYXY – SECOND PARTY	
(Signature & Stamp)	
Name:	
Date:	
WITNESSES	
Signature:	Signature:
Name:	Name:
Date:	Date:

For and on behalf of the "COMPANY/INSTITUTE"– the THIRD PARTY duly authorized vide Board Resolution No ..... dated ..... of its Board of Directors:	
(Signature & Stamp)	
Name:	
Date:	
WITNESSES	
Signature:	Signature:
Name:	Name:
Date:	Date:

Schedule-1

Sanction Order:

ANNEXURE - III

LICENSE AGREEMENT

FOR LICENSING OF (XXXXX)

LICENSE AGREEMENT FOR LICENSING OF (XXXXX)

By and Between

INDIAN COUNCIL OF MEDICAL RESEARCH

And

M/s..... (Name of the company) .....

Ministry of Health & Family Welfare,
Government of India

The LICENSE AGREEMENT (hereinafter referred to as the "Agreement") is entered into as of ..... day of ..... 202_. (Effective Date)

By and Between

The **INDIAN COUNCIL OF MEDICAL RESEARCH**, an apex body in India for formulation, coordination and promotion of biomedical research under the Department of Health Research, Ministry of Health & Family Welfare, Government of India, a Society registered under the Societies Registration Act, 1860, having registered office at V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi – 110029, India (hereinafter referred to as the "**LICENSOR**"), which expression shall include its successors and assignors unless the context requires a different construction;

AND

M/s. (NAME OF THE COMPANY) ..... an existing company within the meaning of and registered under the Companies Act, 1956, (or Companies Act, 2013) having its registered office at **(ADDRESS OF THE COMPANY)** (hereinafter referred to as the "**LICENSEE**") which expression shall include its successor-in interest/businessand permitted assigns).

Each herein referred to individually as a "**PARTY**", or collectively as the "**PARTIES**".

1. Background

1.1. **WHEREAS the LICENSOR,** Indian Council of Medical Research (ICMR), New Delhi, through its Institute ICMR - XXX has developed a new and useful Technology, _____ (Name of the Technology/process/know-how) _____and owns _____rights in process/technology/know-how and is interested in licensing the same to suitable license having necessary experience & expertise (Details at Schedule - I)

1.2. **WHEREAS LICENSEE (Name of the company)** has approached the Licensor for seeking License to use, sell, and exploit commercially the process/technology/know-how including intellectual property owned by the Licensor.

1.3. **WHEREAS the LICENSOR,** in furtherance of its objectives is agreeable to grant to the Licensee such License, subject to covenants and conditions hereinafter contained.

2. DEFINITIONS

2.1. **AGREEMENT** means the License Agreement to be executed between the Licensor and the Licensee and includes any amendments, schedules hereto made in accordance with the provisions hereof.

2.2. **COMMERCIALIZATION** shall mean in relation to the Intellectual Property, to use, make, manufacture, have made or manufactured, sell, advertise, promote, distribute, hire, supply or otherwise dispose of any Product (being manufactured using the Intellectual Property), or to keep it for the purpose of doing any of those things in each country and area and space throughout the universe and to assign, License it to any third Party to do the same.

2.3. **CONFIDENTIAL INFORMATION** shall mean any and all information and know-how in any form, whether of a technical, financial, business or other nature, including, without limitation, the terms of this Agreement, information relating to the Parties' research, development, inventions, products, production, manufacturing, finances, marketing, business plans, trade secrets, know-how, data or other confidential communications, that is or has been disclosed to or otherwise received or obtained by either Party, whether or not in connection with or pursuant to this Agreement but excludes any information that: (1) was lawfully in the possession of the Recipient before receiving it from the Disclosing Party; (2) is provided in good faith to the Recipient by a third Party without breaching any rights of the Disclosing Party or any other Party; (3) is or becomes generally available to, or accessible by, the public through no fault of the Recipient; (4) is independently developed by the Recipient without use of the disclosed Confidential Information or (5) is required by public authority, by law or decree.

2.4. **DATA** means a representation of information, facts, concepts, opinions or instructions in a manner suitable for communication, interpretation or processing by human beings or by automated means (as defined under The Digital Personal Data Protection Act, 2023).

2.5. **DISCLOSER** shall mean a Party to this Agreement which discloses Confidential Information to any other Party.

2.6. **DISPOSE OR DISPOSITION** shall mean the manufacture, use, sale, lease or other transfer.

2.7. **EFFECTIVE DATE** shall mean the date of execution of this Agreement by all Parties. In the event Parties to this Agreement affix their signatures on different dates, the Effective Date shall mean the date on which the last of the executing Parties affixes its signatures to the Agreement.

2.8. **IMPROVEMENTS** shall mean, in connection with the Licensed Patent(s), any and all improvements, enhancements, variations, or modifications of the Technology described in the Licensed Patent(s) and all inventions, designs, information, know-how, specifications, formulae, data, processes, methods, techniques arising in connection with the development, manufacture and production of any Products used in, generated or otherwise created using the Licensed Patents encompassing the Technology.

2.9. **INTELLECTUAL PROPERTY OR 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; and shall include without limitation, the Technology, Licensed Patents and Licensed Trademarks, developed/ created through ICMR support.

2.10. **LICENSEE** shall mean any business, organization or institute that has been given legal permission in form of a License, by ICMR to commercialize the technology.

2.11. **LICENSED PATENT(S)** shall mean Indian Patent Application or granted patent or any patent application derived or arising from the foregoing in the Territory.

2.12. **NET SALES** shall mean Revenue from sales of goods or services by all ICMR Grantees/ Licensees based on the net sales realization from operations, net of discounts and indirect taxes, as defined by the Cost Accounting Standards-24 and certified by the Chartered Accountant.

2.13. **NON-EXCLUSIVE LICENSE** shall mean that the Licensee has the right to make, use, or sell the technology for commercial purposes, but ICMR remains free to grant any number of other Licensees, the same rights to make, use, or sell the technology for commercial purposes or any other purposes.

2.14. **PERSON** shall mean and includes a legal or natural person or a partnership, firm, trust, company, government or local authority and shall also include the legal representative or successor in interest of such person.

2.15. **PRODUCT** shall mean each Product manufactured by the Licensee, using the Intellectual Property in any manner whatsoever and/or any and all such Products, the manufacture, use, or sale of which would in absence of this Agreement, constitute infringement of the IP.

2.16. **RECIPIENT** shall mean a Party to this Agreement to whom Confidential Information is disclosed.

2.17. **ROYALTY** shall mean Disposition Royalties which are calculated as a percentage of Net Sales and will be payable by Licensee to ICMR under the Provisions of this Agreement.

2.18. **ROYALTY PERIOD** shall mean each consecutive period ending up to 30th September and up to 31st March respectively every year.

2.19. **ROYALTY TERM** shall mean Royalty payable to the Licensor by Licensee from the Net Sales for a period of 10 years from the date of commercialization of Product.

2.20. **SUB-LICENSE** shall mean a person to whom the Licensee grants a Sub-License to commercialize the Licensed Patents, its Improvements, and associated IP;

2.21. **TECHNOLOGY** shall mean any and all discoveries, inventions, processes, methods, techniques, know-how, Intellectual Property and proprietary rights, expressed in whatever form including technical information, processes, procedures, material for trials, methods, formulae, protocols, software, specifications, instructions, data, documents, drawings, images, prototypes and materials encompassing the Licensed Patents and Improvements

thereupon developed through ICMR support (described in Schedule-I hereto).

2.22. **TERRITORY** shall mean the entire world, except for the territories which are not allowed in National Interest.

NOW THEREFORE, it is agreed between the Parties:

3. GRANT OF LICENSE

By this License Agreement, Licensor (ICMR) agrees to grant a non-exclusive license to Licensee (Name of the Company) for the manufacture and sale of the (Technology Name) in the "Territory" for the "Duration of License" (described at Clause 4) from the date of this Agreement becoming effective.

4. DURATION OF LICENSE:

This LICENSE shall be valid for a period of .... XX.... years from the Effective Date unless revoked earlier for reasons as specified elsewhere in the document.

5. GRANT OF SUB-LICENSE:

5.1. The Licensee may enter into a Sub-License Agreement with any person to commercialize the Licensed Patent or Technology, with the prior written consent of the Licensor.

5.2. Sub-License Agreements entered into, if any or any other documents that may be reasonably requested by the Licensor specifically, shall be submitted by the Licensee within 15 days of such request.

5.3. Sub-License Agreement shall contain a clause that the same shall terminate automatically upon the termination or expiration of this Agreement.

6. RESPONSIBILITIES OF LICENSEE

6.1. The Licensee agrees to make all efforts to commercialize the TECHNOLOGY in India or any part of the world as it deems fit.

6.2. Ensure fulfilment of all procedural, legal, regulatory and operational requirements for the commercial utilization of the TECHNOLOGY and selling the same shall be the responsibility of the Licensee.

6.3. The Licensee acknowledges the absolute ownership of the TECHNOLOGY by the Licensor and also shall not dispute the legality, validity or enforceability of the License granted.

6.4. Licensee shall be responsible to apply for the required certifications and approvals necessary for commercialization of the technology nationally and internationally and have them in order at its own cost.

6.5. The Licensee shall not, at any time assign, mortgage, charge, or otherwise deal with possession of the TECHNOLOGY wholly or partially, without prior written consent of the Licensor.

6.6. The Licensee shall not directly or indirectly and either by itself or by its agents use the

TECHNOLOGY otherwise than in accordance with the terms and conditions under this agreement.

6.7. The Licensee shall not oppose or direct or cause any persons to oppose any application seeking Intellectual Property rights relating to the TECHNOLOGY filed by the Licensor.

6.8. The Licensee shall treat as strictly confidential all information/ knowledge obtained from the Licensor, in connection with or relating to the License hereby granted and shall use it only for furtherance of objectives of this Agreement.

6.9. The Licensee shall permit the personnel of the Licensor or its representative or duly authorized officials, at all convenient time to enter into and upon the premises of Licensee where PRODUCTS under this License, are [manufactured/stocked/sold/ used] for the purpose of inspecting the same and the manufacture thereof, generally to ascertain that the provision of this License are being complied with and quality of the PRODUCT maintained and fulfillment of other terms and conditions.

6.10. The Licensee must ensure to strictly abide/comply with the obligations provided under the "ICMR Guidelines for Technology Development Collaboration" (as amended from time to time).

6.11. Any other required compliances of Government of India, as amended from time-to-time.

7. RESPONSIBILITIES OF LICENSOR:

7.1. The Licensor shall within ...XX... days of the signing of the Agreement, hand over to the Licensee, documents consisting of details of Technology such as essential details of know-how, relevant drawings if any, Product details, specifications of formulation, process details, parameters and details of packaging/handling, registration of the product etc. (which hereinafter will be collectively referred to as "**Technology Transfer Documents (TTD)**".

7.2. The Licensor shall at the request of the Licensee, demonstrate or cause to be demonstrated, as it considers appropriate, the working of the TECHNOLOGY on the scale at which it has been developed.

7.3. The Licensor may, at the request and at the cost of the Licensee, train or arrange to be trained the owner(s) and/or the authorized employees of the Licensee possessing the requisite qualifications and experience as required for successfully translating the Technology.

7.4. The Licensor may at the request of the Licensee provide any further or other technical assistance to the Licensee for effective and expeditious implementation of this License upon mutually agreed terms and conditions.

7.5. The transfer of Technology shall be deemed as completed "on performance" by the Licensor of the tasks stipulated in provision 7.1 to 7.4 above.

8. CONFIDENTIAL INFORMATION

8.1. **Use of Confidential Information:**

8.1.2. A Recipient must use the Confidential Information solely for the purpose for which it was disclosed and for no other purpose whatsoever, without the prior written consent of the Discloser, which the Discloser shall be at liberty to give or to decline to give in its unfettered and uncontrolled discretion.

8.1.3. The Licensor shall undertake to maintain strict confidentiality and refrain from disclosure thereof, of all or any part of the information and data exchanged/ generated under this Agreement for any purpose other than in accordance with this Agreement.

8.1.4. It shall be the responsibility of both the Parties to ensure maintenance of such confidentiality in respect of their behalf and on behalf of their employees, representatives and associates involved in related activities.

8.2. Non-Disclosure of Confidential Information

A Recipient must keep the Confidential Information secret and confidential, and must not disclose, communicate or otherwise make known to any person any part of the Confidential Information without prior consent of the Discloser, which the Discloser shall be at liberty to give or to decline to give in its unfettered and uncontrolled discretion.

8.3. Disclosures to Directors and Employees or Disclosure for Commercialization:

The Recipient may disclose the Confidential Information to such of its directors and employees as is necessary to enable the Recipient to fully take advantage of Confidential Information for the purpose of this Agreement or disclose Confidential Information for the purpose of exercising its rights pursuant to this Agreement, with prior consent from the Licensor.

8.3.1. The Licensee must ensure that its disclosure of Confidential Information pursuant to 8.3.1 is upon such terms, or is restricted to such an extent as:

8.3.1.1. Protects Confidential Information from unauthorized or improper use or disclosure.

8.3.1.2. Does not prejudice any patent application in relation to what is to be disclosed.

8.4. Breach of confidentiality:

If the Recipient learns or believes that:

8.4.1. any unauthorized person has come into possession of any part of Confidential Information;

8.4.2. any person has made any improper or unauthorized use of Confidential Information; or

8.4.3. any unauthorized person is doing any act or thing in contravention of rights that attach to and arise from the Confidential Information; the Recipient shall immediately report full particulars to the Discloser, and must provide to the Discloser all assistance and information it may request with respect to that information.

9. FINANCIAL TERMS:

9.1. Royalty:

9.1.1. Licensee shall pay the Royalty @2% to the Licensor from the Net Sales for the Royalty term. Payment of Royalty shall fall due beginning with the first sale of the Product(s). This shall be governed by the "ICMR Guidelines for Technology Development Collaboration."

9.1.2. Royalty shall be payable on a half yearly basis as entered in the books of account maintained by the Licensor and within 30 (Thirty) days at the end of each Royalty Period.

9.1.3. Royalty for each financial year shall be payable to the Licensor on half yearly basis. Royalty due up to 31st March must be paid before the last working day of April and for royalty due up to 30th September by last working day of October.

9.1.4. Before 30 days from the last day of a Royalty Period due, Licensee must send to Licensor a written statement for the Royalty Period to which the statement relates including the sale made by Licensee in India and other countries, in the format given at (Schedule-II)

9.1.5. The royalty reports submitted by the Licensee shall be duly certified by the Chartered Accountant.

9.1.6. The details with regard to designated bank account and declaration shall be provided by the Licensor in the format given at Schedule III.

9.2. Delay in Payment of Royalty and Non-Payment

9.2.1. In case of delay in payment of Royalty, the Licensee shall be liable to pay simple interest at the rate of 12 (twelve) percent per annum, on the amount of default in payment of Royalty for the period of delay.

9.2.2. In cases where three consecutive Royalty payments have not been made by the Licensee, it will result in automatic termination of License/ Agreement with prior notice of 30 days to remedy the breach and make the payment.

9.3. Royalty Reporting

9.3.1. Licensee shall pay the Royalties on half yearly basis. Royalty due up to 31st March must be paid before the last working day of April and for Royalty due up to 30th September by last working day of October.

9.3.2. Licensee must submit to ICMR a CA Certified account statement for the Royalty Period in the following format:

Product Name	Unit Sale Price	Total Quantity Sold	Gross Sales Value (INR)	Net Sales value (INR)	% of Royalty Payable	*Royalty Amount (INR)

**Goods and Services Tax (as applicable) shall be paid additionally on Royalties due.*

9.4. Mode of Payment of Royalty

The Royalty on the Net Sales shall be paid by the Licensee by way of account payee crossed cheque OR Demand Draft drawn in favour of "Director General-Indian Council of Medical Research" payable at "New Delhi" or by electronic mode in favour of ICMR.

9.5. Royalty Monitoring & Audit Rights

9.5.1. Licensee must keep, and must ensure that Licensee itself and its each Sub-Licensee (if any) keeps true and accurate accounts and records of the quantities of the Product manufactured, sold, and in stock, Gross Sales Price and Net sales of the products in relation to each of the sub-territories comprising the Territory, all other accounting, stock, ordering, purchasing invoicing, and delivery records in relation to the Products as are required by good accounting practice.

9.5.2. The Licensee must ensure to strictly abide/comply with the Termination clause mentioned in the License Agreement, which shall include strict compliance with the Royalty remittance obligation, non-compliance of the same by the Licensee/ Grantee shall result in the termination of the License.

9.6. Inspection of Accounts by ICMR

9.6.1. ICMR may at any time, appoint a person or reputed auditing firm to inspect the Licensee's and sub- licensee's books and records so maintained for ensuring royalty compliance.

9.6.2. Cost of such Audit shall be borne by the Licensee.

10. INTELLECTUAL PROPERTY RIGHTS (IPR) / INTELLECTUAL PROPERTY(IP)

10.1. Ownership of Intellectual Property

Subject to the terms and conditions provided in this Agreement:

The Parties acknowledge that the Licensed I.P. is the property of ICMR. The Licensee must not directly or indirectly consent or impair the ICMR's ownership of the Licensed I.P. nor represent that it has any ownership interest in the Licensed I.P. Any IP generated during the course of the Licensing/Co-development shall be jointly owned by ICMR and the Licensee/Co-developer.

10.2. Patent Ownership

10.2.1. Subject to the terms and conditions contained in this Agreement, all applications for provisional patents and patents which claim their priority from or which are obvious modifications and improvements to the inventions disclosed in the Licensed Patents or its improvements in accordance with Clause 10.3, shall be jointly owned by ICMR and the Licensee.

10.2.2. Licensee is required to register its novel product derived from the patents licensed by ICMR / co-developed with ICMR on GeM portal of the Ministry of Commerce and Industry, Government of India, at a discounted price for all government hospitals/departments/bodies.

10.2.3. Parties shall employ best possible efforts to prepare, file, prosecute and maintain Licensed Patents, Licensed Trademarks and other patents filed in India claiming priority therefrom or obvious modifications and improvements to the inventions disclosed in Licensed Patents with mutual consensus followed by approval by the Competent Authority, ICMR.

10.3. **Improvements**

10.3.1. If the Licensee makes, devises, discovers or otherwise acquires rights in, any improvement which claims from or which are obvious modifications and improvements to the inventions disclosed in the Licensed Patents, it is agreed that ICMR shall co-own all Intellectual Property in such improvements throughout the Territory and in perpetuity and any patent rights in such improvements shall be deemed to fall within the definition of the term Licensed Patents for the purpose of this Agreement.

10.4. **Infringement of Intellectual Property**

Licensee shall solely be responsible for instituting or defending any proceedings concerning the Licensed Patents, Products or any improvements made thereof and shall be responsible for all legal fees and disbursements with respect to such proceedings. The Licensee shall duly inform the Licensor of any such actions taken by the Licensee.

11. DATA RIGHTS

11.1. The Parties shall have joint and equal rights on the data generated during the collaboration under this Agreement and shall be free to use the data for any purpose including for further Research and Teaching purpose. Licensee shall take reasonable steps to prevent the Licensor's data, documents or other confidential and proprietary information from unauthorized usage or falling into unauthorized hands. The Licensee shall ensure that its personnel working on such assignment shall sign appropriate agreements (acceptable to the Parties) to prevent unauthorized usage and disclosure of specific data, documents, or other confidential and proprietary information thereof.

11.2. Data rights in cases where Artificial Intelligence is involved shall be dealt separately.

11.3. Licensee to ensure that data is anonymized, kept confidential and strictly abide by the provisions of IT Act, 2000 and The Digital Personal Data Protection Act, 2023 while dealing with such data.

12. BRANDING AND ACKNOWLEDGEMENT

12.1. Support of Licensor must be suitably acknowledged in the publications (papers, reports, advertisements, brochures, websites, flyers etc.) and products (labels, leaflets, package inserts etc.) arising out of the Licensed Patents by the Licensee.

12.2. The support of ICMR shall suitably be displayed on each and every product by the Licensee. Similarly, every advertisement, publicity material/customer literature/hoardings etc. in respect of the Product shall include the same legend in bold letters as aforesaid, at a conspicuous place in such advertisements/publicity material/customer literature/ hoardings, etc.

12.3. Licensee shall be permitted to use the ICMR Logo only post approval by the Competent Authority, ICMR and as per the Brand Guidelines of ICMR.

13. PRESS RELEASE AND PUBLIC ANNOUNCEMENTS

13.1. Prior written permission must be taken by the Licensee from ICMR prior to any press releases, public announcements, or media statement with respect to the technology that has been licensed from ICMR for commercialization.

13.2. ICMR reserves the rights to make any modifications for incorporation by the Licensee in the proposed Publication/Press Release.

14. PUBLICATION

14.1. 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).

14.2. Support of ICMR must be duly acknowledged in all publications.

14.3. ICMR Scientists may be given due advantage of authorships in the publications arising out of transfer/co-development.

15. RELEASE & INDEMNIFICATION

15.1. Release

15.1.1. Licensee unconditionally releases ICMR, and its officers, employees, sub-contractors and agents absolutely from and against all actions, claims, proceedings or demands and in respect of any loss, death, injury, illness or damage (whether personal or property, and whether special, direct, indirect or consequential, including consequential financial loss)suffered by the Licensee, its affiliates, or any third Party arising out of such Party's Commercialization or use of the Intellectual Property, or the Products.

15.1.2. To the full extent permitted by law, ICMR and its officers, employees, sub-contractors and agents will not be liable to the other Party/Licensee for any special, indirect or consequential damages, including consequential financial loss arising out of the Commercialization or use of the Intellectual Property, by the Licensee, its affiliates, or the Products derived from the Intellectual Property, by the Licensee, its affiliates.

15.2. Indemnification

Licensee indemnifies and agrees to keep the ICMR, and its officers, employees, sub-contractors and agents indemnified from and against: (i) all actions, claims, proceedings or demands (including those brought by third Parties) which may be brought against any of them, whether on their own or jointly, in respect of any loss, death, injury, illness or damage (whether personal or property, and whether special, direct, indirect or consequential, including consequential financial loss) arising out of the Commercialization or use of the Intellectual Property, or any Products; (ii) any breach of any provisions,

including of the representations and warranties, any and all misrepresentation, liabilities, obligations, commitments; and/or (iii) any violation of the applicable laws.

15.3. **No-warranty**

15.3.1. ICMR shall make no warranty, express or implied about the workability of the technology/IPR/Data/Records being transferred by ICMR. The same are being transferred by ICMR on an "as is where is" basis.

15.3.2. ICMR will not have any liability to the Licensee or any other person resulting from the use of the records, or any other information supplied or for any opinions expressed by any of them or for any errors, omissions, or misstatements.

15.3.3. Among other things, ICMR disclaims any express or implied warranty of merchantability, of fitness for a particular purpose, i) of non-infringement or ii) arising out of any course of dealing.

16. NON-PERFORMANCE

16.1. In the event the Licensee is unable to commercialize the Product within 2(Two) years from the (Effective date). ICMR shall have the March-in-Rights and the Licensee shall be obligated to transfer the know-how to as many third parties as ICMR may advise.

16.2. In the event the Licensee is unable to commercialize the Product within the stipulated period, due to unavoidable circumstances and causes beyond the control of the Licensee, the Licensee shall make a request in writing for extension of the time limit before the expiry of the date giving detailed reasons. This request will be carefully examined and considered on merit by the ICMR.

16.3. Upon expiration or termination of Agreement for any reason, the rights granted to Licensee shall terminate immediately. The Licensee may however be allowed using the know-how for period not exceeding more than 30 days to complete such orders that are in production at the time of termination and also existing stock lying on the date of termination shall be allowed to be liquidated.

17. TERM AND TERMINATION

This Agreement shall be co-terminus on the expiry of Duration of License provided in clause 4 of this Agreement.

17.1. **Automatic Termination**

The License may be subject to automatic termination for default in payment of amounts due and non- payment of Royalties due for payment for three consecutive Royalty reporting periods.

17.2. **Termination by Licensor**

ICMR shall notify the Licensee regarding the breach of provisions under which License was given, thereby, invoking the provisions of termination giving one-month notice to remedy the breach. ICMR shall have the right to foreclose and terminate if the default prevails even after serving notice, under following circumstances:

17.2.1. for failure to achieve milestones within the timelines agreed between ICMR and the Licensee,

17.2.2. On account of submission of false reports or misrepresentations by the Licensee,

17.2.3. For non-fulfilment of obligations pursuant to the Grant-in-assistance or License, If the Licensee suspends or discontinues manufacture of the Product for a period exceeding 1 year without obtaining prior written permission or extension in this regard from the ICMR, except for reasons beyond the control of the Licensee and that are agreed by the ICMR.

17.2.4. Failure of the Licensee to strictly abide/comply with obligations provided under the "ICMR Guidelines for Technology Development Collaboration", non-compliance of the same by the Licensee shall result in the Termination of this Agreement.

17.3. **Termination by Licensee**

Licensee may at any point of time choose to terminate the applicable agreements after giving reasons, by giving prior notice of at least three months. Under such circumstances, the Licensee shall:

17.3.1. Meet all the financial liabilities including Royalty payments due till that point of time,

17.3.2. Submit a confidential report detailing the status of Technology development till that point of time, and;

17.3.3. Cooperate with the ICMR in transferring the Technology or IP to third Party.

18. WAIVER

18.1. Any indulgence shown by the Licensor to the Licensee in any manner shall not constitute waiver of its rights and remedies against the Licensee. The waiver, if any, by the Licensor, of any right of the Licensor or of any breach by Licensee, of any term, condition or obligation of this License shall not in any event be construed as a waiver of any subsequent right or remedy or breach as the case may be or of any other right or remedy or breach of the same or different nature.

18.2. None of the Parties hereto shall be construed as an agent or representative of the other Party.

18.3. The Licensee hereby waives any requirement of warranties and guarantees, in terms hereof, or arising by law or in contract or tort or otherwise, including any implied warranty or guarantee as regards the quality or merchantability of the PRODUCT or fitness, utility or the workability of the TECHNOLOGY, except what is contained in the dossier provided by the Licensor, and/or the process for any purpose whatever.

19. NOTICES

All notices required to be served should be mailed, postage prepaid and addressed to the respective Parties, as follows:

To LICENSOR	To LICENSEE
Name	**Name**
Designation	**Designation**
Address	**Address**
Email	**Email**
Phone No.	**Phone No.**

20. ENTIRE AGREEMENT

This Agreement constitutes the final agreement between the Parties and it supersedes all prior verbal understandings, and other correspondence/ communications between the Parties with respect to the subject matter hereof.

21. AMENDMENTS

No amendment/ modification/ alternation of any of the terms of this Agreement shall be valid till it is reduced to writing and duly signed by both the Parties. Any amendment of financial/commercial nature shall be subject to final approval by the Competent Authority of ICMR.

22. GOVERNING LAW, JURISDICTION &DISPUTE RESOLUTION MECHANISM

22.1. This Agreement and the associated undertaking shall be governed and interpreted in accordance with the laws of India subject to the exclusive jurisdiction of the Courts at New Delhi.

22.2. Disputes to 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 in writing to the other of its request that such a meeting be held, then, the Dispute shall be resolved by arbitration as per the provisions of the Arbitration and Conciliation Act, 1996 and the Rules there under, as amended from time to time.

22.3. 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 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 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 New Delhi International Arbitration Centre (NDIAC) Act, 2019and as per 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 Agreement expiring or ceasing to exist or being terminated or foreclosed.

23. SURVIVABILITY

If at any point one or more terms and conditions within this Agreement are deemed to be unenforceable or void, the Parties agree to substitute a similar term or condition to replace the defective one.

24. FORCE MAJEURE

Parties shall not be held responsible for non-fulfilment of their respective obligations under the agreement due to the exigency of one or more of the force majeure events such as but not limited to Acts of God, war, flood, earthquakes, strike, lockouts, epidemics, riots, civil commotion, etc. provided on the occurrence and cessation of any such events, the Party affected thereby shall give a notice in writing to the other Party within one month of such occurrence or cessation. If the force majeure conditions continue beyond six months, the Parties shall then mutually decide about the future course of action.

25. SURVIVAL

Notwithstanding the termination or foreclosure, Licensee shall continue to be bound by the following provisions:

25.1. Clause 8 (Confidential Information)
25.2. Clause 9.3 (Royalty Reporting)
25.3. Clause 10 (Intellectual Property Rights)
25.4. Clause 11 (Data Rights)
25.5. Clause 12 (Branding and Acknowledgement)
25.6. Clause 13 (Press release and Public Announcements)
25.7. Clause 14 (Publication)
25.8. Clause 15 (Release & Indemnification)
25.9. Clause 16 (Non-Performance)
25.10. Clause 22 (Governing Law, Jurisdiction & Dispute Resolution)

IN WITNESS WHEREOF, the duly authorized officers of the Parties have executed this License Agreement to be effective as of the AGREEMENT date

For and on behalf of the ICMR	For and on behalf of Licensee
Signature: Name: Designation: Date:	Signature: Name: Designation Date:
Witness	**Witness**
Name: Designation: Date:	Name: Designation: Date:
Name: Designation: Date:	Name: Designation: Date:

Schedule-I

DESCRIPTION OF TECHNOLOGY/ KNOW HOW TO BE LICENSED

TITLE:

DEVELOPED BY: ICMR XXX (Institute Name)

IP DETAILS:

TECHNOLOGY DETAILS:

Schedule-II

Licensed Product name	Unit Sale Price#	Total Quantity Sold#	Gross Sales value (INR)	Net Sales value (INR)	% of Royalty Payable	Royalty* Amount (INR)

* Goods Service Tax (as applicable) shall be paid on Royalties due.

In India & other countries, as applicable.

- The above statement should be duly audited by the Chartered Accountant (CA) other than the Licensee's Auditors;
    i. Supporting documents substantiating the sales like relevant excise records accomplished with the statement;
    ii. Copies of all reports and advice from each Licensee indicating the quantities of each Licensee's sales in the relevant Royalty Periods;
    iii. Supporting documents confirming payment of the Royalty.

Schedule-III

DESIGNATED BANK ACCOUNT DETAILS AND DECLARATION

Beneficiary Name:	
Name of the Bank:	
Branch:	
Account No:	
RTGS / NEFT IFSC:	

To be filled by Licensor's Appointed Officials

The aforesaid details are checked and verified by Licensor's Appointed Officials and is approved/ disapproved for submission through RTGS/NEFT, with following observations:

1. _____

2. _____

3. _____

Licensee is hereby directed to submit confirmation of deposition of payment before due date

Dated: / /

Signature of Authorized Representative of Licensor

ANNEXURE - IV

MEMORANDUM OF AGREEMENT

FOR

VALIDATION OF TECHNOLOGY

MEMORANDUM OF AGREEMENT (MOA)

Between

INDIAN COUNCIL OF MEDICAL RESEARCH

And

ICMR-XXX / XYXY- .....

And

YYY

Ministry of Health & Family Welfare,
Government of India

FOR VALIDATION OF TECHNOLOGY

MEMORANDUM OF AGREEMENT

THIS MEMORANDUM OF AGREEMENT ("MoA/Agreement") is formalized and effective on ....."Effective Date"

By and Between

The INDIAN COUNCIL OF MEDICAL RESEARCH, an apex body in India for formulation, coordination and promotion of biomedical research under the Department of Health Research, Ministry of Health & Family Welfare, Government of India, registered as a Society under the Societies Registration Act, 1860, having its registered office at V. Ramalingaswami Bhawan, Ansari Nagar, Post Box 4911, New Delhi – 110029, India (hereinafter referred to as "**ICMR**" which expression shall wherever the context so admits include its successors and permitted assignees), the **PARTY OF THE FIRST PART; (FIRST PARTY)**

AND

ICMR-XXX (XXX), _____ with _____, as the designated Project Investigator (PI), a constituent laboratory/institute of Indian Council of Medical Research (ICMR), Department of Health Research, Ministry of Health & Family Welfare, Government of India having its Registered office at _____ (hereinafter referred to as ICMR-XXX), the **PARTY OF THE SECOND PART; (SECOND PARTY)**

OR

_____ **XYXY**, an institute/laboratory established under _____ Act of Parliament/society registered under the Societies Registration Act, 1980/ Trust registered under Indian Trusts Act, 1882 having its registered office at _____ (hereinafter referred to as XYXY which expression shall wherever the context so admits include its successors and permitted assignees), the **PARTY 1, PARTY 2, PARTY 3..... OF THE SECOND PART (as applicable); (SECOND PARTY)**

AND

YYY, a company registered and incorporated under the Companies Act 1956 (or Companies Act, 2013) and having its registered office at _____ (hereinafter referred to as 'COMPANY' which expression shall wherever the context so admits include its successors in interest, liquidators, administrators and permitted assignees)/ _____ (Mention the name of Society/ University/Research Institute/ College wherein the Research/development is being conducted)_____ (hereinafter referred to as "INSTITUTE") the **PARTY OF THE THIRD PART; (THIRD PARTY)**

The FIRST PARTY, SECOND PARTY and THIRD PARTY are hereinafter collectively referred to as the "Parties".

WHEREAS:

1. THIRD PARTY has developed a vaccine/ device/ diagnostic kit/digital data etc. "....."/ certain synthesized chemical entities/drugs/biomolecules etc. (hereinafter referred to as the **"PRODUCT")** with potential for screening and diagnosis of ..... and is interested in evaluating the ..... activity of the same (herein after called **"VALIDATION");**

2. Considering that the PRODUCT has the potential for ..... and therefore may have large scale societal impact, the FIRST PARTY through its ..... has agreed to support the validation of the PRODUCT and has authorized the SECOND PARTY, that has the facilities and expertise required for the VALIDATION and has expressed its willingness to undertake this VALIDATION for commercialization and/or translation potential for the PROJECT **OR** Considering that the PRODUCT has the potential for ..... and therefore, may have large scale societal impact, XYXY/ICMR - XXX has agreed to support the validation of the PRODUCT and has the facilities and expertise required for the VALIDATION and has expressed its willingness to undertake this VALIDATION for commercialization and/or translation potential under the PROJECT.

3. FIRST PARTY while extending its support shall only be the nodal centre for **"Validation"** undertaken by the SECOND PARTY and requested by the THIRD PARTY as mentioned in Clause 3 below, herein after referred to as the **"PROJECT".**

NOW THEREFORE, Parties, each in consideration of the covenants and agreements of the other and intending to be legally bound, agree as follows:

1. REPRESENTATIONS AND WARRANTIES OF THE THIRD PARTY

THIRD PARTY represents and warrants the following:

1.1. The THIRD PARTY has all requisite authority to enter into this Agreement and to perform and fulfil its obligations under this Agreement;

1.2. The execution and delivery of this Agreement and the performance or fulfilment of the THIRD-PARTY obligations under this Agreement will not conflict with, or result in breach of, or constitute a default under, or require the consent of any third party under any applicable laws, Agreement, or instrument to which the THIRD PARTY is bound;

1.3. There are no pending or threatened lawsuits, actions, or any other legal or administrative proceedings against the THIRD PARTY, its promoters, or directors, or dean/heads which, if adversely determined against them, would have a material adverse effect on the ability of the THIRD PARTY to perform its obligations under this Agreement.

2. DEFINITIONS

2.1. **Background Intellectual Property** ("BGIP") shall mean any Intellectual Property/IP that is created or owned by the Party prior to the Effective Date of this Agreement between the Parties.

2.2. **"Disclosing Party"** shall mean the Party to the MoA, or its employees, agents and other authorized representatives disclosing the Confidential Information to the other Party to

the MoA, or its employees, agents, and other authorized representatives.

2.3. **"Effective Date"** shall mean the date of signing of this MoA or the date of issuance of Sanction Order by the FIRST PARTY (as applicable). In the event the Parties affix their signatures to this Agreement on separate dates, the Agreement shall be effective from the date on which the last set of signatures is affixed thereto. Three copies of the Agreement shall be signed by each of the Parties and one copy each shall remain in the custody of each Party.

2.4. **Intellectual Property** shall mean and include the following (a) Invention (as defined herein) or discovery (whether patentable or not); manner, method or process of manufacture; method or principle of construction; chemical composition or formulation; biological material; computer program; integrated circuit, circuit layout or semiconductor chip layout or design; plan, drawing; or scientific, technical or engineering information or document; (b) Invention(s), improvement, modification or development of any of the foregoing; (c) patent, application for grant of a patent, right to apply for grant of a patent or similar rights for or in respect of any subject matter referred to in sub-paragraphs (a) or (b) above; (d) trade secret, know-how, or right of secrecy or confidentiality in respect of any information or document or other Intellectual Property referred to in sub-paragraphs (a) or (b) above; (e) copyright or other rights in copyright subsisting in any works or other subject matter referred to in sub-paragraphs (a) or (b) above; (f) circuit layout rights.

2.5. **Net Sales** shall mean Revenue from sales of goods or services by all ICMR Grantees/ Licensees/ Sub-licensee(s) based on the net sales realization from operations, net of discounts and indirect taxes, as defined by the Cost Accounting Standards - 24 and certified by the Chartered Accountant.

2.6. **PRODUCT** shall mean each product under development/ expected to be developed under this PROJECT or .....

2.7. **PROJECT** shall mean the research proposal entitled .....

2.8. **Project Review Committee (PRC)** shall mean a Monitoring Committee comprising of eminent experts from the relevant field(s) which will be constituted by FIRST PARTY to monitor the progress of the objective(s) of the PROJECT.

2.9. **Receiving Party** shall mean the Party, its employees, agents, or other authorized representatives, receiving Confidential Information from the other Party, its employees, agents, or other authorized representatives.

2.10. **Royalty term** shall mean Royalty payable from the net sales for a period of 10 years from the date of commercialization of product.

2.11. **Scope of Work** shall mean, in respect to the PROJECT, the scope as detailed in this MoA, including any document or agreement executed pursuant to this MoA or as mutually agreed and executed between the Parties.

2.12. **Technology** shall mean any and all discoveries, inventions, processes, methods, techniques, know- how, Intellectual Property and proprietary rights, expressed in whatever form including technical information, processes, procedures, material for trials, methods, formulae, protocols, software, specifications, instructions, data, documents, drawings, images, prototypes and materials encompassing the Licensed Patents and Improvements there upon developed for the purpose of this PROJECT.

2.13. **Term** shall mean the term or duration of this MoA commencing from the Effective Date and continuing for ..... ( ) years thereafter, or extended with the agreement of the Parties in writing, unless terminated earlier in accordance with Clause 21 (Termination) of this Agreement.

3. SCOPE OF WORK

This Agreement is being done for undertaking validation for the use of the **"PRODUCT"** for ..... at the following sites of the SECOND PARTY:

Site- A. .....

Site- B .....

Site- C ..... and

Site- D .....

4. OBLIGATIONS OF THE FIRST PARTY

4.1. FIRST PARTY shall be the nodal agency for coordination of the Validation and shall oversee the progress of the PROJECT.

4.2. The FIRST PARTY will provide logistic support (monitoring/ administrative) or financial support as approved by the PRC/Competent Authority. The FIRST PARTY reserves the right to extend the PROJECT as and when required, FIRST PARTY approval for PROJECT, Sanction Order/Letter is placed at Schedule-1.

4.3. The FIRST PARTY shall validate the claims for the Product/ batches (as the case may be), made by the THIRD PARTY, as required under mandatory regulatory compliances in India, as per the requirements of the PROJECT, under this Agreement.

4.4. There will be no financial or other obligation(s) on the FIRST PARTY after the proposed duration of this Agreement and/or premature termination (under Clause 21) of this agreement.

4.5. The FIRST PARTY through its Project Review Committee (PRC) shall evaluate the reports of the Validation and give recommendations on its successful completion for extension of the PROJECT, if recommended by PRC and approved by the Competent Authority.

4.6. The FIRST PARTY agrees to abide by the confidentiality obligations as per Clause 10, defined hereafter.

5. OBLIGATIONS OF THE SECOND PARTY (PARTY 1, PARTY 2, PARTY 3..... OF THE SECOND PART)

5.1. SECOND PARTY shall be responsible to co-ordinate with other Parties/ conduct the Validation and successful completion of the PROJECT under this Agreement.

5.2. The SECOND PARTY shall nominate a Project Investigator (PI) who shall be responsible for rendering timely deliverables under this PROJECT and co-ordination with the Parties for complying with the terms and conditions of this Agreement.

5.3. The PI of the SECOND PARTY shall ensure that the activities for this PROJECT are executed in timely manner for successful completion of the PROJECT within the stipulated Term of this Agreement.

5.4. The PI of the SECOND PARTY shall ensure the use of the PRODUCT is strictly for the intended purpose of the PRODUCT for which the Agreement is being made and not for any other purposes. The SECOND PARTY will conduct the validation study as per the agreed protocol and will share the anonymized findings with the THIRD PARTY.

5.5. The SECOND PARTY agrees to return the PRODUCT(s) after the termination of the Agreement if/whenever asked by the THIRD PARTY. There is no obligation on any party to enter into a purchase process after the Agreement is over.

5.6. The SECOND PARTY shall maintain and provide complete and accurate records and all supporting documentation as sufficient and necessary as may be provided under this Agreement in such connection.

5.7. The SECOND PARTY shall take all measures necessary to ensure secrecy and confidentiality of confidential and/proprietary information relevant to the THIRD PARTY as well as the patients, including such other or additional measures as may be required while conducting the study.

5.8. The SECOND PARTY shall be responsible for the proper and intended usage of the PRODUCT(S) provided by the THIRD PARTY under this Agreement.

5.9. The SECOND PARTY agrees to abide by the confidentiality obligations as per Clause 10, defined hereafter.

6. OBLIGATIONS OF THE THIRD PARTY

6.1. In consideration of the mutual covenants hereunder, the THIRD PARTY hereby agrees to provide adequate number of PRODUCTS as per the requirements of the PROJECT, along with... , and other essential items for the PRODUCT to use/ validate/ test for ..... at no cost to SECOND PARTY;

6.2. The THIRD PARTY agrees to cover the maintenance and accidental damage by appropriate insurance and will repair/replace the unit(s) immediately when so needed and provide complete backup support to enable FIRST PARTY to successfully complete the Validation study.

6.3. The THIRD PARTY agrees to provide the necessary safety items for the operator/ technician for ensuring patient care and safety with each PRODUCT.

6.4. The THIRD PARTY will depute trained personnel with each PRODUCT for managing and controlling the PRODUCT at each site;

6.5. The THIRD PARTY hereby, declares that the PRODUCT has certified quality and safety standards as per the requirements of the PROJECT (to be defined on case-to-case basis);

6.6. The THIRD PARTY shall provide undertaking that no extraneous substance has been added to the PRODUCT(s) provided for VALIDATION.

6.7. In case, the THIRD PARTY fails to accomplish the requirements (e.g., documents/validation charges) stated by the SECOND PARTY, the PRODUCTs under consideration/PRC-approved PRODUCT under validation would be rejected at any stage of VALIDATION.

6.8. The THIRD PARTY shall notify FIRST PARTY of any material change in its incorporation status, shareholding, entity status, Project Coordinator, implementation site or any such change that would impact the performance of its obligations under the PROJECT and this Agreement.

6.9. The THIRD PARTY shall not assign or transfer the PRODUCT/PROJECT interests/ rights to any third party directly or indirectly without prior written consent from FIRST PARTY and SECOND PARTY till full and final settlement of all dues as mutually agreed by the Parties.

6.10. The THIRD PARTY shall be responsible to apply for the required certifications and approvals necessary for commercialization of the technology nationally and internationally and have them in order at their own cost.

6.11. The THIRD PARTY is required to register its novel PRODUCT if it is co-developed with FIRST PARTY and/or SECOND PARTY under this Agreement, on GeM portal of the Ministry of Commerce and Industry, Government of India.

6.12. The THIRD PARTY must ensure to strictly abide/comply with all the obligations provided under the "ICMR Guidelines for Technology Development Collaboration" (as amended from time to time).

6.13. The THIRD PARTY agrees to obtain any other required compliances of Government, as amended from time-to-time.

6.14. The THIRD PARTY agrees to abide by the confidentiality obligations as per clause 10, defined hereafter.

7. INTELLECTUAL PROPERTY RIGHTS (IPR) OR INTELLECTUAL PROPERTY (IP)

7.1. Intellectual Property (I.P) shall mean and includes the following (a) an idea or invention or discovery (whether patentable or not); manner, method or process of manufacture; method or principle of construction; chemical composition or formulation ; biological material; computer program; integrated circuit; circuit layout or semiconductor chip layout or design; plan, drawing; or scientific, technical or engineering information or document (a)product(s)/prototype(s) (b) improvement, modification or development of any of the foregoing; (c) patent, application for a patent, right to apply for a patent or similar rights for or in respect of any subject matter referred to in sub-paragraphs (a) or (b) above ; (d) trade secret, know-how, or right of secrecy or confidentiality in respect or confidentiality in respect of any information or document or other Intellectual property referred to in sub paragraphs (a) or (b); (e) copyright or other rights in the nature of copyright subsisting in any works or other subject matter referred to in sub-paragraphs (a) or (b); (f) circuit layout rights.

7.2. Background Intellectual Property ("BGIP") shall remain the sole and exclusive property of the respective Parties generating the BGIP.

7.3. All forms of Intellectual Property such as 'Patents', 'Copyrights' or 'Trademarks' developed from the PROJECT study, if any shall be jointly owned by Indian Council of Medical Research and the THIRD PARTY.

7.4. The PRODUCTs and know-how generated through VALIDATION as per this Agreement may be utilized by the FIRST PARTY and SECOND PARTY for research purposes, depending on its research potential.

7.5. Any improvement which claims priority from or which are obvious modifications of the jointly owned I.P. (as evidenced by potential application of Improvements and improvements to the inventions) it is agreed that the FIRST PARTY and the THIRD PARTY shall jointly own all Intellectual Property in such Improvements throughout the Territory of India and abroad and in perpetuity and any IP Rights in such Improvements shall be deemed to fall within the scope of this Agreement. In case of modifications and improvements which do not claim priority from and are substantially different from the inventions, the party conceptualizing shall exclusively and absolutely own all Intellectual Property in such Improvements, throughout the Territory and in perpetuity, wherein 'Improvements' shall mean, any and all improvements, enhancements, variations, or modifications of the Technology and all inventions, designs, information, know-how, specifications, formulae, data, processes, methods, techniques arising in connection with the development, manufacture, and production of any products used in, generated or otherwise created using the Technology; and 'Field of use' shall mean in the domain of "PROJECT."

7.6. The THIRD PARTY shall be responsible for suitable protection including filing and prosecution of 'Jointly owned IP', if so generated. Further, the transfer of jointly developed IP and associated sharing of revenue shall be governed as per 'ICMR Guidelines for Technology Development Collaboration'.

8. COMMERCIALIZATION FOR SOCIETAL IMPACT

8.1. Indian Council of Medical Research, New Delhi shall provide the funding for carrying out the PROJECT and shall be the apex body to oversee the progress of the PROJECT. All Intellectual Property rights developed from the PROJECT study shall be jointly held by the Indian Council of Medical Research and THIRD PARTY.

8.2. It shall be the responsibility of the THIRD PARTY to make every effort to commercialize the PRODUCT at discounted price to the Government of India/ as declared in National Interest and the final decision will be that of the Government of India.

8.3. The THIRD PARTY agrees to keep the price of the PRODUCT fixed at the discounted prices mentioned in Clause 8.2 above for supplies in the .....

9. ROYALTY PAYOUTS

9.1. Royalty remittance obligations to the THIRD PARTY shall be applicable as per the "ICMR Guidelines for Technology Development Collaboration", as amended from time-to-time.

9.2. The THIRD PARTY agrees that the Royalty @1% (one percentage) on Net Sales of the PRODUCT shall be paid for the royalty term on half yearly basis as entered in the books of account maintained by the THIRD PARTY, up to 30th September and 31st March respectively every year regularly and punctually.

9.3. To pay royalty under and in terms of this sub-clause shall accrue upon the commencement

of the commercial sale of the PRODUCT ("Royalty"). These reports shall show for the period in question based on Net Sales made by the THIRD PARTY and its Affiliates, if any, of the PRODUCT(S), details of the quantities of the PRODUCT sold, Net Sales made by the THIRD PARTY and the royalty due to the FIRST PARTY from both Government and Non-Government sales.

9.4. Royalty Reporting

9.4.1. The THIRD PARTY shall pay the royalties on half yearly basis. Royalty due up to 31st March must be paid before the last working day of April and for royalty due up to 30th September by last working day of October.

9.4.2. THIRD PARTY must submit to the FIRST PARTY a CA Certified account statement for the Royalty Period in the following format:

Product Name	Unit Sale Price	Total Quantity Sold	Gross Sales Value (INR)	Net Sales value (INR)	% of Royalty Payable	*Royalty Amount (INR)

**Goods and Services Tax (as applicable) shall be paid additionally on Royalties due.*

9.5. Mode of Payment of Royalty to the FIRST PARTY

The Royalty on the Net sales shall be paid by the Grantee by way of account payee crossed cheque OR Demand Draft drawn in favour of "Director General-Indian Council of Medical Research" payable at "New Delhi" or by electronic mode in favour of ICMR.

9.6. Delay in Payment of Royalty and Non-Payment

9.6.1. In case of delay in payment of Royalty, the THIRD PARTY shall be liable to pay simple interest at the rate of 12 (twelve) per cent per annum, on the amount of default in payment of royalty for the period of delay.

9.6.2. In cases where three consecutive Royalty payments have not been made by the THIRD PARTY, it will result in Automatic termination of the Agreement with prior notice of 30 days to remedy the breach and make the payment.

9.7. Royalty Monitoring & Audit Rights

9.7.1. Grantee must keep, and must ensure that THIRD PARTY itself and each of its Sub-Licensee keeps true and accurate accounts and records of the quantities of the PRODUCT manufactured, sold, and in stock, Gross Sales Price and Net sales of the PRODUCT(s) in relation to each of the sub-territories comprising the Territory, all other accounting, stock, ordering, purchasing invoicing, and delivery records in relation to the PRODUCT(s) as are required by good accounting practice.

9.7.2. The THIRD PARTY must ensure to strictly abide/comply with the Termination Clause mentioned in this Agreement, which shall include strict compliance with the Royalty remittance obligation provided under the "ICMR Guidelines for Technology

Development Collaboration," non-compliance of the same by the THIRD PARTY shall result in the Termination of this Agreement.

9.8. Inspection of Accounts by the FIRST PARTY

9.8.1. The FIRST PARTY may at any time, appoint a person or reputed auditing firm to inspect the THIRD PARTY books and records so maintained for ensuring royalty compliance.

9.8.2. Cost of such Audit shall be borne by the THIRD PARTY.

10. CONFIDENTIALITY

10.1. "Confidential Information" means all information (whether in oral, written or electronic form) relating to the minutia of research and development proposals, presentations, Intellectual Property stated in the research and development proposals, due diligence reports, in-house analysis reports and Freedom to operate reports, information on business and finances, unpublished data, organizational and individual information, proposed technology or intended inventions/ procedures, nature of research and/or plans for prioritizing research, commercialization strategy, technical validation, budgets and strategies, minutes of the meeting(s) or other agnate materials including any notes or summaries derived from those materials of the Disclosing Party and confidential information received by the Disclosing Party from third parties. All information under the MoA shared between the parties shall be treated as confidential information and shall be subject to restrictions on disclosure other than for the purpose of this MoA.

10.2. During the tenure of the Agreement, the Parties, undertake to maintain strict confidentiality and refrain from disclosure thereof, of all or any part of the information and data exchanged/generated from the PROJECT under this Agreement for any purpose other than purposes in accordance with this Agreement. It shall be the responsibility of the Parties to ensure maintenance of such confidentiality including on behalf of their employees, representatives and associates involved in the PROJECT.

10.3. The Parties shall not have any obligation of confidentiality with respect to any information that is proved with documentary evidence that it:

a. Is in the public domain by use and/or publication at the time of its disclosure by the disclosing party; or

b. Was already in possession of the recipient prior to receipt from the disclosing party; or

c. Is properly obtained by the recipient from a third party with a valid right to disclose such information and such third party is not under confidentiality obligation to the disclosing party; or

d. Was disclosed to any third party on a non-confidential basis prior to commencement of the PROJECT; or

e. Was developed by the recipient, as established by acceptable written record, independently of the disclosure of information by the disclosing party; or

f. Is required by public authority, by law or decree.

10.4. Notwithstanding anything contained herein, the provisions of Confidentiality shall survive early termination or expiration of this Agreement for a period of ten (10) years from early termination or expiration, as the case may be.

11. PUBLICATION

11.1. 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).

11.2. Support of ICMR must be duly acknowledged in all publications.

11.3. ICMR Scientists and Scientist/officials of the validation site may be given due advantage of authorships in the publications arising out of the validation study.

12. BRANDING AND ACKNOWLEDGEMENT

12.1. Support of ICMR must be suitably acknowledged in the publications (papers, reports, advertisements, brochures, websites, flyers etc.) and PRODUCT(s) (labels, leaflets, package inserts etc.) by the Grantee/Licensee.

12.2. Use of ICMR Logo on PRODUCT packages:

12.2.1. The name/logo of ICMR shall suitably be displayed on each and every PRODUCT by the THIRD PARTY at its own cost.

12.2.2. The THIRD PARTY shall be permitted to use the ICMR Logo following approval by the Competent Authority of ICMR and as per the Brand Guidelines of ICMR.

13. DATA RIGHTS AND DATA PRIVACY

13.1. The FIRST PARTY shall have joint and equal rights on the data generated during the collaboration and shall be free to use the data for any purpose, including for further Research and Teaching purposes. THIRD PARTY shall take reasonable steps to prevent the FIRST PARTY data, documents or other the FIRST PARTY confidential and proprietary information from unauthorized usage or falling into unauthorized hands. THIRD PARTY shall ensure that its personnel working on such assignment shall sign appropriate agreements (acceptable to the FIRST PARTY) to prevent unauthorized usage and disclosure of specific data, documents or other FIRST PARTY confidential and proprietary information thereof.

13.2. Data rights in cases where Artificial Intelligence is involved shall be dealt with separately.

13.3. In case patient data is being used by the THIRD PARTY it must ensure that the data is anonymized, and it must ensure to strictly abide by the provision of Information Technology (IT) Act, 2000 and The Digital Personal Data Protection Act, 2023 while dealing with such data.

14. PRESS RELEASE AND PUBLIC ANNOUNCEMENTS

14.1. Prior written permission must be taken by the THIRD PARTY from ICMR before making any press releases, public announcements, or media statement with respect to the PRODUCT that has been given grant-in-assistance by the FIRST PARTY as per this Agreement.

14.2. The FIRST PARTY reserves the rights to make any modifications for incorporation by the THIRD PARTY in the Proposed Publication/Press Release.

15. NO LIABILITY

In case of any legal or tax related issues arising between THIRD PARTY & SECOND PARTY, concerned authorities related to sales, etc. or any other terms of this Agreement, the FIRST PARTY will have no bearing on the same and such matters shall be exclusively dealt by the THIRD PARTY.

16. NO-WARRANTY CLAUSE

16.1. The FIRST PARTY shall make no warranty, express or implied about the workability of the technology/IPR/Data/Records being transferred by the FIRST PARTY. The same shall be transferred by the FIRST PARTY on an "as is where is" basis.

16.2. The FIRST PARTY will not have any liability to the THIRD PARTY or any other person resulting from the use of the records, or any other information supplied or for any opinions expressed by any of them or for any errors, omissions, or misstatements.

16.3. Among other things, the FIRST PARTY shall disclaim any express or implied warranty of merchantability, of fitness for a particular purpose, 1. of non-infringement or 2. arising out of any course of dealing.

17. RELEASE AND INDEMNIFICATION

17.1. **Release**

17.1.1. The THIRD PARTY unconditionally releases ICMR including its Institutes, study sites, officers, employees, sub-contractors, and agents absolutely from and against all actions, claims, proceedings or demands and in respect of any loss, death, injury, illness or damage (whether personal or property, and whether special, direct, indirect or consequential, including consequential financial loss) suffered by the THIRD PARTY, its affiliates, any sub-licensee(s) or any third party arising out of such party's Commercialization or use of the PRODUCT(s), or the Intellectual Property.

17.1.2. To the full extent permitted by law, the FIRST PARTY, its Institutes, study sites, and its officers, employees, sub-contractors, and agents will not be liable to the other for any special, indirect or consequential damages, including consequential financial loss arising out of the Commercialization or use of the PRODUCTs or the Intellectual Property, by the THIRD PARTY.

17.2. **Indemnification**

17.2.1. The THIRD PARTY/PARTY _____OF THE SECOND PART shall indemnify and shall agree to keep ICMR and its officers, employees, sub-contractors and agents indemnified from and against: (i) all actions, claims, proceedings or

demands (including those brought by third parties) which may be brought against any of them, whether on their own or jointly, in respect of any loss, death, injury, illness or damage (whether personal or property, and whether special, direct, indirect or consequential, including consequential financial loss) arising out of the Commercialization or use of the Intellectual Property, or any PRODUCTs; (ii) any breach of any provisions, including of the representations and warranties, any and all misrepresentation, liabilities, obligations, commitments; and/or (iii) any violation of the applicable laws.

17.2.2. The THIRD PARTY shall, always, indemnify and keep indemnified ICMR against all claims/damages etc. by any infringement of any Intellectual Property Rights (IPR) while fulfilling their responsibilities/work under the PROJECT and this Agreement.

17.2.3. The provision under this Agreement by the FIRST PARTY does not create any liability, explicit or implicit, on the FIRST Party including, SECOND PARTY, in respect of the workforce engaged in the PROJECT.

18. FORCE MAJEURE

Neither Party shall be liable hereunder by reason of any failure or delay in the performance of its obligations hereunder on accounts of riots, fires, flood, storm, explosions, act of God, war, governmental action, lockdown, epidemic, pandemic, labor conditions, earthquakes or any other cause which is beyond the reasonable control of such Party provided the affected Party gives the other Party prompt written notice of the occurrence of any Force Majeure event and the nature and extent to which the affected Party will be unable to perform its obligations under this Agreement. The affected Party agrees to use commercially reasonable efforts to correct the Force Majeure event as quickly as possible. Performance shall be excused only to the extent of and during the reasonable continuance of such Force Majeure event, provided that either Party may terminate this Agreement if such Force Majeure event continues for a period of 30 (thirty) days or more. Any deadline or time for performance specified in this Agreement which falls due during or subsequent to the occurrence of a Force Majeure event shall be automatically extended for a period of time equal to the period of the Force Majeure event.

19. TENURE OF THE AGREEMENT

The Agreement will be valid from the Effective Date for a period of _____( ) Months. In case of Foreclosure/Termination of the PROJECT as per terms of this Agreement, the Agreement shall be valid till the date of the Foreclosure/Termination Letter issued by the FIRST PARTY.

20. AMENDMENTS TO THE AGREEMENT

No amendment or modification of this Agreement shall be valid unless the same is made in writing by the Parties or their authorized representatives specifically stating the same to be an amendment of this Agreement. The modifications shall be effective from the date on which they are made/executed unless otherwise agreed to.

21. FORECLOSURE AND TERMINATION

21.1. **Automatic Termination**

Automatic termination for default in payment of amounts due and non-payment of royalties due for payment for three consecutive Royalty reporting periods.

21.2. **Termination by the FIRST PARTY**

The FIRST PARTY shall notify the THIRD PARTY regarding the breach of provisions under this Agreement, thereby, invoking the provisions of termination giving one-month notice to remedy the breach. The decision of the FIRST PARTY shall be final in all respects. The THIRD PARTY shall immediately refund any amount unutilized out of the FIRST PARTY's disbursements to the FIRST PARTY. The FIRST PARTY shall have the right to foreclose and terminate if the default prevails even after serving notice, under following circumstances:

21.2.1. For failure to achieve milestones within the timelines agreed between the FIRST PARTY and the THIRD PARTY.

21.2.2. On account of submission of false reports or misrepresentations by the THIRD PARTY.

21.2.3. For non-compliance with the royalty remittance obligation.

21.2.4. Failure to submit CA audited documents (upon royalty remittance) certifying the actual sales made by the THIRD PARTY.

21.2.5. For non-fulfilment of obligations pursuant to the Grant-in-assistance.

21.2.6. If the THIRD PARTY suspends or discontinues manufacture of the PRODUCT for a period exceeding 1 year without obtaining prior written permission or extension in this regard from the FIRST PARTY, except for reasons beyond the control of the THIRD PARTY and that are agreed by the FIRST PARTY.

21.3. **Termination by the THIRD PARTY**

The THIRD PARTY may at any point of time choose to terminate this Agreement after giving reasons, by giving prior notice of at least three months. On serving such notice to FIRST PARTY and SECOND PARTY, the THIRD PARTY shall be bound to complete the following obligations for effective termination.

21.3.1. Meet all the financial liabilities including Royalty payments due till that point of time.

21.3.2. Submit a confidential report detailing the status of Technology development/ validation till that point of time.

For effective Termination, the above obligations shall be subject to approvals by the Competent Authority, ICMR.

22. NO JOINT VENTURE

Nothing contained in this Agreement will be construed as creating a joint venture, agency, partnership, or employment relationship between the Parties hereto, nor will any Party have the right, power or authority to create any obligation or duty, express or implied, on behalf of the other Party.

23. ENTIRE AGREEMENT

This Agreement as well as any exhibits attached shall for all considerations be the entire Agreement for the properties listed. Furthermore, this Agreement will take precedence over all previous communications including, but not limited to, any oral or written understandings & other correspondence between the Parties.

24. SEVERABILITY

In case any one or more of the provisions or parts of a provision contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provision or part of a provision of this Agreement; and this Agreement shall, to the fullest extent lawful, be construed as if such invalid or illegal or unenforceable provision, or part of a provision, had never been contained herein.

25. SURVIVABILITY

If, at any point one or more terms and conditions within this Agreement are deemed to be unenforceable or void, the Parties agree to substitute a similar term or condition to replace the defective one.

26. WAIVER

The failure to enforce or uphold any aspect of this Agreement shall not constitute a waiver of any other aspect of the Agreement.

27. REGULATORY COMPLIANCE

The THIRD PARTY shall primarily be responsible for complying with all applicable laws, regulatory approvals and obtaining such regulatory approval shall be read as integral part to this Agreement.

28. GOVERNING LAW, JURISDICTION AND DISPUTES SETTLEMENT

28.1. The MoA shall be considered, interpreted, and governed by the laws of India and Courts at Delhi shall have exclusive jurisdiction in all such matters.

28.2. 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 no resolution is reached within 30 (Thirty) days following the date on which one party first notifies in writing to the other of its request that such a meeting be held, then, the Dispute shall be resolved by arbitration as per the provisions of the Arbitration and Conciliation Act, 1996 and the Rules there under, as amended from time to time.

28.3. 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 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 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 New Delhi International Arbitration Centre Act, 2019 (NDIAC) and as per 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 Agreement expiring or ceasing to exist or being terminated or foreclosed.

29. NOTICES

Any notice to be given to the FIRST PARTY shall be considered as duly served if the same shall have been delivered by registered mail to the FIRST PARTY and the THIRD PARTY at their addresses as stated below:

FIRST PARTY
Director General, ICMR
V. Ramalingaswami Bhawan, Ansari Nagar, Post Box 4911, New Delhi – 110029

Similarly, any notice to be given to SECOND PARTY shall be considered as duly served if the same shall have been delivered by registered mail to SECOND PARTY at their addresses as stated below:

SECOND PARTY

All notices and other communications required to be served on the THIRD PARTY including for violation of the terms of this Agreement shall be considered to be duly served if the same shall have been delivered either in person, via courier, or via registered mail to the THIRD PARTY at its address as stated below.

THIRD PARTY

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30. SURVIVAL

Notwithstanding the termination or completion of the term of this Agreement, as per terms of the clause twenty-eight above, the following clauses shall survive and continue to have effect:

30.1. Clause 7 ('IPR')

30.2. Clause 8 ('Commercialization for Societal Impact')
30.3. Clause 9 ('Royalty payouts')
30.4. Clause 10 ('Confidentiality')
30.5. Clause 11 ('Publication)
30.6. Clause 12 (Branding and Acknowledgement')
30.7. Clause 13 ('Data Rights and Data Privacy')
30.8. Clause 14 ('Press Release and Public Announcements')
30.9. Clause 15 ('No Liability')
30.10. Clause 22 ('No Joint Venture')
30.11. Clause 24 ('Severability')
30.12. Clause 25 ('Survivability')
30.13. Clause 28 ('Governing Law, Jurisdiction and Disputes Settlement')

IN WITNESS WHEREOF, the FIRST PARTY, SECOND PARTY and the THIRD PARTY have signed this Agreement on the day, month, and year mentioned herein before

For and on behalf of the FIRST PARTY:	
(Signature & Stamp)	
Name:	
Date:	
WITNESSES	
Signature:	Signature:
Name:	Name:
Date:	Date:

For and on behalf of the SECOND PARTY:	
(Signature of PI with Director/Head and stamp)	
Name:	
Date:	
WITNESSES	
Signature:	Signature:
Name:	Name:
Date:	Date:

For and on behalf of the "THIRD PARTY" duly authorized vide Board Resolution No _____dated _____of its Board of Directors/duly authorized/vide Authority Letter Dated _____by its concerned Authority:	
(Signature & Stamp)	
Name:	
Date:	
WITNESSES	
Signature:	Signature:
Name:	Name:
Date:	Date:

Schedule-I

Sanction Order/Letter

ANNEXURE - V

DEFINITIONS

1. **Applicable Agreements** shall mean an agreement that needs to be executed by the Grantee or Licensee under different categories on whom the provisions of Revenue sharing shall be applicable;

2. **Commercialization** shall mean in relation to the Intellectual Property, to use, make, manufacture, have made or manufactured, sell, advertise, promote, distribute, hire, supply or otherwise dispose of any Product (being manufactured using the Intellectual Property), or to keep it for the purpose of doing any of those things in each country and area and space throughout the universe and to assign, license or sub-license it to any third party to do the same;

3. **Competent Authority** shall mean an officer, employee, or any person that has been legally delegated or vested authority, capacity, or power to perform a designated function by the ICMR;

4. **Confidential Information** shall mean any and all information and know-how in any form, whether of a technical, financial, business or other nature, including, without limitation, the terms of this Agreement, information relating to the Parties' research, development, inventions, products, production, manufacturing, finances, marketing, business plans, trade secrets, know-how, data or other confidential communications, that is or has been disclosed to or otherwise received or obtained by either Party, whether or not in connection with or pursuant to this Agreement;

5. **Exclusive License** shall mean that no person or business other than the named licensee has right to make, use, or sell the licensed technology/ IP for commercial purposes;

6. **Grantee** shall mean a person, Institute, or organization private, public, or Government that receives grant-in-aid funding or any other support from ICMR at any stage from ideation to the commercializing of the technology;

7. **Intellectual Property or IP or IPR or Intellectual Property Rights** 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; and shall include without limitation, the Technology, Licensed Patents and Licensed Trademarks, developed/ created through ICMR support;

8. **Licensee** shall mean any business, organization, institute, or individual that has been given

legal permission in form of a license, by ICMR to commercialize the technology;

9. **Licensing & Collaboration Committee** shall mean a committee comprising a senior member of administration ICMR; a senior member of Finance, ICMR; a senior member of the IPMO, and one or more external subject matter expert with expertise in licensing/collaboration processes.

10. **Net Sales** shall mean Revenue from sales of goods or services by all ICMR Grantees/ Licensees/ Sub-licensee(s) based on the net sales realization from operations, net of discounts and indirect taxes, as defined by the Cost Accounting Standards - 24 and certified by the Chartered Accountant;

11. **Non-exclusive License** shall mean that the licensee has the right to make, use, or sell the technology for commercial purposes, but ICMR remains free to grant any number of other licensees the same rights to make, use, or sell the technology for commercial purposes or any other purposes;

12. **Person** shall mean and includes a legal or natural person or a partnership, firm, trust, company, government, or local authority and shall also include the legal representative or successor in interest of such person;

13. **Principal Investigator or PI** shall mean the individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project;

14. **Public Interest** shall mean Public Interest, as declared by Government of India from time to time;

15. **Royalty Period** shall mean each consecutive period ending 31st March, 30th September respectively each year;

16. **Royalty Term** shall mean Royalty shall be payable to ICMR from the Net sales for a period of 10 years from the date of commercialization of product;

17. **Sub-License** shall mean a person to whom the Licensee grants a Sub-License to Commercialize the Licensed Patents, its Improvements, and associated IP;

18. **Technology** shall mean any and all discoveries, inventions, processes, methods, techniques, know-how, and Intellectual Property and proprietary rights, expressed in whatever form including technical information, processes, procedures, material for trials, methods, formulae, protocols, software, specifications, instructions, data, documents, drawings, images, prototypes and materials encompassing the Licensed Patents and Improvements thereupon developed under ICMR Programs.

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