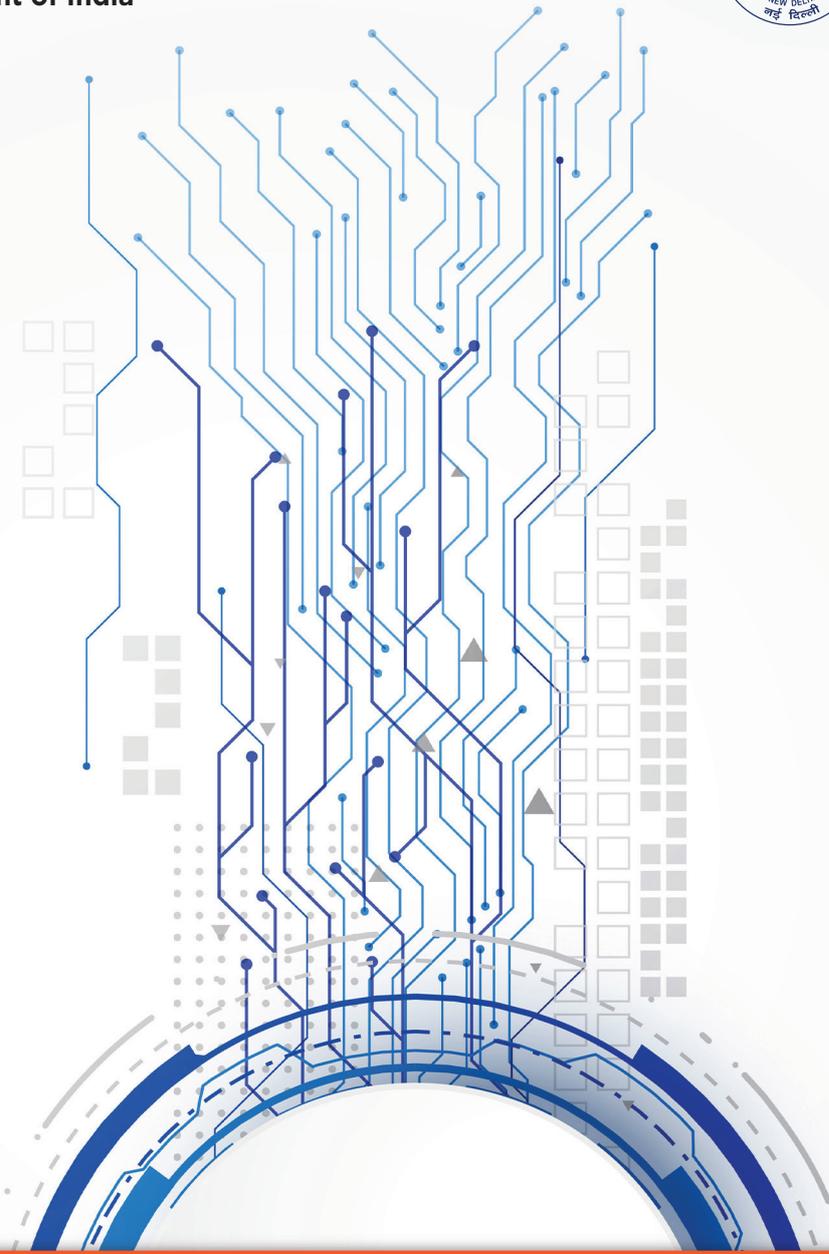




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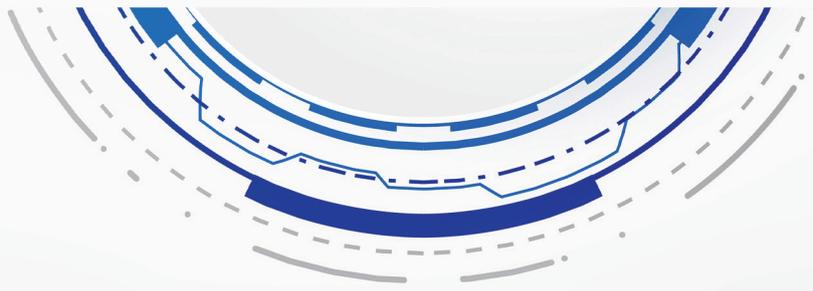


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**ICMR-DHR POLICY**  
**ON BIOMEDICAL INNOVATION & ENTREPRENEURSHIP**

For Medical Professionals, Scientists and Technologists at  
Medical, Dental, Para-Medical Institutes/Colleges



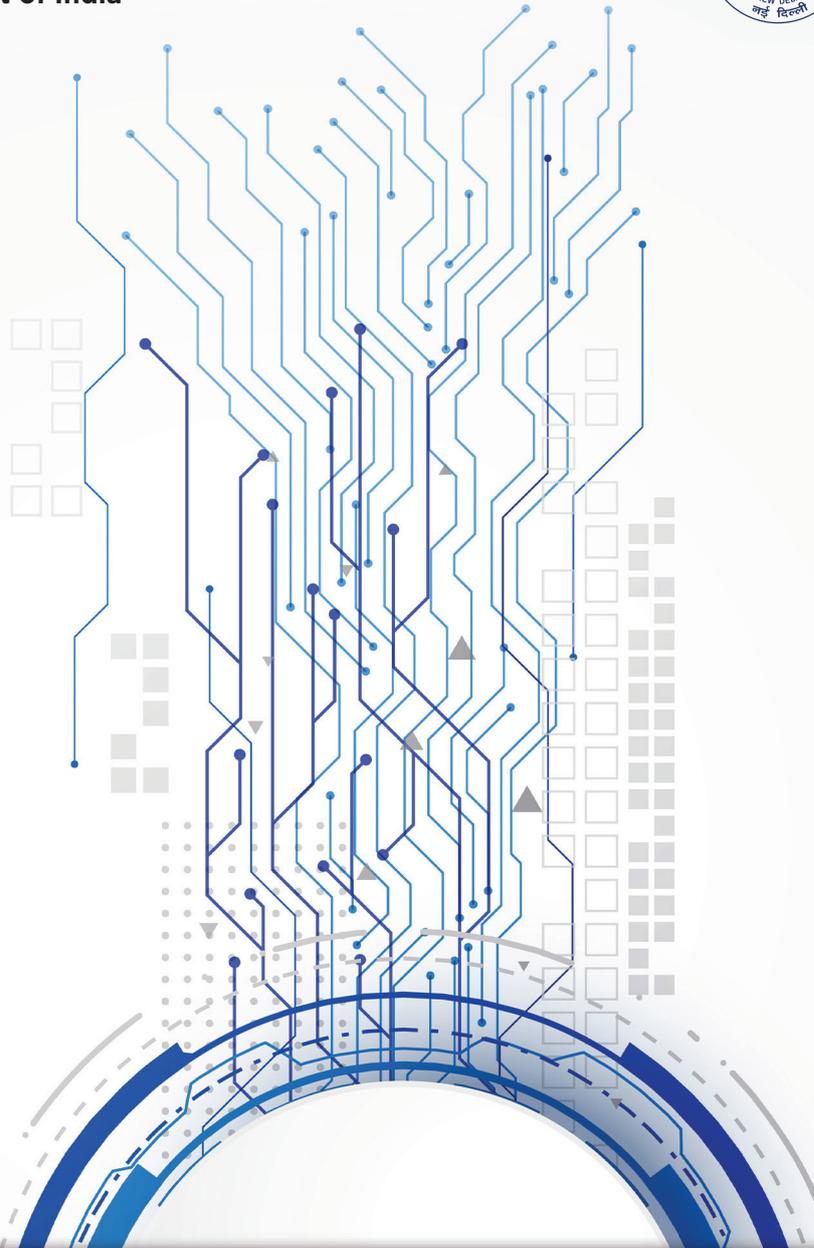




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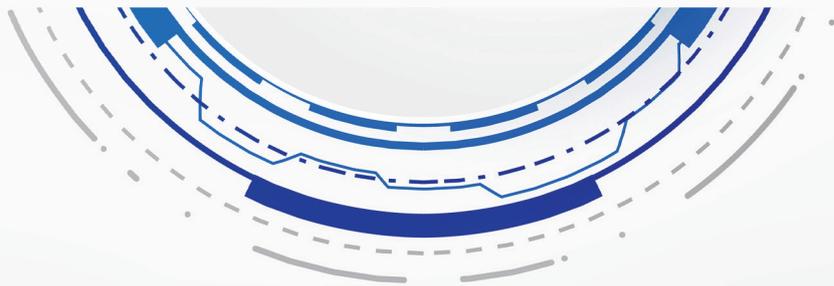


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स्वास्थ्य एवं परिवार कल्याण  
व रसायन एवं उर्वरक मंत्री  
भारत सरकार

Minister for Health & Family Welfare  
and Chemicals & Fertilizers  
Government of India



### MESSAGE

Innovation and Entrepreneurship are the key components for transforming healthcare system in India. Biomedical researchers have immense potential in terms of talent, knowledge, and skills. They play a vital role in identification of unmet needs of healthcare sector, their successful validation and translation into products of public health importance.

With an aim to promote innovation and entrepreneurship at Medical, Dental, Para-Medical Institutes and allied Biomedical Research and Academic Institutions, the Indian Council of Medical Research (ICMR, Department of Health Research (DHR), has brought out National Policy Guidelines on Biomedical Innovation and Entrepreneurship. I hope these will be useful for all the stakeholders and will ensure multi-disciplinary collaboration, promote start-up culture and develop an innovation led ecosystem at the medical institutes across the country. I urge the various stakeholders to make all efforts to ensure that this policy is implemented in true spirit in the country.

This policy document is envisaged to promote *Make-in-India*, *Start-Up-India* and *AtmanirbharBharat* initiatives of the Government of India. I hope that the Make-in-India products developed by inter-disciplinary group of doctors, biomedical innovators and engineers by adoption of this policy will benefit the poor and vulnerable groups in the country and help in furtherance of sustainable development goals.

I convey my appreciation for bringing out this very important policy document.

(Dr. Mansukh Mandaviya)





डॉ. भारती प्रविण पवार  
Dr. Bharati Pravin Pawar



स्वास्थ्य एवं परिवार कल्याण राज्य मंत्री  
भारत सरकार

MINISTER OF STATE FOR  
HEALTH & FAMILY WELFARE  
GOVERNMENT OF INDIA



#### MESSAGE

In Biomedical research, clinicians, medical professionals and scientists play a key role in the innovation cycle. Though the innovations from the medical, dental, para-medical institutes may hold the potential for their translation to socially relevant products, for a successful commercialization, a medical institute needs inputs from diverse areas of expertise. Therefore, there is a necessity to develop a suitable mechanism for promoting biomedical innovation and entrepreneurship in Medical Institutes to foster development of unmet need driven, socially impactful technologies for societal benefit.

The Government of India, under the visionary leadership of Hon'ble Prime Minister Shri Narendra Modi ji, is committed to meet the health needs of the people of India and this initiative of Indian Council of Medical Research (ICMR)-Department of Health Research (DHR), Ministry of Health and Family Welfare will foster biomedical innovation and entrepreneurship in India especially for providing cultural ecosystem is a welcome step. It will support, invigorate, accelerate, and motivate the culture around innovation, creativity and entrepreneurship in medical professionals and medical institutes.

It gives me immense pleasure to know that this Policy will catalyse the biomedical innovation and entrepreneurship in the country leading to the Make-in-India product development for an under Aatmanirbhar Bharat campaign, the vision of new India envisaged by the Hon'ble Prime Minister Shri Narendra Modi.

I wish to convey the bio-innovators a huge success.

(Dr. Bharati Pravin Pawar)

“दो गज की दूरी, मास्क है जरूरी”





सत्यमेव जयते

**प्रोफेसर (डा.) बलराम भार्गव**, पदम श्री

एमडी, डीएम, एफआरसीपी (जी.), एफआरसीपी (ई.), एफएसीसी,  
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**सचिव, भारत सरकार**

स्वास्थ्य अनुसंधान विभाग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं

**महानिदेशक, आई सी एम आर**

**Prof. (Dr.) Balram Bhargava**, Padma Shri

MD, DM, FRCP (Glasg.), FRCP (Edin.),  
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**Secretary to the Government of India**

Department of Health Research

Ministry of Health & Family Welfare &

**Director-General, ICMR**



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स्वास्थ्य अनुसंधान विभाग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

भारत सरकार

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**Indian Council of Medical Research**

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Ministry of Health & Family Welfare

Government of India

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New Delhi - 110 029

## MESSAGE

The world is changing at a fast pace with a growing recognition of the important role of innovation and academic entrepreneurship for Medical Professionals, Scientists and Technologists at Medical Colleges/ Hospitals/ Institutes. With 605 Medical Colleges/Institutes and nearly 1 lakh doctors graduating annually in the country, Indian Council of Medical Research (ICMR) as the apex medical research institution realized that there is a need to strongly promote healthcare innovation and entrepreneurship at Medical, Dental, Para-Medical Institutes/Colleges and allied Biomedical Research and Academic Institutions by creating a sustainable innovation ecosystem in the country as the healthcare innovations and entrepreneurship is making forays in the Indian economy.

A critical ingredient of a successful and sustainable innovation ecosystem is to explore opportunities for collaboration among the medical professionals, healthcare organizations, academia, government and industry. With immense knowledge and exposure to the unmet healthcare needs, Medical Professionals, Scientists and technologists should be at the forefront of biomedical innovation.

The policy will enable medical institutions to actively support their personnel in contributing towards the innovation and entrepreneurial ventures with the ultimate goal of positively impacting human-health & well-being. It resonates with the motto of our Hon'ble Prime Minister to "Innovate, Patent, Produce and Prosper" by promoting *Make-in-India*, *Start-Up-India* and *Atmanirbhar Bharat* initiatives of the Government of India.

This policy is forward looking and is based on experiential learnings. Each expert deserves appreciation for their dedicated comments/ suggestions, revision and efforts towards successful completion of this policy document. I am confident that the Policy guidelines will spur the culture of innovation and entrepreneurship in the country for a wider societal impact.

I wish the bio-innovators & entrepreneurs a huge success!!

(Balram Bhargava)



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## ABBREVIATIONS

<b>AI</b>	Artificial Intelligence
<b>AIM</b>	Atal Innovation Mission
<b>BIRAC</b>	Biotechnology Industry Research Assistance Council
<b>CfHE</b>	Center for Healthcare Entrepreneurship, IIT Hyderabad
<b>COI</b>	Conflict of Interest
<b>DBT</b>	Department of Biotechnology
<b>DHR</b>	Department of Health Research
<b>DPIIT</b>	Department for Promotion of Industry and Internal Trade
<b>DST</b>	Department of Science and Technology
<b>EC</b>	Ethics Committee
<b>FITT</b>	Foundation for Innovation and Technology Transfer, IIT Delhi
<b>HTIC</b>	Healthcare Technology Innovation Centre, IIT Madras
<b>ICMR</b>	Indian Council of Medical Research
<b>IP</b>	Intellectual Property
<b>IPR</b>	Intellectual Property Rights
<b>MoU</b>	Memorandum of Understanding
<b>ML</b>	Machine Learning
<b>MoHFW</b>	Ministry of Health and Family Welfare
<b>OLIVE</b>	Office of Licensing of Innovation Ventures & Enterprise
<b>PPP</b>	Public-Private-Partnership
<b>SIB</b>	School of International Biodesign
<b>SOP</b>	Standard Operating Procedures
<b>SINE</b>	Society for Innovation and Entrepreneurship, IIT Bombay
<b>SIPP</b>	Start-ups Intellectual Property Protection



## ABOUT ICMR & DHR

Department of Health Research (DHR) was created as a separate Department under the Ministry of Health & Family Welfare on 17th Sept'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 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. The 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 the network of its institutes/centres and extramural research support system 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 innovation and entrepreneurship. ICMR endeavours to encourage and promote new intellectual property development, technology transfer, start-up creation by medical, dental, para medical professionals and scientists at medical, dental, para-medical colleges/institutes and biomedical research institutions in the country for a huge societal impact.







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# POLICY DOCUMENT





## INTRODUCTION

Over the last decade, there has been a growing recognition of the important role of innovation driven academic entrepreneurship at national, state and institutional policy-making levels. This is especially true for academic medical and research institutions funded by public, private, or by not-for-profit sector. This is to be enabled through a cohesive ecosystem that fosters cross-functional, multi-pronged partnerships amongst medical and biomedical research, clinical medicine, private industry and the not-for-profit sectors. As required, technological institutions may have a key role to play in this ecosystem. Fostering such innovations will lead to innovation-driven growth, sustainable employment creation and equitable economic development.

Several important initiatives have been taken by the Government at the national, state and institutional levels that focus on supporting inventions, innovations, entrepreneurship and start-ups in higher educational institutions. e.g. Start-up India, Atal Innovation Mission (AIM), Scheme for Facilitating Start-ups Intellectual Property Protection (SIPP) by DPIIT etc and Several innovation driven programs/ Centres have also been set-up to foster biomedical innovations e.g. Foundation

for Innovation and Technology Transfer (FITT) at IIT Delhi, School of International Biodesign (SIB) at AIIMS, New Delhi and IIT Delhi (supported by DBT), Healthcare Technology Innovation Centre (HTIC) at IIT Madras (Supported by DBT), Center for Healthcare Entrepreneurship (CfHE) at IIT Hyderabad, Society for Innovation and Entrepreneurship (SINE) at IIT Mumbai and so on. These initiatives have already started bearing fruits as demonstrated by the commercialisation of socially impactful innovations. Several policies of Government of India and its agencies continue to promote involvement of faculty at educational institutions towards entrepreneurship related activities.

Most appropriate solutions with strong clinical impact leading to sizable return on investment are expected to emerge out of Indian healthcare system. Innovations from the sectors “Outside” to the core sector enabling the convergence of medicine, pharmaceutical, biotechnology, quantitative science, engineering, design, and social sciences may hold the potential for their translation to commercialization. A successful commercialization of an academic research is the key for its social impact, however, this translation into clinical impact cannot be fulfilled by the

academic institutes alone. To accomplish this, an institute needs help from diverse areas of expertise. Therefore, necessity to develop a suitable mechanism through policy intervention for promoting interdisciplinary research is of paramount importance in the current context.

In biomedical research leading to IP and thus entrepreneurship, clinicians/ scientists play a key role for success as they possess deep and meaningful involvement throughout the innovation cycle. Their role is vital not only in the identification of unmet needs but also to position and support the innovation during various stages of its development. Involvement of the biomedical researchers including clinical scientists into entrepreneurship activities is essential because of the following reasons:

#### **1. In-depth awareness of unmet needs:**

Academic clinicians in India treat thousands of patients every month. This gives them an unmatched grasp over what is causing the most unmitigated suffering and the extent of problem for identifying the unmet needs to be addressed.

#### **2. Familiarity with the state-of-the-art technology and the gaps:**

Being abreast with global trends in medicine and medical technology, academic clinicians are well aware of what solutions are available and what are the precise gaps that need to be filled.

#### **3. Ownership of flow of care:**

Clinicians own the flow of care and know it inside out. Therefore, they can reasonably predict what will work and

what won't work - from a flow-of-care perspective.

#### **4. Awareness of and influence over current expert consensus:**

Medical/dental/paramedical college faculty, by virtue of their experience and excellence are often the thought leaders in respective fields. They are aware of all current evidence and thinking in professional circles. Conversely, by virtue of their commitment to objectivity and knowledge of evidence-based medicine, they also wield considerable influence on contemporary professional thinking.

#### **5. Key opinion leaders and potential end users:**

Medical professionals are the Key Opinion Leaders (KOLs) and end users of the proposed inventions. Therefore, their deep involvement also builds credibility to the innovations/product(s) developed and validated, leading to their market penetration.

#### **6. Expertise in clinical validation:**

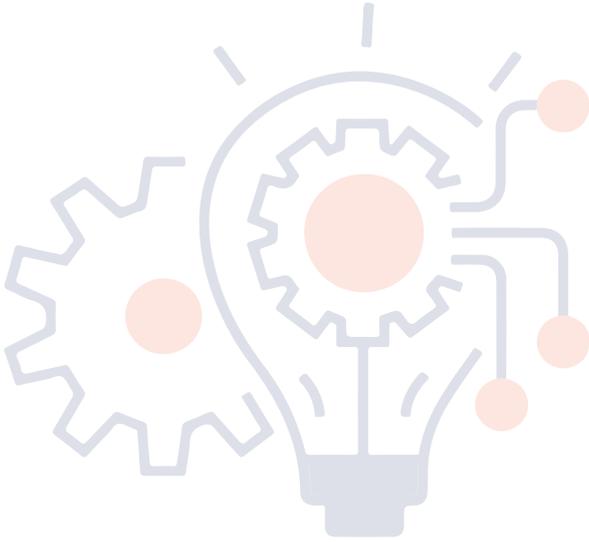
No medical innovation can be successful in the absence of strong clinical validation. The latter requires deep trust of the clinician in the innovation. When clinicians themselves are the innovators, such trust becomes natural, and required evidence becomes easier to adopt. In this scenario, medical college faculty is uniquely positioned given the large number of patients they treat.

#### **7. Long earned credibility:**

Any innovation originating within a respected medical institution is likely

to be more credible for the outside world compared to those coming from elsewhere – from a start-up for example. The ICMR/DHR Policy on Biomedical Innovation & Entrepreneurship aims to encourage innovation, entrepreneurship and creation of, or participation in, spin-

offs & start-ups by faculty members/scientists/staff members/trainees of academic medical institutions and publicly funded medical institutions based on innovative ideas and research output of the former.





## VISION, MISSION & OBJECTIVES

The Policy aims to promote biomedical innovations at medical, dental, para medical colleges/institutes, Biomedical research and academic institutions by faculty, scientists, residents, students, research scholars and technologist(s) as measured by socially impactful commercialization of these innovations. It is widely accepted that entrepreneurship is one of the most promising, if not the only medium through which meaningful medical innovations can be brought to patients who need them. There is therefore, a need to enable institutions to actively support their personnel to contribute in innovation and entrepreneurship associated activities. It is envisaged that every biomedical institute/college in the country will develop their own Intellectual Property (IP) policies for integrating innovation and entrepreneurship as part of their curriculum. Innovation and entrepreneurship are challenging journeys in their own way irrespective of the settings. Often times, employment with an academic-medical or allied institute tends to add further layers of complexity- making them all the more challenging. As long as institutional policies are designed to regulate and control entrepreneurial activities, rather than encourage and facilitate them, innovative output from biomedical academia may remain low. Keeping this in view, ICMR/DHR aim to motivate the Medical Institutes/

Colleges across the country to facilitate their personnel to innovate based on this Policy for Innovation and Entrepreneurship. The vision, mission statements and key objectives of the policy are as follows:

### Vision

To create an innovation-led entrepreneurial ecosystem in India with the ultimate goal of positively impacting human health and well-being.

### Mission

To formulate overarching policy for creating Nation-wide innovation & entrepreneurial framework at Medical Colleges/ Hospitals/ Biomedical Institutes for Societal Impact.

### Objectives

1. To encourage Medical, Paramedical, Dental Colleges and Biomedical Institutes to create enabling Policies and Ecosystem for promoting Innovation and Entrepreneurship development by its Faculty/ Students/Staff.
2. To promote Biomedical Innovations and Entrepreneurship by Medical Professionals, Scientists and Technologists to foster development of unmet need driven, socially impactful Technologies/ Products for societal benefit.



## SCOPE OF THE POLICY

The scope of this Policy is to cover all stages of the entrepreneurship continuum, in line with the existing National Policies specifically in view of the prevailing needs in the biomedical domain. The Policy has been drafted keeping in view the provisions under the DSIR OM No. 3/3/2009-TU/V/ Knowledge-to-equity dated May 25, 2009 for its effective adaptation in Medical, Dental, Para-medical colleges/institutes and other biomedical research and academic institutions [1]. Therefore, the scope of the Policy is to “promote, educate, and support trainees/ healthcare professionals for potential careers at the convergence of basic and translational research, healthcare-delivery, science, and emerging digital health technologies”. Additionally, this will foster development of career paths that incorporate new analytical or technological tools, including connected devices, behaviour change, and social media for young trainees and faculty.

This document covers innovation in all facets that impact the creation and functioning of the national healthcare system. This includes innovations in Public health delivery systems, Healthcare Business Model Innovations (including digital healthcare delivery systems) and category specific innovations such as those

pertaining to Pharmaceuticals (Drugs and Biosimilars), Nutraceuticals, Vaccines, Diagnostics and Medical Devices (including healthcare software systems and health and wellness mobile apps as medical devices) and inter-disciplinary innovations.

The health-tech start-ups in India can be broadly classified under 11 categories including diagnostics, medical devices, healthcare IT, online pharmacy, personal health management, home healthcare, telemedicine, fitness & wellness, biotech R&D, genomics and bio-pharma. Within India, start-ups are operating in one of these verticals and are using Artificial Intelligence or Machine Learning and other modern technologies to improve quality of healthcare, access and affordability. The scope of the policy is as follows:

1. The Policy is applicable to Medical/ Paramedical Colleges/Institutes, Biomedical Research and Academic Institutions;(Collectively referred to as Institutes and Institute singularly) and;
2. All Medical Professionals and Scientists at Medical, Dental, Paramedical Institutes/ Colleges and other Biomedical Research Institutions which includes: (i) Academic staff (professors, lecturers, assistant lecturers) (ii) Medical residents, Doctoral trainees

and research/ technical assistants (iii) paramedical staff (iv) incubator or support staff or (v) any other short term or long term trainee or employee of the said institutions who may be engaged in biomedical innovations, technology access and utilization,

entrepreneurship, health-tech start-ups/ spin-offs or related activities (Collectively referred to as Innovators and Innovator singularly).





## SALIENT FEATURES

Creating a true culture of innovation in an academic medical institution has been a challenge in the past due to the rigors of academic careers, milestones for faculty and institutions, and limitations arising from financial concerns or mistrust of developing partnerships with the Industry. However, innovation for many academic medical institutions is now becoming the fourth pillar of academic excellence. It is therefore imperative to develop a holistic ecosystem where academic surgeons/ physicians and trainees can be more effective innovators and translate their solutions for beneficial impact to the patients [2].

Institutions need to create or strengthen an institutional framework or structure to oversee, support and facilitate an innovation-led entrepreneurial ecosystem in India with the ultimate goal of positively impacting human health and well-being.

### 6.1. For the Institutes:

**6.1.1.** The Institutes shall establish a holistic innovation promoting system that (a) recognises what motivates each of the relevant stakeholders and (b) enables the stakeholders to receive the specific benefit they expect in exchange for their contribution to the innovation process. The framework shall incentivise participation, ensure due recognition to stakeholders

and establish well enunciated measurable incentives.

**6.1.2.** Investment in Research & Development and Entrepreneurship from private sector shall be encouraged through established Public- Private Partnership (PPP) process such as Collaboration/ contract research mechanism. The joint use of resources is considered as one of the main drivers of stakeholders to engage in public-private partnerships. Academic research can offer a high degree of disruptive innovation to diversify therapeutic research; vice versa the private industry can provide the technical, organisational, and financial means to scale-up early research & catalyse proof-of-concept to translational stage. The closer collaboration between government, academia, and the private research community shall enable more efficient use of complementary strengths in order to generate and deploy innovation for health.

**6.1.3.** The Institutes shall create an ecosystem for innovation including incubation centre and other initiatives for creation and transfer of knowledge. The incubator established at the Institutes shall be in the form of legal entity that will enable statutory registrations, access funding and facilitate free formation

of PPPs. The Institution shall conduct workshop/seminars on Intellectual Property Rights (IPR), grant writing, hackathons, prototyping workshops and Industry-Academia innovative practices. Awards for innovation won by Institution(s)/teachers/research scholars/trainees, start-ups incubated on-campus shall be explicitly commended by the Institution.

**6.1.4.** The Head of the Institute shall develop a suitable mechanism or a platform to utilise various schemes of the Government of India like Start up India, Start-Ups Intellectual Property Protection (SIPP) schemes by Department for Promotion of Industry and Internal Trade (DPIIT), Atal Innovation Mission (AIM), Skill India etc. implemented by various agencies. The Head of the institute shall endeavour to enable the faculty members to balance the academic and patient care responsibilities along with research and innovation activities. More importantly, acquiring Intellectual property rights, their successful translation and promoting entrepreneurship shall be given equitable weightage along with the academic and patient care responsibilities.

**6.1.5.** Institute shall improve utilisation of Government and Private Sector schemes that support greater, better and purposeful protection, use and leveraging of IP created by faculty, scientists, researchers and trainees in academic medical institutions and bio-medical research institutions in India. The process for grant application and grant utilisation shall be simplified and standardized.

**6.1.6.** The institute shall encourage and prioritise participation and involvement of its personnel in entrepreneurship and

enable formation of a legal entity at the institute, if required, in the following manner:

Company jointly owned by the faculty members, researchers, scientists, clinical innovators, trainees, and alumni (along with external partners).

Company owned by the faculty members (one or many) along with other entrepreneurs from outside the institute.

Section 8 company or other Society/Non-Profit Organisation jointly owned/managed by Government (Central, State or UT), Institute, faculty member(s), researcher(s), scientist(s), clinical innovator(s), trainee(s) and alumni and/or external partners.

Consortium/ Strategic collaborative research translation project to support a company, including a Section 8 company, or Non-Profit Organisation.

Special Purpose Vehicle such as an LLP, Trust, Society, etc jointly owned/managed by Government (Central, State or UT), institute, faculty member(s), researcher(s), scientist(s), clinical innovator(s), trainee(s) and alumni and/or external partners.

(Note: the term “Company” is being used hereinafter to denote any form of scaffold or entity created in any of the above manner in view of convenience in this Policy)

**6.1.7.** The Institutes shall be encouraged to create suitable mechanisms and also set-aside dedicated funds to reward their Faculty/Student/Staff Innovators.

**6.1.8.** The Institutes shall be encouraged to develop and implement inter-disciplinary course curriculum (for e.g. MD-PhD or ME-PhD or MBBS-MTech etc.) to foster inter-disciplinary innovations.

**6.1.9.** The Institutes shall be encouraged to create suitable policy and earmark funds for facilitating pre-clinical and clinical evaluation of Technologies/biomedical products.

**6.1.10. Institutes to set up Office of Licensing of Innovation Ventureships & Enterprise (OLIVE):**

Medical Colleges/universities/institutes shall be encouraged to set-up Office of Licensing of Innovation Ventureships & Enterprise (OLIVEs) to encourage medical professionals to learn, involve and take up entrepreneurship at the graduate and postgraduate level at the College(s) or institution(s). Workshops and symposiums shall be organized to make trainees and faculty aware of intellectual property rights, collaborative research, product development, funding opportunities and entrepreneurship development and their translation in their respective institutions. This shall enable various modalities required to adopt the conversion of knowledge to entrepreneurship. The OLIVE shall also engage suitable committees with internal and external members (from other incubators or technical institutions or industry having experience in entrepreneurship) to handle Intellectual Property Rights and their translation into entrepreneurship. The OLIVE or its incubated companies may avail funds through various funding mechanisms of Govt. of India (e.g. BIRAC, DST, Atal Innovation or from State entrepreneurship agencies) to establish and promote Incubators at their institutions to incubate innovative companies in-house for promoting entrepreneurship for the period of around 3 years from the date of establishment of

the said company. The OLIVE shall engage/hire external professionals (such as patent agents, chartered accountants, company secretary) or companies, on permanent or contractual basis to provide professional services to the innovative companies established at the OLIVE.

Alternatively, OLIVE may also engage another registered incubator through MOU's to provide support towards IPR and techno-legal activities of the incubated companies.

OLIVE shall be able to provide business development and techno-legal expertise to support investigators' ability to execute partnerships (in-house/outsourcing/empanelment).

The usage of space and facilities of incubator facility (if any) at the Institutes by the faculty owned company may be paid as per existing incubator norms.

The OLIVE shall provide services of chartered accountants/company secretary, patent agent, attorney and other professional services to the company free of cost or at discounted rates for the period of first three years and shall host funding sessions within the Institute's premises for the company.

The OLIVE may hold liability free equity/stakes of ~2-10% in the company for a period of ten years. Against this equity, the Institutes can allow the use of IP developed within the medical institute by the founding faculty members and trainees and provide through the OLIVE, professional services regarding IP, Techno-legal etc. free of cost or at discounted rates for the period of first three years to the Company. If the Company owned by the faculty is incubated at the

institute's incubator, the equity/ stakes against Incubation will be held as per the Incubators Policy of the institute.

All the employees of Government institutions may have the option to apply directly via *OLIVE* for any patenting procedures rather than having the option to only go through the institute's patent office.

**6.1.11.** Till the establishment of *OLIVE*, or alternatively the Institute may take 2-10% (not more than 10 %) equity/ stakes in the company based upon the support provided, brand use and use of institute's IPR. In case, the institute does not have in its rules the ability of taking equity in the company, then the company may pay the equivalent sum to the institute as Royalty. If IP is generated from extramural funded projects (e.g. DST/DBT/ SERB/ ICMR etc), it may be dealt in accordance with the rules of the funding agency.

**6.1.12.** Any patents/copyrights/ trademark/ industrial design etc. filed by the company may continue to be the intellectual property of the company [3]. It is expected that the Institute may license the IP rights for the technology developed within the Institute to the company formed by its Student/Faculty at inventor friendly terms. The involved faculty member(s) and trainee(s) may sign such an agreement with the institute. The company may utilize the testing facilities of the institute as per the institute's prevailing norms. During the incubation period, within the institute premises, the company may be permitted to use the common laboratory facilities (which is free of charge), library and other facilities which are reasonably chargeable (as per the Institute norms). The available

provisions under Government of India programs can be used to set-up Incubators at their respective campus. However, utilization of lab facilities/ resources may be subject to its availability. Priority may be granted to intramural funded projects of the institute. The utilization norms or the applicable charges, if any, may be subject to norms of the concerned department/ common guidelines of the Institute as and when it deems it is required. In case institute facilities are not used for the purposes of IP creation or start-up generation, a separate agreement may be signed between the faculty member and the institute.

**6.1.13. Duration:** The start-up company established by the faculty or staff of the institute may be allowed to operate up to the duration of ~ 3 years within the Institute. After 3 years, it may be spinned-off from the *OLIVE* premises. However, the faculty may be allowed to maintain equity in the company functioning outside the premises also. An extension beyond the initial housing period (further up to three years) may be granted to the company upon request to the *OLIVE*, based on the merits of the business opportunity it holds.

**6.1.14. Impact Assessment:** Faculty's entrepreneurial initiatives maybe assessed regularly using well defined assessment parameters:

Monitoring and evaluation of IP(s) filed, technologies licensed or commercialised, products developed by the faculty maybe assessed.

Number of employments generated, start-ups created, support system provided at the institutional level and satisfaction of participants, new business relationships created by the institutes maybe recorded

and used for impact assessment.

Impact assessment may also include the support system provided by the medical institute to the faculty member, trainee and other staff for IPR protection, technology incubation, industrial collaboration, exposure to entrepreneurial eco-system etc.

The impact assessment may also include sustainable social, financial and technological impact parameters, as may be identified by the Institute(s). For the technologies which are at pre-commercial stage, development of sustainable enterprise model is critical. Commercial success is the best measure for long term assessment.

## 6.2 For the Innovator(s):

(Subject to Institutional policy)

- i. Role of Faculty Member/ Researchers/ Trainees as Innovators may differ from being an owner/ direct promoter, advisor, consultant or as member of the start-up. It is expected that the innovator Faculty/ Researcher(s)/ Trainee(s) would be owners /shareholders of the company/ start-up/ spin-off and may hold the position of a Non-Executive Director on Board while simultaneously working as faculty/ researcher/ trainees. Also, the Faculty Member(s) / Researcher(s)/ Trainee(s) may opt for an operational/ full time role (Scientific Advisor, Consultant, CEO, On-board Executive Director/ member etc) in the company only after taking sabbatical from the institute. The Faculty Member/ Researcher(s)/ Trainee(s) may choose one of the following options as may be applicable:
  - ii. He/ She may opt for sabbatical and work full-time in the company. He/ She may avail maximum leave (as sabbatical/ casual leave/unpaid leave/ earned leave) of one semester per year which may be permitted to the faculty member/ Innovator. This may be extended based upon the decision of the review committee constituted by the institute. The maximum period of 2 years at a stretch may be permitted.
  - iii. He/ She may dedicate a part or all of the days for consultancy work in the company start-up/ spin-off. However, under no circumstance the total number of days of non-institutional activities would exceed the institution's norms.
  - iv. The Innovator may act as a licensor to the business, whereby the business pays a recurring licensing fee/ royalty/ any other form of benefit sharing to the Faculty/ Researcher(s)/ Trainee(s) for the intellectual property created by the Faculty/ Researcher(s)/ Trainee(s) for the business.
  - v. The Innovator shall ensure that his/her duties and responsibilities conform to his/her institution's policy regarding conflict of interest and commitment. This may, amongst other things, ensure that the balance of time spent by Faculty/ Researcher(s)/ Trainee(s) amongst his/ her diverse duties and responsibilities conforms to his/her institution's policy regarding conflict of commitment.
  - vi. The Innovators may undertake projects (Public or Private funded) that could be conducted at the medical institute/ college, and managed through their companies. However, the institute's

overhead charges shall be duly paid as per the applicable norms and standards of the institution concerned.

- vii. The Innovator may spend up to 20% of their allocated time on research linking entrepreneurship. The equity of up to 20%/ similar proportion of stake may be taken by the research team of the institute. If the equity is being taken by faculty (research teams)- the time of faculty may be considered to be 'off-duty/leave without pay'. If the equity is being transferred to the research institute, the research time of up to 20% may be taken as on duty (in line with the substantial interest of Tax Law).
- viii. The Bank account of the innovation-driven spin-off or start-up maybe kept separate and maybe audited from time-to-time, by a certified chartered accountant.
- ix. Any honorarium/overhead obtained as a result of consultant for engaging in a company-in incubator or sponsored project of an innovation will be considered as income and the percentage of income bifurcation needs to be made as an institute/college share and consultant share for such remunerations.
- x. Financial, non-financial disclosure, collaborative research and any other necessary agreements need to be signed as per the existing institute norms and standards of practice. In case the faculty is involved in a clinical validation of bio-medical research and innovation in start-up, prior ethics committee (EC) approval may be obtained from the institute. Any scientific presentation coming out of such initiative may have

the clear disclosure about the faculty's financial interest in such innovations.

- xi. Any financial assistance (in form of salary, honorarium, or consultancy or licensing fee) paid to the founding members of the company may be considered entirely as income of the involved faculty members during the incubation period within the campus. Once the company moves out of the institute, the faculty member may be permitted to take sabbatical and work with the company as per the existing rules of the institute. He/she may also receive financial assistance in the form of consultancy fee as per the applicable rules of the institute.

#### **6.2.1. Outsourcing of sponsored research/ consultancy assignment:**

In case transfer of equity is being done through empanelled techno-legal facilitator agencies, the provisions of this section may be referred to. The techno-commercial facilitators (such as Kalam Institute of Health Technology, FITT, Sree Chitra Tirunal Institute for Medical Sciences and Technology- Technology Business Incubator for Medical Devices and Biomaterials SCTIMST-TIMed under DST, Atal incubators under NITI Aayog, Technology Transfer Office (TTO) under DBT-BIRAC, Bio-Nest centres under DBT, etc.) may be allowed to take up to 2% equity for their role. Outsourcing of institute's projects (part or full) to faculty owned company, if permissible, would be governed by institutes existing policy. In absence of such policy framework, the outsourcing decision would be undertaken on a case-to-case basis by a committee comprising Director of the medical institute,

Head of the concerned department and a representative from sponsoring agency. The existing policies prevailing in other institutes like IITs may be taken as a guide while taking such decisions.



## INTELLECTUAL PROPERTY

The Intellectual Property (IP) ownership, IP Licencing and Revenue sharing to be laid down by the Institute may be as per the provisions laid down under Annexure-I.



## TAXATION OF INNOVATION, ENTREPRENEURSHIP AND START-UPS

The tax applicability shall be as per the provisions of Taxation of Innovation, Entrepreneurship and Start-ups placed at Annexure-II.



## CONFLICT OF INTEREST AND ITS RESOLUTION

It is imperative for the faculty member to disclose development of a Conflict-of-Interest (COI) Management Plan to clarify allowable research activities and to ensure that such activities occur within the boundaries of institutional policy and applicable laws. The faculty member may always operate from the principle that the primary duties and obligations towards his/her institute are supreme.

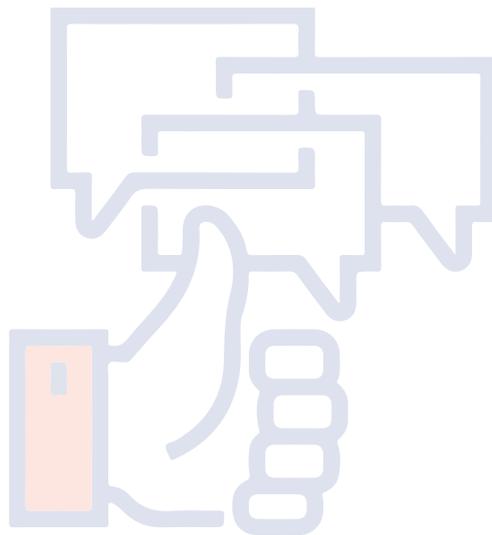
- i. The innovator shall inform and take prior permission from the Institute before starting any Company or associating with any enterprise, and shall abide by the consideration decided by the Institute.
- ii. The Innovator shall not influence a departmental decision for acquisition of laboratory and/or equipment which could benefit the Company and/or any associated enterprise.
- iii. The Innovator shall not circumvent the prevailing policies for making use of institute's facilities for the benefit of the Company and/or any associated enterprise.
- iv. The Innovator shall comply with the different provisions & Government rules & regulations.
- v. Internal complaint redressal mechanisms shall be adopted by the Institute for resolving any Conflict of Interest. If case any conflicts arises when trainee(s)/ postdoctoral fellow(s)/ resident doctor(s) supervised by the faculty member who are working on a research project sponsored by that faculty's start-up company or due to other entrepreneurial endeavours, an ombudsman/ independent committee may be appointed to deal with such conflicts/complaints.
- vi. In case of any disputes which are not settled within the independent committee, the matter may be taken for arbitration/ conciliation as a dispute resolution mechanism as per the Arbitration and Conciliation Act 1996 amended as on date.



## **POLICY REVIEW MECHANISM**

ICMR-DHR will formulate a standing sub-committee to review the policy periodically or as per need to address the challenges faced in its implementation. ICMR-DHR shall also undertake in a consultative

manner an evidence based review to the extent possible of this policy document once in every two-year period or as per requirements and update the policy periodically.





Department of Health Research  
Ministry of Health and family Welfare  
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# ANNEXURE





## Annexure-I

### Intellectual Property

The role of Intellectual Property protection and ownership is to prevent an invention from being replicated, created, used and sold by another party without permission and thus promote successful commercialization of innovations. We encourage all academic medical, technical and biomedical research institutions to develop and implement IP policies that are innovation/innovator friendly, consistent with national goals and institutional mandates resources and governance structures. Needless to mention, where required, the necessary funding and procedural framework will need to be created along with such IP policies.

Implementation of the Policy will enable Institutes to acquire a portion of the recurring revenue stream from commercialization of an invention, which in turn can help make the intra-mural innovation process of the institute self-sustaining. The above would require putting in place effective techno-legal-administrative framework in place to complete the circuit from institutional ownership of IP to licensing it, realizing royalty on it and then re-investing the collected royalty into further innovations.

With the above background, the Institutes with existing IP policies may refer to this Policy while revising their existing policies

and Institutes which do not have an IP Policy are encouraged to refer to this documents while drafting their IP policy. Institutes shall practice the following regarding ownership and management of IP pertaining to medical technology innovations at academic, technical and biomedical research institutions (hereinafter collectively referred to as “institutions” for the ease of reference.

**The following broad framework is recommended:**

- 1. National IP Policy:** The National IPR Policy [4] and National Innovation and Startup policy [5] shall be the guiding force based on which the Institutes may formulate their own IP Policy. Institutes should have a comprehensive IP policy: describing in detail pertinent questions pertaining to ownership and protection of IP and laying down standard operating procedures for creation, management, protection, licensing and monetization of IP.
- 2. Institutions with existing IP Policies:**
  - i. Institutes with existing IP Policies may continue to follow the same policy with refinements from time-to-time as necessary. All institutions shall have a comprehensive IP policy describing in detail pertinent questions pertaining

to ownership and protection of IP and laying down standard operating procedures for creation, management, protection, licensing and monetization of IP. Institutions are encouraged to make these policies more and more innovator and innovation friendly, and consistent with the relevant national goals. The goal of an institutional IP policy shall be to promote innovation and facilitate its rapid, successful and scalable translation to societal impact.

- ii. Institutions shall have a duly constituted IP and Technology Transfer Committee. A person designated as point of contact for all IP related matters shall be identified by the Committee and/or the Institute. To expedite IP related decisions, a single person in-charge may be made responsible for all decision making with support from the committee and to take rational case-by-case decisions on IP related matters.
- iii. The technical communications may be directly transmitted by Innovator to the point of contact/ Committee and such innovation related technical communications between Innovator and the point of contact/ Committee may be treated as highly “Confidential Information”
- iv. Institutions may try to have a pool of funds dedicated for the management of IP/ Technology Transfer activation.
- v. Institutions may have a mechanism to receive royalty and licensing fees from IP licensee(s) (including sub-licensees) and other entities such as industry and corporate.
- vi. Whenever an institutional affiliate writes

to the IP committee with a question or request regarding IP ownership or management, the committee may respond with a decision in no more than 30 days.

- vii. All institutions may have a mechanism to allow collaboration with industrial partners for development and validation of novel medical technologies, provided that the said technologies have been rigorously evaluated and found fit for further work. ICMR guidelines for ethical biomedical research [6] may be referred for the same along with applicable laws as per the requirements of the Government of India.

### **3. Institutions which do not have an IP policy**

Institutions that do not have an IP and Technology Transfer policy and SOP, IP & Technology Transfer committee, Point of contact, IP fund, and royalty receipt and licensing mechanisms may establish each of these in place. The IP Policy document may be made readily available to all institutional affiliates. Institutions seeking to develop new IP policies, may include:

#### **3.1 Inventorship**

All participating faculty, trainees or personnel who have contributed significantly to the conceptualization of IP maybe named as inventors and maybe given a share in the proceeds of commercialization of the IP. If there are multiple inventors, the distribution of the percentage of royalty proceeds shall be decided by the Chief inventor and an agreement shall be made with mutual consent of all inventors.

#### **3.2 IP Ownership**

3.2.1 If there is an express provision of the

extra-mural funding agency, then IP may be owned by the extra-mural funding agency that funded the research and development that led to the generation of IP.

3.2.2 If the funding agency does not have ownership condition, then IP may be owned by the institute under following circumstances:

- i. Any IP that has been generated by the employee(s)/Consultant(s)/student(s) of the Institute within the scope of employment or engagement.
- ii. Research and development leading to the generation of the said IP that has made significant (more than incidental) use of institutional resources.
- iii. When the institute has sufficient and appropriate resources, know-how, processes to adequately protect and manage the IP across the necessary geographies.
- iv. When the innovator does not have well defined procedures for IP filing, IP licensing and/ or commercializing the same for societal impact.
- v. In-case the IP rights are transferred to the innovator and he/she fails to commercialize the technology/product within a given time period, the IP rights may be transferred back to the institute for licensing/ commercialization of the technology for societal impact.

3.2.3 IP shall be owned by the inventor when one or more of the following conditions are met:

Research and development leading to the generation of said IP has made only minimal (no more than incidental) use of institutional resources.

When the institute does not have sufficient interest in owning protecting and managing the said IP.

When the inventor(s) have adequately demonstrated to the IP committee/ corresponding authority at the institute that they are adequately equipped and committed to properly protecting and diligently commercializing the said IP.

### 3.3 IP Licensing

The institute may, through concerted efforts render itself well equipped to own and manage the IP. However, the end goal of protecting and managing IP is to commercialize the technology to create large scale societal impact. For this, the institute may seek to license the IP to a suitable entity, including a company formed by its faculty/student. The institutional employee/ affiliate/ student who has invented the IP shall have the right of first refusal for receiving a license to the IP. Such license may be given to them individually, collectively or to a company co-founded by them. IP Licensing shall also include sub-licensing provisions.

### 3.4 Revenue Sharing

The IP Licensing Agreement executed with a company or a legal entity or with the institutional employee/ affiliate, company may have suitable provisions regarding equity or royalty sharing on successful commercialization. A reasonable part of such revenue may be pooled back by the company to the institute(s), as per Institute's IP Policy.



## Annexure-II

### Taxation of Innovation, Entrepreneurship and Start-ups

The statutory provisions related to tax applicability for legal entities, royalty, fee proceeds, income etc as notified by Government from time to time will prevail for all legal purposes. However, the following guidance is to create necessary awareness of the related aspects;

#### 1.1) Eligibility for Start-up India:

As per the Start-up India Action plan, the following conditions may be fulfilled, in order to be eligible as Start-up:

- i. Being incorporated or registered in India for less than seven years and for biotechnology start-ups up to 10 years from its date of incorporation.
- ii. Annual turnover not exceeding Rs 25 Cr in any of the preceding financial years.
- iii. Aims to work towards innovation, development, deployment or commercialization of new products, processes or services driven by technology or intellectual property.
- iv. It is not formed by splitting-up or reconstruction of a business already in existence.

- v. It may obtain certification from the Inter-Ministerial Board setup for such a purpose.
- vi. It can be incorporated as a private limited company, registered partnership firm or a limited liability partnership.

Tax exemptions allowed to Eligible Start-ups under Start-up India Program

#### Following tax exemptions have been allowed to eligible start-ups:

1-3 year tax holiday in a block of seven years

The Start-up incorporated after April 1, 2016, is eligible for getting 100% tax rebate on profit for a period of three years in a block of seven years provided that annual turnover does not exceed Rs 25 Cr. in any financial year. This will help the start-ups to meet their working capital requirements during their initial years of operation.

(The Start-ups incorporated between 1st April, 2016, till 31st March 2021 were eligible for this scheme. Budget 2021 has extended the eligibility to 1st March 2022. The company shall be liable for Tax exemption as per Start-up India Policy).

### **1.2) Exemption from tax on Long-term capital gains:**

A new section 54 EE has been inserted in the Income Tax Act for the eligible start-ups to exempt their tax on a long-term capital gain if such a long-term capital gain or a part thereof is invested in a fund notified by Central Government within a period of six months from the date of transfer of the asset. The maximum amount that can be invested in the long-term specified asset is Rs 50 lakh. Such amount shall remain invested in the specified fund for a period of 3 years. If withdrawn before 3 years, then exemption will be revoked in the year in which money is withdrawn.

### **1.3) Tax exemption on investments above the fair market value:**

The government has exempted the tax being levied on investments above the fair market value in eligible start-ups. Such investments include investments made by resident angel investors, family or funds which are not registered as venture capital funds. Also, the investments made by incubators above fair market value are exempt.

### **1.4) Tax exemption to Individual/HUF on investment of long-term capital gain in equity shares of Eligible Start-ups u/s 54GB:**

The existing provisions u/s 54GB allows the exemption from tax on long-term capital gains on the sale of a residential property if such gains are invested in the small or

medium enterprises as defined under the Micro, Small and Medium Enterprises Act, 2006. But now this section has been amended to include exemption on capital gains invested in eligible start-ups also.

Thus, if an individual or HUF sells a residential property and invests the capital gains to subscribe the 50% or more equity shares of the eligible start-ups, then tax on long term capital will be exempted provided that such shares are not sold or transferred within 5 years from the date of its acquisition. The start-ups shall also use the amount invested to purchase assets and shall not transfer asset purchased within 5 years from the date of its purchase.

This exemption will boost the investment in eligible start-ups and will promote their growth and expansion.

### **1.5) Set off of carry forward losses and capital gains allowed in case of a change in Shareholding pattern:**

The carry forward of losses in respect of eligible start-ups may be allowed if at all the shareholders of such company who held shares carrying voting power on the last day of the year in which the loss was incurred continue to hold shares on the last day of previous year in which such loss is to be carry forward. The restriction of holding of 51 per cent of voting rights to be remaining unchanged u/s 79 has been relaxed in case of eligible start-ups. <https://www.startupindia.gov.in/content/sih/en/startup-scheme.html>.



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