स्वास्थ्य अनुसंधान विभाग
DEPARTMENT OF HEALTH RESEARCH
सत्यमेव जयते

INDIAN COUNCIL OF MEDICAL RESEARCH
Serving the nation since 1911

INDIAN COUNCIL OF MEDICAL RESEARCH (ICMR)

INTELLECTUAL PROPERTY POLICY

Patron:

Dr. Rajiv Bahl
Secretary, Department of Health Research & Director General, ICMR

Guidance:

Ms. Manisha Saxena
Sr. Deputy Director General (Admn), ICMR

Compiled & Edited by:

Dr. Suchita Markan, Scientist E & Mission in-Charge, MDMS, ICMR
Ms. Nidhi Jain, Project Research Scientist D, ICMR

Technical Assistance:

Ms. Aarti Aeran, Project Research Scientist D, ICMR

Published by:

Medical Device and Diagnostics Mission Secretariat (MDMS), Division of Development Research, Indian Council of Medical Research, New Delhi-110029

स्वास्थ्य अनुसंधान विभाग
DEPARTMENT OF HEALTH RESEARCH

icmr
INDIAN COUNCIL OF MEDICAL RESEARCH
Serving the nation since 1911

INDIAN COUNCIL OF MEDICAL RESEARCH (ICMR)

INTELLECTUAL PROPERTY POLICY

FOREWORD

Hon'ble Prime Minister Shri Narendra Modi has emphasised the strength of imbibing a 'culture of innovation' as a cornerstone for achieving a 'Viksit Bharat' by 2047. In line with his vision and recognizing the crucial role of nurturing an environment where creativity flourishes and where research can be leveraged to enhance healthcare outcomes nationwide, the Indian Council of Medical Research (ICMR) came out with the ICMR Intellectual Property (IP) Policy.

This policy is a significant step forward in ICMR's commitment to advancing medical research and innovation through effective management and protection of intellectual property.

Our National IP Policy underscores the importance of safeguarding intellectual property generated by Indian scientists and researchers. The ICMR IP Policy aligns with this national focus by detailing suitable mechanisms for protecting the intellectual property created within ICMR and its institutes, as well as IP resulting from Intramural and Extramural funding schemes or collaborative research. The policy will act as a catalyst to foster 'Make in India' by stimulating innovation in healthcare and biomedical research.

The ICMR IP Policy provides clear guidelines for effectively protecting and managing intellectual assets, ensuring the rights of inventors while addressing the needs of all stakeholders, including researchers, industry partners, and the public at large. This policy reflects ICMR's commitment to transparency, fairness, and responsible stewardship of intellectual assets.

I am thankful to our researchers, legal experts, administrators, and industry partners for shaping this policy. I would also like to acknowledge the hard work of all my colleagues at ICMR Headquarters, especially the Medical Device and Diagnostics Mission Secretariat (MDMS) Team under the Division of Development Research, who have worked tirelessly in developing this policy.

I encourage all ICMR researchers, staff, and partners to familiarize themselves with the IP Policy and actively engage in its implementation.

Dr. Rajiv Bahl,
Secretary to Government of India, Department of Health Research
and Director General, Indian Council of Medical Research

Contents

स्वास्थ्य अनुसंधान विभाग
DEPARTMENT OF HEALTH RESEARCH
सत्यमेव जयते

INDIAN COUNCIL OF MEDICAL RESEARCH
Serving the nation since 1911

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 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, technology transfer, start-up creation and establishing suitable mechanisms for protecting, managing and utilizing intellectual property (IP) created within ICMR and its institutes, as well as IP resulting from its Intramural and Extramural funding schemes or collaborative research. This ICMR I.P. Policy is expected to play an important role in strengthening the innovation ecosystem for the envisaged Viksit Bharat.

Preface

Preface

1.1 Context and Institution Mission

1.1.1. The Indian Council of Medical Research ("Institution" or "ICMR") is the apex body in India for the formulation and coordination of biomedical research. It is an autonomous body under the Department of Health Research (DHR), Ministry of Health and Family Welfare (MoHFW), Government of India 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.

1.1.2. The Institution is tasked with the mandate ("Mandate") of:

- **i.** Formulating, coordinating and promoting biomedical research
- **ii.** Conducting, coordinating and implementing medical research for the benefit of the society and
- **iii.** Translating medical innovations into products/processes and introducing them into the public health system.

1.1.3. The core mission ("Mission") of the Institution is to:

- **i.** Generate, manage and disseminate new knowledge,
- **ii.** Increase focus on research on the health problems of the vulnerable, disadvantaged and marginalized sections of the society,
- **iii.** Harness and encourage the use of modern biology tools in addressing health concerns of the country,
- **iv.** Encourage innovations and translation related to diagnostics, treatment, methods/vaccines for prevention, and
- **v.** Inculcate a culture of research in academia especially medical colleges and other health research institutions by strengthening infrastructure and human resource.

1.1.4. The Institution is committed to ensuring that Intellectual Property (IP) emanating from its activities is used in support of its Mandate and Mission, and in accordance with its legal obligations, for the benefit of the Institution, the ICMR Institutes, the Inventors of Intellectual Property, and the society-at-large.

1.2 Purpose of the IP Policy

1.2.1. **Innovation and IP creation:** This IP Policy seeks to promote innovation, innovative activities and creative endeavours within the ICMR, ICMR Institutes and among individuals or entities collaborating with the Institution, and further seeks to encourage and enable the creation of IP arising from such innovation, innovative activities and/or creative endeavours.

1.2.2. Promotion of IP utilization: The intent of this IP Policy is to facilitate the widespread use, through various modalities of access to, of the Institution's IP.

1.2.3. IP Protection and IP management: The IP Policy seeks to set the framework for the translation of IP arising from research into products, services and processes by the Institution and the ICMR Institutes. It encourages *inter alia* scientists, faculty, fellows, staff members, students, recipients of intramural or extramural funding schemes, beneficiaries of adjunct faculty schemes, participants in inter-institutional collaborations, start-up entities and entrepreneurs associated with the Institution and/or the ICMR Institutes, industry-based collaboration partners, and external partners (such as recipients of outsourced work assignments and providers of contract manufacturing services), to become inventors and to identify and protect IP with potential commercial value. It also establishes policies for the protection, management and commercialization of such IP generated at the Institution and/or the ICMR Institute(s) or through collaborations with the Institution and/or the ICMR Institute(s).

1.2.4. Balance of interests: The IP Policy seeks to ensure legal protection, where applicable, effective management and commercialization of Institution IP, while at the same time enabling the traditions of education and scholarship, academic freedom, open and timely publications, Institution independence, and the Institution's Objectives and Mission, while serving the public interest.

Definitions

ARTICLE 2

Definitions

2.1 Definitions in the IP Policy

Without prejudice to any applicable laws, the definitions set out below shall apply in this IP Policy:

2.1.1 Appointment: A formal agreement between any person and the Institution, or between any person and any ICMR Institute, setting out the terms and conditions for such person's employment, or participation in or conducting of research, scholarship, creative work, or any award of a fellowship, or teaching at the Institution or at the ICMR Institute(s).

2.1.2 Author: Any person to whom this IP Policy is applicable, who individually or jointly with others makes a design, a mark or a copyrightable work and who meets the criteria for authorship under the IP laws of India or under WIPO-administered treaties/agreements or other IP treaties/agreements, to which India is a signatory or party, as the case may be.

2.1.3 Background IP: Any pre-existing IP created prior to an inventor becoming subject to this IP Policy, either by virtue of any Appointment or by virtue of any registration or admission in the case of a student.

2.1.4 Biodesign Program: The Biodesign program is an inter-institutional collaborative program which is implemented in collaboration between medical and engineering institutes. The aim of this program is to focus on the development of medical devices or in-vitro diagnostics as per unmet needs of India through structured Biodesign process involving Clinical Immersion, Need Identification, Need Filtration, Concept Generation and Product Development.

2.1.5 Biological Resource(s): Any plant, animal and micro-organism or part thereof, their genetic material and by-products (excluding value added products) with actual or potential use or value, but not including human genetic material.

2.1.6 Commercialization: Any form of utilization of IP intended to generate value, which may be in the form of a marketable product, process or service, commercial returns, or other benefit to the society. Commercialize is similarly defined.

2.1.7 Commercialization Entity: A company that has access to Institution IP, through any one or more of the available Commercialization modes, to produce new products, processes or services. This can also be a spin-off or start-up.

2.1.8 Competent Authority: The Director General of ICMR.

2.1.9 Copyright: Copyright is a right given to creators of literary, dramatic, musical and artistic works and producers of cinematograph films and sound recordings. Works are as defined under the Copyright Act, 1957.

2.1.10 Design or Industrial design(s): Design means only the features of shape, configuration, pattern, ornament or composition of lines or colours applied to any article whether in two dimensional or three dimensional or in both forms, by any industrial process or means, whether

manual, mechanical or chemical, separate or combined, which in the finished article appeal to and are judged solely by the eye; but does not include any mode or principle of construction or anything which is in substance a mere mechanical device. The term is defined under Section 2 (d) of the Designs Act, 2000.

2.1.11 Extramural funding scheme: The Extramural funding scheme in the schemes of Indian Council of Medical Research (ICMR) which provides financial assistance for Indian scientists working outside ICMR institutes to conduct research in the fields of medicine, public health, and allied disciplines aimed at improving health of Indians under its Extramural Research Programme.

2.1.12 Genetic Material: Any material of plant, animal, microbial or other origin containing functional units of heredity.

2.1.13 Genetic Resources or GRs: Genetic material of actual or potential value.

2.1.14 ICMR Institute(s): The Institutes and Regional Medical Research Centres identified in Schedule A.

2.1.15 IP Revenue: All revenue received by the Institution on Commercialization of Institution IP.

2.1.16 Indemnity: Where one party promises to save the other from loss caused to him by the conduct of the promisor himself, or by the conduct of any other person is termed as Indemnity. The obligation of a party who has provided an indemnification to another party, to provide the legal defence of all claims covered by such indemnification and to pay the amount of any such claim (subject to the right to defend it) up to the limits of such indemnification, as provided for in terms of Article 13.1.

2.1.17 Infringement: An infringement is a violation, a breach, or an unauthorized act. Infringement refers to the unauthorized use, duplication, or sale of materials or products that are legally regarded as protected intellectual property (IP) of Institution/ICMR Institute(s).

2.1.18 Institution: Indian Council of Medical Research, Headquarters at New Delhi.

2.1.19 Institution IP: IP owned or co-owned by ICMR and/or ICMR Institute(s).

2.1.20 Intellectual Property or IP: All outputs of creative endeavour in any field for which legal rights may be obtained or enforced pursuant to the law as per the Laws of India and also as provided under Article I of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), refers to all categories of intellectual property that are subject of Sections 1 to 7 of Part II of the TRIPS Agreement. IP may include:

i. Literary works, including publications in respect of research results, and associated materials, including drafts, data sets and laboratory notebooks,

ii. Teaching and learning materials

iii. Other original literary, dramatic, musical or artistic works, sound recordings, films, broadcasts, and typographical arrangements, multimedia works, photographs, drawings, and other works

iv. Databases, tables or compilations, computer software, preparatory design material for a computer program, firmware, courseware, and related material,

v. Patentable and non-patentable technical information,

vi. Designs including layout designs (topographies) of integrated circuits,

vii. Plant varieties and related information,

viii. Trade secrets,

ix. Trade mark(s) and service mark(s),

x. Copyrights and related rights such as rights of the performers, producers of sound recordings and broadcasters.

xi. Know-how, information and data associated with the above, and

xii. Any other works commissioned by the Institution or any ICMR Institute, that is not included above.

2.1.21 Intellectual Property Rights or IPRs: The proprietary rights that may be granted for any IP as provided under Article 2.1.20.

2.1.22 Intramural funding scheme: The Intramural funding scheme in the schemes of Indian Council of Medical Research (ICMR) which provides financial assistance to ICMR Institutes to promote research in the field of medicine, public health and allied areas under its Intramural Research Program.

2.1.23 Inventor: Any person to whom this IP Policy is applicable, who individually or jointly with others makes an invention and who meets the criteria for inventorship under the laws of India or WIPO administered treaties/agreements or other IP treaties/agreements, to which India is a signatory or party, as the case may be. Without limitation to the generality of the above, Inventors may include individuals who have provided intellectual contribution towards, and who have played a critical role in conceptualizing as well as developing any technology that is covered by IP, including persons who have contributed towards development, design engineering, experimental data, testing data, and analytical data.

2.1.24 IP Disclosure Form: A disclosure form to be completed by inventors and submitted to IP Management Office (IPMO) to document their creation.

2.1.25 IP Evaluation Committee: The body within the Institution, set up in terms of Article 4.3, which is responsible for IP evaluation and for recommendations relating to evaluation of IP, and relating to securing, filing, prosecuting, and maintaining Institution IP.

2.1.26 IP Management Office (IPMO): The Institution has an established IPR Unit which shall act as an IP Management Office (IPMO) as well as a Technology Transfer Office (TTO), referred to as IP Management Office (IPMO) in this Policy having responsibilities set out in Article 4.2, which is responsible for the management of Institution IP and for enabling the implementation of provisions of this IP Policy.

2.1.27 Licensing and Collaborations Committee: The body within the Institution established in terms of Article 4.4, responsible for recommendations relating to licensing, collaborations, and relating to obtaining and transferring Institution IP.

2.1.28 Limitation of Liability: The limitation of liability provisions that shall be included as part of any collaboration, transfer or licensing arrangement involving technology or Institution IP, as provided for in terms of Article 13.2.

2.1.29 Liability: Liability means any liability arising out of, relating to or resulting from any actual or alleged infringement, misappropriation or other violation of any clauses of agreement or of Intellectual Property Rights of third parties.

2.1.30 Non-Disclosure Obligations: Any agreement or contractual provisions setting out non-disclosure obligations and / or confidentiality obligations owed by one or more parties to such agreement to any other party.

2.1.31 Patent: Patent is an exclusive right granted for an invention, which is a product or a process that provides a

new way of doing something, or offers a new technical solution to a problem. The term is defined under Section 2(m) of the Patents Act, 1970.

2.1.32 Plant Variety: A form of intellectual property right granted to the breeder of a new plant variety concerning certain acts and the exploitation of the protected variety, which requires the prior authorization of the breeder. The term is defined under the Protection of Plant Varieties and Farmers' Rights Act, 2001.

2.1.33 Public Disclosure: The communication of information, relating to IP, to external parties. Public Disclosure includes, but is not limited to, disclosure in written or oral form; communication by email; posting on a web blog; disclosure in a news report, audio-video display; press release or interview; publication in a journal, abstract, poster, or report; presentation at a conference; examination of a thesis; demonstration of an Invention at a trade show; or the industrial application of an invention.

2.1.34 Public Domain: The freely accessible public realm in which works that are not protected by IPRs, either because the rights have been forfeited or because the rights have expired, are thereby held by the public at large and available for all to use without permission from the inventor or owner.

2.1.35 Strategic Collaborations: Inter-Institutional or Institution-Academic or Institution-Industry Collaboration for furthering the Mission and Mandate of the Institution.

2.1.36 Substantial Use: Extensive use of the resources of the Institution or of any ICMR Institute, which include but are not limited to facilities, equipment, human resources or funds.

2.1.37 Trade Mark: A mark capable of being represented graphically and which is capable of distinguishing the goods or services of one person from those of others and may include shape of goods, their packaging and combination of colours. The term is defined under Section 2(1)(zb) of the Trade Marks Act, 1999.

2.1.38 Trade Secret: Confidential information not publicly available that has commercial value because of its confidential nature, and which the owner has taken reasonable efforts to keep secret.

2.1.39 Traditional Knowledge or TK: A living body of knowledge resulting from intellectual activity in a traditional context, which includes know-how, practices, skills, and innovations. TK embodies the traditional lifestyles of indigenous peoples and local communities and is transmitted from generation to generation, often forming part of the cultural and spiritual identity of the community.

Scope of the IP Policy

ARTICLE 3

Scope of the IP Policy

3.1 This IP Policy applies to:

3.1.1 All IP generated at the Institution or at any ICMR Institute,

3.1.2 All IP generated in collaboration with the Institution or any ICMR Institute, and

3.1.3 All IP generated pursuant to any of Intramural or Extramural funding schemes of the Institution or any ICMR Institute, pursuant to contractual, project consultants, scientists, project scientists, technical officers, administrative staff etc. positions with the Institution, pursuant to adjunct faculty schemes of the Institution or any ICMR Institute, pursuant to inter-institutional collaborations involving the Institution or any ICMR Institute, by start-up entities or entrepreneurs that are associated with, or supported or funded by the Institution or any ICMR Institute, by industry-based partners pursuant to collaboration with the Institution or any ICMR Institute, CSR funds recipients and by external partners of the Institution or any ICMR Institute (such as recipients of outsourced work assignments and providers of contract manufacturing services).

3.2 Background IP:

Upon Appointment by the Institution or any ICMR Institute, or upon being granted enrollment as a student or fellow or scientists or project scientists, or consultants or technical officer with the Institution or any ICMR Institute, or upon entering into a collaboration or contractual arrangement with the Institution or any ICMR Institute, and prior to commencing any work for or collaboration with the Institution or any ICMR Institute, fellows, scientists, faculty, staff members, students, recipients of intramural or extramural funding schemes, beneficiaries of adjunct faculty schemes, participants in inter-institutional collaborations, start-up entities and entrepreneurs associated with the Institution, industry-based collaboration partners, CSR funds providers/recipients and external partners (such as recipients of outsourced work assignments and providers of contract manufacturing services), must declare any existing IP they wish to exclude from the application of this IP Policy due to creation of such IP prior to their employment, enrollment, appointment by the Institution or any ICMR Institute, or prior to their entering into a collaboration or contractual arrangement with the Institution or any ICMR Institute.

3.3 Applicability:

This IP Policy applies to all scientists, faculty, fellows, staff members, consultants, students, recipients of Intramural or Extramural funding schemes, beneficiaries of adjunct faculty schemes, participants in inter-

institutional collaborations, start-up entities and entrepreneurs associated with the Institution or any ICMR Institute, industry-based collaboration partners, CSR funds providers/recipients and external partners (such as recipients of outsourced work assignments and providers of contract manufacturing services) of the Institution or any ICMR Institute, and obligations under this IP Policy shall survive any termination of employment, enrollment or Appointment at the Institution or at any ICMR Institute, and any termination or expiry of any collaboration or contractual arrangement with the Institution or any ICMR Institute.

3.4 Binding effect of the IP Policy:

This IP Policy constitutes an understanding that is intended to be binding on the Institution and all ICMR Institutes, and on all scientists, faculty, fellows, staff members, students, recipients of intramural or extramural funding schemes, beneficiaries of adjunct faculty schemes, participants in inter-institutional collaborations, start-up entities and entrepreneurs associated with the Institution or any ICMR Institute, industry based collaboration partners, CSR funds providers/recipients and external partners (such as recipients of outsourced work assignments and providers of contract manufacturing services) of the Institution or of any ICMR Institute. The Institution and the ICMR Institutes shall ensure compliance of the above named persons and entities with the terms of IP Policy through express provisions in contracts, agreements or terms of Appointment / Appointment letters, endorsed Declaration, Acceptance Letters executed with or issued to said persons or entities.

Governance and Operation

ARTICLE 4

Governance and Operation

4.1 Institution

4.1.1 The Institution shall be responsible for:

i. Implementation of this IP Policy,

ii. Securing, filing, prosecuting, and maintaining Institution IP, including IP arising out of activities of scientists, faculty, fellows, staff members, students, recipients of intramural or extramural funding schemes, beneficiaries of adjunct faculty schemes, start-up entities and entrepreneurs associated with the Institution or any ICMR Institute, and external partners (such as recipients of outsourced work assignments and providers of contract manufacturing services) or recipients of CSR funds.

iii. Entering into appropriate contractual arrangements with participants in inter-institutional collaborations, and/or industry-based collaboration partners, and/or recipients of extramural funding schemes for setting out the respective responsibilities of the Institution or any ICMR Institute on the one side, and such participants or collaboration partners on the other side, in connection with securing, filing, prosecuting, and maintaining of IP arising out of such collaborations, and in connection with the respective rights and obligations of the Institution or any ICMR Institute, and the collaboration partners in respect of such IP. For avoidance of any doubt, in any contractual arrangement that the Institution or any ICMR Institute enters into with any participants in inter-institutional collaborations, and/or industry-based collaboration partners, and/or recipients of extramural funding schemes, permitting such non-Institution party to assume responsibility for securing, filing, prosecuting, and maintaining of IP arising out of collaborations with the Institution or any ICMR Institute, such contractual arrangements shall necessarily include a detailed mechanism for ensuring that the Institution and the ICMR Institute is kept fully informed of all activities and decisions implemented by the non-Institution party in connection with such IP,

iv. Implementing a centralized system for IP filing and management within the Institution,

v. Developing and/or implementing an online software for IP data management within the Institution,

vi. Engaging one or more external specialized agencies for assisting the Institution in IP filing and maintenance,

vii. Implementing regular IP sensitization, orientation and guidance programs for ICMR Institute(s), and for scientists, faculty, staff members, fellows, consultants, students, recipients of extramural funding schemes, beneficiaries of adjunct faculty schemes, participants in inter-institutional collaborations, start-up entities and entrepreneurs associated with such ICMR Institute(s), and

viii. Managing and commercializing Institution IP in a form that will most effectively promote its development and use for economic and social benefit.

4.1.2 The Institution shall discharge its responsibilities through the IPMO, the IP Evaluation Committee, the Licensing and Collaborations Committee and any other body or committee that it may set up in this regard.

4.2 Intellectual Property Management Office (IPMO)

4.2.1 **Purpose:** The Institution has an established IPR Unit which shall act as Intellectual Property Management Office (which may also be referred to as the Technology Transfer Office) and shall task it with the responsibility for the management of Institution IP, for enabling implementation of provisions of this IP Policy, for overseeing the implementation and monitoring of the IP Policy, and for providing strategic inputs and subject matter expertise and guidance to the IP Evaluation Committee and to the Licensing and Collaborations Committee. The IPMO shall additionally be tasked with the responsibility for recommending for approval by the Competent Authority, implementing, and managing, overseeing technology transfers and/or facilitating Strategic Collaborations that involve Institution IP.

4.2.2 **Responsibilities:** The IPMO shall be responsible for executing on behalf of the Institution, the responsibilities of:

i. Securing, filing, prosecuting, and maintaining Institution IP, including IP arising out of activities of scientists, faculty, fellows, staff members, consultants, technical officers, students, recipients of intramural or extramural funding schemes, beneficiaries of adjunct faculty schemes, start-up entities and entrepreneurs associated with the Institution or any ICMR Institute, and external partners (such as recipients of outsourced work assignments and providers of contract manufacturing services), or recipients of CSR funds.

ii. Considering and submitting on a case-by-case basis, recommendations to the Competent Authority on whether to pursue foreign filings for IP protection of any Institution IP, and in the event of approval from the Competent Authority for pursuing any foreign filings for IP protection of any institution IP, securing, filing, prosecuting and maintaining such Institution IP in the approved foreign jurisdictions. IPR protection in foreign countries may be done by Patent Cooperation Treaty (PCT) application route or by convention application route on case-to-case basis.

iii. Implementing a centralized system for IP filing and management,

iv. Engaging one or more external specialized agencies for assisting the Institution in IP filing and maintenance,

v. outreach/awareness to inventors, and relationship management with inventors,

vi. Facilitating IP costs and settlement,

vii. Implementing regular IP sensitization, orientation and guidance programs for ICMR Institute(s), and for fellows, scientists, faculty, staff members, technical officers, administrative officers, students, recipients of extramural funding schemes, beneficiaries of adjunct faculty schemes, participants in inter-institutional collaborations, start-up entities and entrepreneurs associated with such ICMR

Institute(s),

viii. Enabling and assisting Institution and ICMR Institutes to set up Office(s) of Licensing of Innovation Ventureship and Enterprise (OLIVE) as provided for in the ICMR-DHR Policy on Biomedical Innovation and Entrepreneurship, while simultaneously assisting such ICMR Institutes to conform to the objectives and provisions within this IP Policy,

ix. Engaging an external/ independent agency to conduct an annual or biannual (depending on the number of IP filings by the Institution) IP audit of Institution IP, and circulating the audit report received from the external/independent agency to the IP Evaluation Committee, the Licensing and Collaborations Committee, and to all other interested stakeholders within the Institution,

x. Implementing, in consultation with the IP Evaluation Committee, periodic review of Institution IP based on technical, IP, market and regulatory perspectives to assess whether protection of any Institution IP requires to be discontinued due to obsolescence or lack of potential for commercialization as laid down in Article 7,

xi. Floating an expression of interest, and inviting applications from potential licensees, external partners and / or Commercialization Entity(ies) for entering into IP licensing arrangements with the Institution for the purposes of commercializing Institution IP, following approval by the Competent Authority,

xii. Facilitating strategic collaborations including drafting & vetting of Agreements, for entering into an appropriate contractual arrangement with external entities and external collaborators, or interested third parties (including any participants in inter-institutional collaborations, and/ or industry-based collaboration partners), for setting out the respective responsibilities of the Institution or any ICMR Institute on the one side, and external entities and/or external collaborators on the other side, in connection with Commercialization of Institution IP or Commercialization of any other IP that has been developed in collaboration with or in participation with the Institution or any ICMR Institute,

xiii. Technology marketing and IP license negotiation,

xiv. Recommending for approval by the Competent Authority, implementing, and managing, and overseeing technology transfers that involve Institution IP,

xv. Assisting Inventors in seeking permissions from the National Biodiversity Authority, India in cases where any biological materials or genetic materials are accessed or involved in research activities undertaken or IP generated by such Inventors.

4.3 IP Evaluation Committee

4.3.1 **Purpose:** The Institution shall establish an IP Evaluation Committee and task it with the responsibility for IP evaluation and for recommendations relating to evaluation of IP and for recommendations relating to securing, filing, prosecuting, and maintaining

Institution IP.

4.3.2 Composition: The IP Evaluation Committee shall consist of:

i. A senior member of the Institution having designated administration responsibilities,

ii. A senior member of the Institution having designated finance related responsibilities,

iii. One or more external subject matter experts*, with expertise in IP, and

iv. A senior member of the IPMO.

v. Optionally, any other member(s) nominated by a consensus among the remaining members.

**Subject to confidentiality clause as decided by the Institution in case of external experts.*

4.3.3 Responsibilities: The IP Evaluation Committee is the body responsible for assessing and making recommendations relating to evaluation of IP and for recommendations relating to securing, filing, prosecuting, and maintaining Institution IP. The IP Evaluation Committee shall *inter alia* be responsible for:

i. Making recommendations for engaging one or more external specialized agencies for assisting the Institution in technology evaluation, and/or assessment or evaluation of the strength of any technology or IP under consideration by the IP Evaluation Committee,

ii. Assessing and making recommendations relating to evaluation of IP and for recommendations relating to securing, filing, prosecuting, and maintaining Institution IP.

4.3.4 Meetings: The IP Evaluation Committee shall establish regular meetings and also be available for ad hoc meetings as per the requirements. Meetings of the IP Evaluation Committee shall be chaired by a member selected by consensus of members of the IP Evaluation Committee.

4.3.5 Decisions on Recommendations: All recommendations made by the IP Evaluation Committee shall be placed before the Competent Authority for necessary approvals and the decision or approval of the Competent Authority shall be with due consideration of the recommendations of the IP Evaluation Committee. The decision or approval by the Competent Authority shall be final and binding.

4.4 The Licensing and Collaboration Committee

4.4.1 Purpose: The Institution shall establish a Licensing and Collaborations Committee and task it with the responsibility for recommendations relating to licensing, collaborations, and relating to obtaining and transferring Institution IP.

4.4.2 Composition: The Licensing and Collaborations Committee shall consist of:

i. A senior member of the Institution having designated administration responsibilities,

ii. A senior member of the Institution having designated finance-related responsibilities,

iii. A senior member of the IPMO, and

iv. One or more external subject matter experts, with expertise in licensing/ collaboration processes.

v. Optionally, any other member(s) nominated by a consensus among the remaining members.

4.4.3 Responsibilities: The Licensing and Collaborations Committee is the body responsible for making recommendations relating to licensing, collaborations, and for obtaining and transferring Institution IP. The Licensing and Collaborations Committee shall *inter alia* be responsible for making recommendations for:

i. Evaluating the technologies generated by the ICMR Institute/ Inventor for technology readiness and their eligibility as per the ICMR Guidelines for Technology Transfer and Revenue Sharing, 2021, revised and renamed as ICMR Guidelines for Technology Development Collaboration for floating an expression of interest, and inviting applications from potential licensees, external partners and/ or Commercialization Entity(ies) for entering into IP licensing arrangements with the Institution for the purposes of commercializing Institution IP, following approval by the Competent Authority.

ii. Engaging one or more external specialized agencies for providing the rates of cost recovery in cases wherein no royalty is applicable. As per the ICMR Guidelines for Technology Transfer and Revenue Sharing, 2021, revised and renamed as ICMR Guidelines for Technology Development Collaboration, the Cost Recovery model shall be applicable in cases wherein no royalty is applicable, considering the nature of the support provided by ICMR. Applicable cost recovery rates would be determined in consultation with third party taking into account the operational costs such as man-hours and resources etc. being used for the said activity.

iii. Recommending key terms for entering into appropriate contractual arrangements with external entities and external collaborators, or interested third parties (including any participants in inter-institutional collaborations, and/or industry-based collaboration partners), for setting out the respective responsibilities of the Institution or any ICMR Institute on the one side, and external entities and/or external collaborators on the other side, in connection with Commercialization of Institution IP or Commercialization of any other IP that has been developed in collaboration with or in participation with the Institution or any ICMR Institute.

iv. Enabling Commercialization of Institution IP in a form that will most effectively promote its development and use for economic and social benefit, including through the grant of licenses to external entities or third parties, and

v. Technology marketing and IP license negotiation.

vi. Evaluation and selection of the Licensee.

4.4.4 Meetings: The Licensing and Collaborations Committee shall establish regular meetings and also be available for ad hoc meetings as per the requirements. Meetings of the Licensing and Collaborations Committee shall be chaired by a member selected by consensus of members of the Licensing and Collaborations Committee.

4.4.5 Decisions on Recommendations: All recommendations made by the Licensing and Collaborations Committee shall be placed before the Competent Authority for necessary approvals and the decision or approval of the Competent Authority shall be with due consideration of the recommendations of the Licensing and Collaborations Committee. The decision or approval by the Competent Authority shall be final and binding.

Ownership of IP and Rights of Use

ARTICLE 5

Ownership of IP and Rights of Use

5.1 Ownership of IP

5.1.1 Subject to the remaining provisions of this Article 5, ownership of IP generated at the Institution or in collaboration with the Institution shall be determined as follows:

i. All rights in IP generated by beneficiaries of ICMR fellowship scheme(s), scientists, faculty, staff members, consultants, technical officers, beneficiaries of emeritus scientist schemes and/or beneficiaries of adjunct faculty schemes, shall be owned solely by the Institution,

ii. All rights in IP generated as an outcome of research or other work carried out under Intramural funding schemes, shall be owned solely by the Institution,

iii. All rights in IP generated as an outcome of ICMR-outsourced work assignments, or contract manufacturing services, shall be owned solely by the Institution,

iv. All rights in IP generated as an outcome of research or other work carried out under Extramural funding schemes, shall be owned either solely by the Institution or jointly by the Institution and the other collaborators. Ownership and ownership shares in the case of jointly owned IP shall be determined on a case-by-case basis depending on all relevant factors.

v. All rights in IP generated as an outcome of research or other work carried out under inter-institutional collaborations involving the Institution and/or one or more ICMR Institute(s) collaborating with one or more external institutions or entities, shall be owned jointly by the Institution and the other collaborating institution or entity. Ownership and ownership shares in case of jointly owned IP shall be determined on a case-by-case basis depending on all relevant factors. Ownership and licensing terms offered to collaborating individuals/entities shall be consistent with the broad mandate of 'Make-in-India' or any other Government Scheme towards innovations and Entrepreneurship and decisions on whether to offer nominal licensing fees or to waive licensing fees altogether, and whether to offer non-exclusive or conditional exclusive licensing terms, can be taken on a case-by-case basis.

vi. All rights in IP generated as an outcome of research or other work carried out by start-up entities/entrepreneurs associated with or supported by the Institution or any ICMR Institute(s) shall be owned solely by the Institution, or jointly by the Institution and the collaborating start-up entities/entrepreneurs, or solely by the start-up entities/entrepreneurs. Ownership and

ownership shares in the case of jointly owned IP shall be determined on a case-by-case basis depending on all relevant factors. Further, in the case of jointly owned IP, the sponsoring partner may have sole ownership of IP after payment of suitable share/royalty as agreed upon by the parties.

vii. Ownership of IP generated by start-ups incubated or supported within the Institution's fully supported biodesign program(s) shall be fully owned by the Institution. The Institution may at its sole discretion, based on consideration of all relevant factors, and subject to prior approval by the Competent Authority, permit incubated start-ups to secure joint ownership rights or sole-ownership rights in such IP – provided that such approval may be granted only in cases involving projects or technology that has or have been partially or fully developed by the start-up(s) prior to commencement of incubation or support by the Institution or by any ICMR Institute.

viii. Any start-up incubated or supported within the Institution's fully supported biodesign program(s) may seek from the Institution, an exclusive license or an assignment of Institution IP that has been generated by such start-up for promotion of entrepreneurship. The Institution may at its sole discretion, based on consideration of all relevant factors, and subject to prior approval by the Competent Authority, agree to assign such Institution IP to the start-up, on mutually agreeable terms and conditions for such assignment, including mutually acceptable payment terms.

ix. All rights in IP generated as an outcome of research or other work carried out under collaborations involving the Institution and/or one or more ICMR Institute(s) collaborating with one or more industry partners, shall be owned jointly by the Institution and the collaborating industry partner.

x. In cases wherein Institution owns a joint IP, the Institution shall perpetually retain, royalty free license to use the IP solely for research and educational purposes.

5.1.2 When Copyrights are concerned, the ownership of academic works, books, articles, monographs, projects, dissertations, thesis, lectures, speeches, audio-video materials and other communications produced by the fellows, scientists, faculty, staff members, students in the course of research and teaching shall be owned by the authors. However, the Copyright protectable work, including software, created by the Institution personnel with significant use of Institution resources, in due course of their appointment, shall be owned by the Institution. If the work is produced within the ambit of sponsored or collaborative activity, specific provisions made in the Agreements governing such activity, shall determine the ownership of IP.

5.1.3 The ownership of all Trademarks relating to the Institution shall be owned solely by the Institution. The Institution may at its sole discretion, based on consideration of all relevant factors, and subject to prior approval by the Competent Authority, agree to assign such Institution IP to the start-up, on mutually agreeable terms and conditions for such assignment, including mutually acceptable payment terms. If the trademark is created for a start-up or spin-off associated with the Institution, then the IP right on the

trademark shall be owned by the start-up or spin-off.

5.1.4 The ownership of all Industrial Design relating to the Institution shall be owned solely by the Institution.

5.2 Moral Rights

5.2.1 Recognition: The Institution undertakes to respect and protect the moral rights which copyright law confers on Authors of copyright works.

5.2.2 Rights granted: The Institution acknowledges that moral rights vest in Authors of copyright works irrespective of the copyright ownership thereof and include:

i. The right of attribution of authorship in respect of the copyright works,

ii. The right not to have authorship of the copyright works falsely attributed, and

iii. The right of integrity of authorship in respect of the copyright works.

5.2.3 Release into the public domain: The Institution will be fully entitled to release IP into the Public Domain in the following circumstances:

i. Where it is deemed to be in the public interest,

ii. If the IP has low commercial or other development potential and low prospects of fostering the development of new products or services, or

iii. If deemed necessary by the Institution.

Publication, Non-Disclosure and Trade Secrets

ARTICLE 6

Publication, Non-Disclosure and Trade Secrets

6.1 Right of Publication

6.1.1 Inventors shall seek and obtain written permission from the Institution prior to publishing the results of any research or any data or information relating to inventions, works or IP that has arisen pursuant to such inventor's association or collaboration with the Institution or any ICMR Institute.

6.2 Non-disclosure for IP protection

6.2.1 Even in the event that the Institution has granted permission for publication in accordance with Article 6.1, inventors should be aware that premature Public Disclosure may result in loss of IPRs. Therefore, inventors are strongly encouraged to make all reasonable efforts to identify any protectable IP as early as possible, and shall consult IPMO and obtain permission from the Institution before making any Public Disclosure of potential Institution IP. In exceptional cases, if advised by IPMO, the inventors may enter into non-disclosure agreements with other parties before any disclosure of IP may be introduced. The non-disclosure agreements may provide for:

i. Vesting the ownership of IP in the confidential information with the disclosing party.

ii. Prohibiting the receiving party to file any application for seeking intellectual property rights based on the information disclosed to it by the disclosing party.

6.3 Trade Secrets

6.3.1 The Institution may designate certain confidential information as a Trade Secret, owned by the Institution. In that event, all inventors will be obligated to maintain the secrecy of the Trade Secret and to follow the directions for the management of the Trade Secret as provided by the IPMO.

Determinations by the IP Evaluation Committee

ARTICLE 7

Determinations by the IP Evaluation Committee

7.1 Responsibility to Disclose IP

7.1.1 Recording: Inventors shall keep appropriate records of their research and make reasonable efforts to ensure that only those individuals within the Institution or the concerned ICMR Institute who have a need to have access to such records for the performance of their duties are granted such access.

7.1.2 IP Disclosure: Where an inventor identifies potential IP resulting from his/her research, he/she shall disclose such potential IP to the IPMO promptly by means of an IP Disclosure Form.

7.1.3 Complete disclosure: Inventors must provide to the IPMO, such full, complete and accurate information as the IPMO or the IP Evaluation Committee may reasonably require to enable it to sufficiently assess the technical and related features and functions, ownership, commercial potential and IP protection that might be applicable to such IP.

7.2 Inventorship and Ownership

7.2.1 Inventorship: Inventors shall, upon request, sign any appropriate legal documents provided by the IPMO that attest to inventorship. Each IP Disclosure Form submitted to the IPMO shall include a full list of inventors involved in the generation of the IP, along with detailed information relating to their respective contributions. The list shall also include mention of transfer or retirement cases where an inventor/innovator has left the institution in the mid-course of research, and his/her relative contribution to the invention/innovation. Further, in cases where the individual involved in the invention are transferred or leave the institute due to resignation/superannuation, all information/documents including the know-how should be handed over to the IPMO before leaving. The Inventors named within an IP Disclosure Form shall be approved by the Director of the concerned ICMR Institute within which the IP identified in the IP Disclosure Form has arisen, as well as by the Head of the Department, at the ICMR Institute within which the IP identified in the IP Disclosure Form has arisen, and except in exceptional circumstances that involve prior written approval from the Competent Authority, this approved list of named inventors identified in the IP Disclosure Form for such IP shall be submitted to the Institution headquarters and shall be treated as the definitive list for recordal of inventors for the purposes of any future revenue sharing. Where there is more than one inventor, and there is a dispute as to the contribution to inventorship, the IPMO through IP Evaluation Committee shall, in consultation with the inventors, make a recommendation of the IP inventorship by each inventor and a final decision shall be taken in this regard by the Competent Authority.

7.2.2 Ownership: Once inventorship has been determined, the inventors shall be required to formally assign any right, title or interest they may have in that IP to the Institution in the form of a contract that specifies the rights that will accrue to the Institution.

7.3 Determination as to IP Protection and Commercialization

7.3.1 Evaluation and recommendation: The IPMO will analyze the information disclosed in the IP Disclosure Form. The analysis will include whether or not the subject matter is protectable as IP, an assessment of economic viability or marketability, and determination of any rights of external parties, such as a funder or collaborator. After evaluation, IPMO will, within a reasonable time from receiving the IP Disclosure Form, report its findings to the IP Evaluation Committee – which will enable the IP Evaluation Committee to make a recommendation whether the Institution will proceed with IP protection and Commercialization. In the event, evaluation of the IP disclosure and preparation of a report on its findings to the IP Evaluation Committee requires independent evaluation by any third party organization, the time period for IPMO to conclude obtain the independent evaluation, analyze the evaluation, and prepare and report its findings to the IP Evaluation Committee shall be a reasonable time from receiving the IP Disclosure Form.

7.3.2 Decision to Protect/Commercialize: The IP Evaluation Committee will, within a reasonable time from receiving reported findings from the IPMO under Article 7.3.1, make a recommendation on whether or not the Institution shall protect and/or Commercialize the IP, and a final decision on this shall be taken by the Competent Authority with due consideration to the recommendations.

7.4 Institution Elects not to Protect / Commercialize the IP

7.4.1 IP abandoned or not Commercialized: The Institution reserves the right not to protect or commercialize IP that it owns, for any reason whatsoever, including without limitation, if there is no reasonable prospect of commercial success, or it is not deemed to be in the best interest of the Institution, or it is not deemed to be in the public interest, or is not in accordance with the ICMR mandate.

7.4.2 Transfer of Ownership: In the event the Institution decides not to pursue IP protection and/or commercialization, it will take steps to return said IPRs to the inventor(s), contingent on any other superseding contract rights of external party(ies)/sponsor(s). The inventor(s) may request an assignment of such IPRs from the Institution to itself or themselves or such terms and conditions as may be agreed to between the Institution and the inventor(s) on a case-by-case basis, including without limitation any one or more of:

i. That Institution receives up-front compensation and/or a continuing royalty-based compensation based on a valuation of the IPRs and an evaluation of its prospects for Commercialization,

ii. That upon Commercialization, the Institution be compensated for any expenditure it may have incurred in connection with the protection and/or Commercialization of such IP, and/or

iii. That the Institution be granted a non-exclusive, royalty-free license to use the IP for Research and teaching purposes.

Commercialization of IP

ARTICLE 8

Commercialization of IP

8.1 Determination of the Commercialization Strategy

In the event of a decision to protect or Commercialize the IP under Article 7.3.2, the Institution will determine, with input from the inventors, the most appropriate Commercialization strategy. Any such Commercialization strategy shall be finalized after due consideration of the recommendations/suggestions from the Licensing and Collaborations Committee.

8.2 Assistance to the Institution

Inventors of IP which has been selected for IP protection and Commercialization by the Institution must provide the Institution with all reasonable support in the assessment, protection (including preventing premature disclosure and execution of any documents including deeds of assignment and deeds attesting to inventorship), and Commercialization of the IP.

8.3 Sovereignty and Cooperation

The Institution shall have the sole discretion regarding the Commercialization of IP owned by it. The Commercialization of Institution IP will be planned, executed, and monitored by the IPMO following the recommendation by the Licensing and Collaborations Committee. The rights regarding licensing of jointly owned IP might be mutually decided by the joint owners.

8.4 Commercialization Pathways

Modes of IP Commercialization may include:

8.4.1 License, either non-exclusive (preferably) or exclusive, and variations thereof,

8.4.2 Assignment,

8.4.3 Formation of a Commercialization Entity to which the IP is licensed or assigned in terms of this IP Policy,

8.4.4 Non-profit use or donation,

8.4.5 Joint ventures,

8.4.6 Royalty free access on humanitarian or other grounds, or

8.4.7 Various combinations of the above.

8.5. Guidelines

Regardless of the mode of IP Commercialization, the transaction will be executed in a contract which:

8.5.1 Protects the interests of the Institution,

8.5.2 Retains rights for the Institution to use the IP for educational and research purposes,

8.5.3 Assures that the IP will be utilized in a manner which will serve the public good,

8.5.4 Assures that the IP will be developed and brought to the marketplace as useful goods and services,

8.5.5 Prohibits the "shelving" or "mothballing" of the IP or its use in any illegal or unethical manner, and

8.5.6 Is consistent with the mandate of the Government of India concerning exploitation of IP and/or knowledge by foreign parties i.e., first preference may be given to Indian entities and the terms of Commercialization if and when offered to a foreign entity shall be either the same or different from the terms offered to Indian entities, wherein suitable guidelines/ precedence of Government Institutions on the subject matter may be followed or as recommended by the Licensing and Collaborations Committee on a case-to-case basis.

8.6 Exclusivity of Licensing Arrangements

Each and every proposed licensing arrangement in connection with Institution IP shall be considered and evaluated by the Licensing and Collaborations Committee, to determine whether the licensing arrangement should be exclusive or non-exclusive. The Institution shall, as a preferred option, select non-exclusive licensing arrangements, wherever feasible and where such non-exclusivity does not result in a reduction of potential returns under any proposed commercialization arrangement. However, on a case- to-case basis, the Licensing and Collaborations Committee may recommend an exclusive licensing arrangement, provided it can be demonstrated that a grant of exclusivity would improve the likely returns from commercialization for the Institution and/or result in improved public access to the technology or works in which the Institution IP resides. Grant of any exclusive license by the Institution shall be following approval by the Competent Authority & shall be subject to:

8.6.1 Clearly set out stringent performance milestones and/or,

8.6.2 A specific period of exclusivity and/or,

8.6.3 A defined territory for exclusivity and/ or,

8.6.4 Clearly set out conditions for conversion of the exclusive license into a non- exclusive license (e.g. in the event of the licensee's failure to meet performance milestones).

IP Portfolio Maintenance

ARTICLE 9

&

Traditional Knowledge, Genetic Resources and Biological Resources

10

IP Portfolio Maintenance

9.1 Recording and monitoring

IPMO or an external entity designated by the IPMO shall maintain records of the Institution's IP in an appropriate form and in sufficient detail. It shall monitor the deadlines for the payment obligations related to the maintenance or annuity fees of protected IP, and shall, within a reasonable time, inform the person or department designated to make such payments.

9.2 Accounting

IPMO shall maintain income/expense accounting records on each IP so that revenue-sharing allocations can be calculated.

Traditional Knowledge, Genetic Resources and Biological Resources

10.1 Compliance

When research is conducted at the Institution or at any ICMR Institute, using Traditional Knowledge (TK) and/or Genetic resources (GRs) and/or Biological Resources, provisions of The Patents Act 1970 (as amended), The Protection of Plant Varieties and Farmers' Right Act, 2001, The Biological Diversity Act, 2002, Geographical Indications of Goods (Registration and Protection) Act, 1999 and any other enacted laws of India must be observed, especially those provisions relating to prior informed consent, access and benefit-sharing, and the need to obtain any relevant permits.

Conflicts of Interest and Conflicts of Commitment

ARTICLE 11

Conflicts of Interest and Conflicts of Commitment

11.1 Commitment to the Institution

The primary commitment of time and intellectual contributions from fellows, scientists, faculty, staff members, students, recipients of intramural funding schemes, and beneficiaries of adjunct faculty schemes, should be to the education, research and academic programs of the Institution and/or the relevant ICMR Institute.

11.2 Best Interests of the Institution

Scientists, faculty, fellows, staff members, students, recipients of intramural funding schemes, and beneficiaries of adjunct scientist schemes have a primary professional obligation to act in the best interests of the Institution and any concerned ICMR Institute(s); they should avoid situations where external interests could significantly and negatively affect their work ethic and research integrity.

11.3 Agreements with External Parties

It is the responsibility of all scientists, faculty, staff members, fellows, students, recipients of intramural funding schemes, and beneficiaries of adjunct faculty schemes to ensure that their agreements with external parties do not conflict with their duties and responsibilities in terms of this IP Policy. This provision shall apply in particular to private consultancy and other research service agreements concluded with external parties. Each individual should make his/her duties and responsibilities clear to those with whom such agreements may be made and should ensure that they are provided with a copy of this IP Policy.

11.4 Disclosure of External Activities and Financial Interests

All fellows, scientists, faculty, staff members, students, recipients of intramural or extramural funding schemes, beneficiaries of adjunct faculty schemes, participants in inter-institutional collaborations, start-up entities and entrepreneurs associated with the Institution or any ICMR Institute, industry-based collaboration partners, and external partners (such as recipients of outsourced work assignments and providers of contract manufacturing services) shall promptly report all potential and existing conflicts of interest (COI) to the Institution or any concerned ICMR Institute. The Institution will provide the party or entity reporting the potential or existing conflict of interest with an opportunity to resolve the conflict of interest to the satisfaction of the Institution, and failing a satisfactory resolution or elimination of the reported conflict of interest, the party or entity with the potential or existing conflict of interest shall withdraw or exit from its engagement or association with the Institution and any concerned ICMR Institute.

11.5 Conflict of Interest (COI) Policy

The Institution may develop a separate and comprehensive policy on COI, in order to increase the awareness of fellows, scientists, faculty, staff members, students, recipients of intramural or extramural funding schemes, beneficiaries of adjunct faculty schemes, participants in inter-institutional collaborations, start-up entities and entrepreneurs associated with the Institution and/or any ICMR Institute, industry-based collaboration partners, and external partners (such as recipients of outsourced work assignments and providers of contract manufacturing services) about COI; outline requirements for disclosure of COI; and establish procedures to identify them, avoid or properly manage such conflicts.

IP Audit

ARTICLE 12

IP Audit

12.1 The IPMO shall ensure through a duly appointed external/independent agency having the necessary expertise, that an annual or biannual (depending on the number of IP filings by the Institution) IP audit is conducted in respect of all Institution IP, and that the audit report received from the external/independent agency is finalized and circulated to the IP Evaluation Committee, the Licensing and Collaborations Committee, and all other interested stakeholders within the Institution. In the event of an annual IP audit, the IP audit report for each financial year shall be finalized and circulated in accordance with this Article 12.1 prior to March 31 closing of that financial year. In the event of biannual IP audits, the first IP audit report of each financial year shall be finalized and circulated in accordance with this Article 12.1 prior to September 30 of that financial year, and the second audit report of each financial year shall be finalized and circulated in accordance with this Article 12.1 prior to the March 31 closing of that financial year.

12.2 Any IP audit performed pursuant to this Article 12 may include one or more of a systematic review of all Institution IP, status and pending or outstanding requirements or compliance procedures in connection with each item of Institution IP, status of related agreements, how the Institution IP is being used or whether it is unused, whether there are any ongoing infringement proceedings or potential infringement proceedings involving the Institution IP, and any other audit requirements specified by the Institution.

12.3 Prior to commencement of any IP audit by a duly appointed external/ independent agency, the IPMO shall approve and share with such agency a finalized audit checklist – enumerating action items required to be covered in the IP audit. Upon preparation of the IP audit report by such agency, the IPMO shall scrutinize the report for compliance with the checklist and shall treat the IP audit report as final and complete only after determining that all action items enumerated in the checklist have been properly completed.

Implementation of Contractual Safeguards

ARTICLE 13

Implementation of Contractual Safeguards

13.1 Any and all agreements entered into between the Institution and any third party, including without limitation any agreements involving technology or IP collaborations, technology transfer, or technology licensing, shall include provisions whereunder the Institution receives a satisfactory Indemnity from such third party against any legal proceedings, claims arising out of activities carried out under, or pursuant to, or as a consequence of such agreement.

13.2 Any and all agreements entered into between the Institution or ICMR Institute(s) on behalf of the Institution and any third party, including without limitation any agreements involving technology or IP collaborations, technology transfer, or technology licensing, shall include provisions that provide for absolute or appropriate Limitation of Liability of the Institution in respect of any claims arising out of activities carried out under, or pursuant to, or as a consequence of such agreement. Subject matter connected with high potentials of IP creation and development related thereto and required to be assigned or shared as per the law of contract and legislations protecting Intellectual Property Rights being administered by the Central Government shall be in accordance with the General Agreement on Tarrifs and Trade (GATT)/ World Trade Organisation (WTO) Agreements (as applicable).

13.3 Any and all agreements entered into between the Institution or ICMR Institute(s) on behalf of Institution and any third party, including without limitation any agreements involving technology or IP collaborations, technology transfer, or technology licensing, shall include appropriate Non-Disclosure Obligations setting out non-disclosure obligations and/ or confidentiality obligations owed by such third party to the Institution with respect to the subject matter and/or activities carried out under, or pursuant to, or as a consequence of such agreement, and data and information arising as a result of activities carried out under, or pursuant to, or as a consequence of such agreement.

13.4 Not withstanding anything contained in this policy document, no person or entity shall acquire any interests or rights merely by following or relying on the provisions of this policy document without a separate specific agreement executed as per the policy of the Central Government.

13.5 ICMR shall retain the right to prosecute, engage in or desist from becoming a party in any litigation concerning IP and license infringements.

13.6 ICMR shall not be held liable for damages resulting from breaches of any auxiliary contract, irrespective of whether the contract has been approved by ICMR. In case of any conflict with the provisions of such auxiliary contract, the provisions of this policy shall prevail.

Consultation and Dispute Resolution

ARTICLE 14

Consultation and Dispute Resolution

14.1 Any concerns relating interpretation or implementation or performance of this policy document raised by an interested party shall be resolved through consultations among the parties. If at any time a Party or Parties, not a third party has concerns with the implementation of a provision of this Policy, the concerned Party or Parties may submit a written request for consultations to ICMR or the other authorized authority in writing, to which the ICMR or authorized authority shall respond within 30 days. The consultation process shall commence within 45 days. During such consultations, those parties shall attempt to arrive at a mutually satisfactory resolution within 3 months. The parties shall, upon request, enter into consultations with the aim of achieving mutual agreements on any disagreement or concerns relating to the implementation of this policy. Any requests for consultation shall be made in writing.

14.2 Failing above all the disputes or questions of interpretation arising under this IP policy shall be referred to the IPMO for consideration and mediation by the IP Evaluation Committee or any other authority specifically constituted.

14.3 If the matter cannot be resolved by the IPMO with assistance from the IP Evaluation Committee within 2 months, then the dispute or question of interpretation must be referred to the Competent Authority, ICMR or authorized representatives for a decision, and the decision of the Competent Authority, ICMR shall be final in this regard.

14.4 Any and all agreements entered into between the Institution or ICMR Institute(s) on behalf of the Institution and any third party, including without limitation any agreements involving technology or IP collaborations, technology transfer or technology licensing, shall include an appropriate arbitration clause to ensure that disputes arising in connection with such agreement shall be subject to arbitration under the Arbitration and Conciliation Act, 1996 and as per ICADR Arbitration Rules, 1996 read with New Delhi International Arbitration Centre Act, 2019 (NDIAC) (as amended).

14.5 All the legal and constitutional issues arising out of or under this policy shall be settled as per international norms in consensus with domestic laws and policies related thereto.

Amendment

ARTICLE 15

Amendment

15.1 Revision

This IP Policy may be amended at any time by the Institution in consultation with the appropriate committee, following approval by the Competent Authority, ICMR to incorporate appropriate inputs received during its implementation and to ensure compliance with evolving laws and regulations. In case of any amendment:

15.1.1 All IP disclosed on or after the effective date of such amendment shall be governed by the IP Policy as amended, and

15.1.2 All IP disclosed prior to the effective date of the amendment shall be governed by the IP Policy prior to such amendment, provided that the provisions of the IP Policy (as amended) shall apply to all IP licensed or otherwise Commercialized on or after the effective date of any such amendment regardless of when the IP is disclosed.

Schedule A

ICMR

INSTITUTES

ICMR Institutes

A.1 Institutes

A.1.1 ICMR National JALMA Institute for Leprosy & Other Mycobacterial Diseases (NJIL&OMD), Agra

A.1.2 ICMR National Institute of Occupational Health (NIOH), Ahmedabad

A.1.3 ICMR National Institute of Traditional Medicine, Belagavi

A.1.4 ICMR National Centre for Diseases Informatics and Research, Bengaluru,

A.1.5 ICMR Bhopal Memorial Hospital & Research Center (BMHRC), Bhopal

A.1.6 ICMR National Institute for Research in Environmental Health (NIREH), Bhopal

A.1.7 ICMR Regional Medical Research Centre, Chandrasekharpur, Bhubaneswar

A.1.8 ICMR National Institute for Research in Tuberculosis (NIRT), Chennai

A.1.9 ICMR National Institute of Epidemiology (NIE), Chennai

A.1.10 ICMR National institute of Pathology (NIP), New Delhi

A.1.11 ICMR National Institute of Medical Statistics (NIMS), New Delhi

A.1.12 ICMR National Institute of Malaria Research (NIMR), New Delhi

A.1.13 ICMR Regional Medical Research Centre, NE Region, Dibrugarh

A.1.14 ICMR Regional Medical Research Centre, Gorakhpur

A.1.15 ICMR National Animal Resource Facility for Biomedical Research (NARFBR), Hyderabad

A.1.16 ICMR National Institute of Nutrition (NIN), Hyderabad

A.1.17 ICMR National Institute of Research in Tribal Health (NIRTH), Jabalpur

A.1.18 ICMR National Institute for Implementation Research on Non-Communicable Diseases, Jodhpur

A.1.19 ICMR National Institute of Cholera and Enteric Diseases (NICED), Kolkata

A.1.20 ICMR National Institute of Immunohaematology (NIIH), Mumbai

A.1.21 ICMR National Institute for Research in Reproductive and Child Health, Mumbai

A.1.22 ICMR National Institute of Cancer Prevention and Research (NICPR), Noida - Uttar Pradesh

A.1.23 ICMR Rajendra Memorial Research Institute of Medical Sciences (RMRIMS), Patna

A.1.24 ICMR Regional Medical Research Centre, Port Blair

A.1.25 ICMR Vector Control Research Centre (VCRC), Puducherry

A.1.26 ICMR National AIDS Research Institute (NARI), Pune

A.1.27 ICMR National Institute of Virology (NIV), Pune

A.2 Centres

A.2.1 ICMR Regional Occupational Health Centre (Southern) – NIOH, Bengaluru

A.2.2 ICMR Centre for Research, Management & Control of Heamoglobinopathies – NIIH, New Chandrapur

A.2.3 ICMR Centre for Ageing & Mental Health, Kolkata

A.2.4 ICMR Centre for Research in Medical Entomology – VCRC, Madurai

Members of the Drafting Committee

- Dr. Anil Wali, FITT, IIT-Delhi, New Delhi
- Dr. Balram Bhargava, ICMR, New Delhi
- Dr. Deepankar Singh, DRDO, New Delhi
- Dr. K.P. Singh, DRDO, New Delhi
- Dr. K.S. Kardam, Indian Patent Office, New Delhi
- Dr. R Lakshminarayanan, ICMR, New Delhi
- Dr. Raj Hirwani, CSIR-URDIP, Pune
- Mr. R. Ramakrishnan, ICMR, New Delhi
- Mr. Rajeev Roy, ICMR, New Delhi
- Dr. Sadhana Srivastava, ICMR, New Delhi
- Dr. Samiran Panda, ICMR, New Delhi
- Dr. Shiv Kumar, DRDO, New Delhi
- Dr. Suchita Markan, ICMR, New Delhi (Member Secretary)
- Dr. T. Velpandian, AIIMS, New Delhi
- Mr. Jagdish Rajesh, ICMR, New Delhi
- Ms. Sugandhika Mehta, ICMR, New Delhi
- Ms. Varsha Padhi, ICMR, New Delhi