

Intellectual Property Rights Policy (2022)

AIIMS, BHOPAL



अखिल भारतीय आयुर्विज्ञान संस्थान, भोपाल
All India Institute of Medical Sciences, Bhopal

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I. Introduction

With research and innovation being one of its key mandates, AIIMS Bhopal is committed to generate new knowledge and/or create innovation to address the unmet medical needs in the healthcare sector. India's healthcare industry is growing with an annual compounded rate of 22% for the past six years, primarily fueled by the Startups. With the government of India's initiatives such as "Make in India" and our ecosystem being the third largest in the world, it is the perfect time for the institute to contribute to this growing space of biomedical innovations. While the R&D activities of the institute have grown many folds over the years, and is reflected by high number of extramurally funded projects as well as high-quality research publication, the institute needs to make continued efforts in generating/owning intellectual property rights (IPRs). One potential reason for this is inability of many academics in navigating the complex world of IPR.

The purpose of the institute IPR Policy is to guide and motivate researchers in generating intellectual property and safeguarding the ownership of the same. The intended outcome of the IPR policy is to promote academic freedom; ensure responsible and ethical research; facilitate ownership of IP and technology transfer; streamline revenue sharing between the institute and inventors and create the relevant institutional infrastructure and administrative set-up for its effective implementation within the framework of relevant national and international policies for the benefit of the inventors, the institution and the nation, as a whole.

II. Why AIIMS Bhopal needs an institutional IPR policy?

Committed to fulfil the demand of patient care through innovation in medical technologies, AIIMS, Bhopal has already embarked its journey to become a significant player in healthcare innovation space. Researchers at the institute have been securing extramural grants from the various government funding agencies to discover disease biomarkers, conduct operational research and develop new model/technologies to understand and/or treat various disease. The quantum and the corpus of these extramurally funded grants are steadily growing. To further the aspiration of the Institute to be a leader in the healthcare research and innovation, a Translational Medicine Centre, one of its kind in the country, was started with the mandate of developing patentable products, technologies and devices.

Being a medical institute of national importance, AIIMS Bhopal is uniquely positioned to leverage the direct experience and exposure to medical problems, understanding of unmet medical needs and access to biological materials and clinical resources to thrive as a leader in the field of healthcare innovation. Framing

of an institutional IP policy and its implementation under the dedicated supervision of an authorized and well qualified institutional committee (IPR, Copyright & Technology Transfer Committee or IPRTT Committee) will help in guiding and facilitating the institute's researchers and innovators in navigating the detailed procedures and legal intricacies associated with the claiming and safeguarding of IP rights and complying with the relevant legal and procedural requirements.

III. Definitions

Academic freedom: The freedom of the academic staff of the Institute to conduct their own academic activities including teaching, training, basic and clinical research, and development. They should be free to choose their own research field, pursue self-initiated research, and collaborate with others to achieve excellence in and maintain high standards of research.

Applicable Law: Applicable Law in context means and shall include all applicable statutes, enactments, acts of legislature or parliament, laws, ordinances, rules, bye-laws, regulations, listing agreements, notifications, guidelines or policies of any jurisdiction and judicial, quasi-judicial, and/or administrative decisions, interpretations, directions, directives, licenses, permits, judgements, writs, injunctions, arbitral awards, decree, orders, terms and conditions or governmental or regulatory approvals or agreements with any governmental or regulatory authority, applicable in India..

Associated Agreement/Auxiliary Contracts: An Auxiliary Contract means a document created with mutual consent of involved parties defining the rights, roles and responsibilities of each of the parties, for example, Memorandum of Understanding (MOU), Memorandum of Agreement (MOA), Research Agreement, Consultancy Agreement, Non-Disclosure Agreement (NDA), Deed of Assignment, Material Transfer Agreement (MTA), License Agreement, Service Agreements, Confidentiality agreements, Research Contract, Grant Award Letter etc.

Collaborator: Collaborator refers to any Government, quasi-government, public enterprise, non-government or private entities which are involved with AIIMS Bhopal and its employees in the conduct of the research. The collaborator may or may not fund or part fund the study. The collaborator may be national or international entity.

Collaborative Projects: Collaborative Projects are completely or partially funded by the Collaborator and supplemented by provision of inputs from the institute such as laboratory facilities, research material,

human resource, etc. Collaborative Projects could be for upscaling/improving of laboratory level know-how, technology development or generation of IP, etc. The expected project output/results are well defined.

Conflict of Interest: A Conflict of Interest is any circumstance wherein genuine or anticipated interests of a Faculty Member, Research Scholar, Fellow, Supporting staff, Student or Visiting fellow might oppose the interests of the institute or contrarily influence their work or obligations.

Faculty members: Any person professionally qualified to carry out patient care, teaching, training, and/or research employed at AIIMS Bhopal either as a full-time employee or as Emeritus or Visiting professor.

The Institute: The institute refers to AIIMS Bhopal.

Individual Scholarships and Fellowships: No individual scholarship and fellowship tenable at the Institute will normally contain any provision giving the awarding agency any right to Intellectual Property created by the recipient. Intellectual property generated by recipients of such funding will be governed by the Auxiliary Contract between the sponsor of the project and the institute.

Institute Resource: Institute Resource means all facilities and equipment, specific funding, Intellectual Property already owned by the Institute, requisitioning the time and labor of students and Faculty Members through Institute's administrative channels, or at the Institute's expense, and remission by the Institute of any or all of the normal duties of Faculty Members or Students to provide time or resources for the purpose of generating IP.

Intellectual property (IP): Any intangible property, including but not limited to patent, copyrights, trade secret, trade mark, industrial design, utility models, design rights, IC layout designs, biotechnology inventions and plant variety as defined under the Copyright Act, 1957, the Patents Act, 1970, the Trademark Act 1999, the Designs Act, 2000, the Semiconductor Integrated Circuits Layout-Design Act, 2000, and the Protection of Plant Varieties and Farmers' Rights Act, 2001.

Inventor(s): A person or a group of persons responsible for creating intellectual property (IP).

IP Fund: IP Fund shall mean the fund generated out of revenue licensing fee and royalties in accordance with Section IX. The initial fund shall be generated through seed funding as decided by the institute.

Material Transfer Agreement (MTA): A Material Transfer Agreement is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes.

Non-Disclosure Agreement (NDA)/Confidentiality Agreement: Non-Disclosure Agreement /Confidentiality Agreement intends to protect proprietary or confidential information among the parties involved in executing an NDA.

Patentee: A patentee is a person who has been granted a patent.

Project Staff/Supporting Staff: A person employed temporarily on a contract under a research project in a defined capacity to support/carry out part of the research activity or any other activity at AIIMS Bhopal for a defined period of time.

Research Project: Research Project means any project that forms the basis of Research undertaken by the institute and includes projects undertaken by a Fellow, Student or under the supervision of a Faculty Member or a Research Scholar, as part of a research degree program.

Research Scholar: Any person working as a scientist/research fellow or enrolled in PhD program of the institute.

Revenue: Revenue refers to the amount derived from the technology transfer and commercialization of IP (by the inventor if commercialized by the inventor or by the institute if commercialized by AIIMS Bhopal), net of taxes, expenses (which may be carried forward from year to year to offset gross revenue) incurred in the IP protection, maintenance and commercialization, and includes, without limitation, proceeds from royalties, profit-sharing, lump sum payments, and sale of rights as applicable.

Scholarly Works: Scholarly Works include all copyright works which are the outputs of Faculty Members, Students, Research Scholars, Project staff/Supporting staff or Visiting Fellows including research, creative and other outputs in area(s) of his expertise or professional acumen. It does not include Course Materials.

Sponsor: Sponsor will refer to Government, quasi-government, nongovernment or private entity whether national or international which funds the research/study/survey conducted at AIIMS Bhopal.

Sponsored Projects: Sponsored Projects are the projects which are funded an external sponsor having specific research and development objectives, and having a specific expected outcome, generally resulting into the creation of Intellectual Property. These projects shall involve grant by way of financial inputs, either in full or in part, assistance in kind, e.g., equipment, human resources, training to supplement institute's effort in ongoing or new research & development projects or for creating new capabilities/facilities. Sponsored projects could be funded by multiple sponsors including individual, public/private entity, government organization.

Student: A person who has registered or enrolled as a full-time student, part-time student, or exchange student from other universities/colleges for professional and research training.

Substantial Use: Substantial Use shall include the extensive use of the Institute Resources which include but are not limited to facilities, equipment, human resources or funds and Background IP that is not publicly available. Routine use of libraries and/or office space is not included.

Visiting Fellow: A person either from India or abroad visiting under a collaborative activity or associated work at AIIMS Bhopal. It is expected that the visit has been approved by the competent authority of the Institute.

IV. The ambit of the institutional IPR policy

- **Researchers/ Innovators covered:** All faculty members of AIIMS Bhopal; research scientists pursuing independent research careers in the institute under schemes like Ramalingaswami Fellowship, INSPIRE fellowship, DHR fellowships, etc; students and research scholars of AIIMS Bhopal pursuing intramural and extramural research work in the institute irrespective of funding; project employees working in any of the research projects in the institute; visitors to the institute pursuing research work in the institute under any exchange program, companies and external sponsors working with or supporting or collaborating with any researcher of the institute (including but not limited to those mentioned above).
- The applicability of the policy shall commence from the date of approval by the competent authority and its notification by the institute Research Cell in the institute website.

V. Core Implementing Body: The IPRTT Committee

- An IPR, Copyright & Technology Transfer Committee or IPRTT Committee to be set up with the following constitution:
 - a) Chairman: Dean (Research)
 - b) Co-chair: Associate Dean (Research)
 - c) Members (4 Nos.) - To be nominated by the Executive Director (ED), AIIMS, Bhopal (from amongst the active researchers working in the institute in different areas to give a wide perspective and logical inputs to accelerate IPR related activities in AIIMS. One of the members should have legal background)
 - d) Member - Accounts Officer (Research Section) - Ex-Officio
 - e) Member - Administrative officer (Research section)- Ex-officio
 - f) Member Secretary - As appointed by the ED, AIIMS, Bhopal
- *The roles and responsibilities of the IPRTT committee would be as follows:*
 - a) Laying down the relevant SoPs for the effective implementation of the IPR policy.
 - b) Arranging awareness campaigns and workshops for orientation of all concerned in the IPR policy
 - c) Processing IPR applications of institute's researchers and innovators.
 - d) Preparing draft agreements to enable IP protection by the institute. The chairperson of the IPRTT will be authorized signatory on behalf of the institute to sign all agreements/power of attorney/MoU and all documents related to IPR & TT.
 - e) Enabling IP portfolio maintenance, IP audit, end-to-end technology transfers.
 - f) Setting policies for funding of any IPR application from any institute researcher/ innovator and taking decisions on such applications.
 - g) Setting policies for establishment of any academic spin-off/ start-up by any institute researcher/ innovator and taking decisions on such proposals.
 - h) Redressal of grievances, complaints, conflicts, etc. related to IPR and interpretation of the policy.
 - i) Empaneling external service providers like IP firms, patent attorneys, etc. both for filing of IP applications and taking steps towards resolution of illegal infringement of the institute's IP.
 - j) Proposing necessary modifications in the policy with due justification.
 - k) Judicious management and allocation of the institute's IP fund

l) Any other task assigned by the competent authority

- Any amendments proposed in the IPR policy will be approved by the Governing Body, through proper channel, as and when felt necessary by the IPRTT Committee to keep it updated and in line with the National IPR policy.

VI. Objectives of the institutional IPR policy:

- To put in place a robust and transparent administrative process for claiming and maintaining IP ownership and copyright
- To promote innovation and entrepreneurship among biomedical researchers of the institute
- To encourage the development of indigenous, cost-effective, novel, reliable and relevant products, devices, processes, services, algorithms that can address unmet medical needs
- To establish a self-sustained institutional mechanism for facilitating and safeguarding IP ownership and simultaneously create a model of revenue sharing between the institute and its innovators with due compliance of appropriate government financial rules
- To protect the institute and its innovators against illegal infringement of IP rights through use of institutional mechanisms of legal support like empaneled advocates and lawyers

VII. Application of the IPR policy

- This policy shall apply to every IP created at the institute by any of its inventors, as listed in Section III above.
- At the time of joining the institute, every researcher will need to clear any existing IP which they wish to exclude from the scope of the institute's IPR policy, owing to their creation prior to their joining the institute.
- The IPR policy of the institute shall be duly disseminated among all categories of researchers of the institute through publication in institutional website and providing reference to the same in student handbooks; admission letters issued to students and offer letters issued to research scholars, project staff, research scientists and faculty members
- An undertaking shall be obtained from all categories of researchers of the institute declaring thorough compliance with the institute IPR policy.

VIII. Scope of Assertion of Rights

- This policy will be applicable to all Intellectual Property (IP), potential IP, and other technology or techniques having commercial applications.
- The inventors are required to disclose the invention to the IPR and Technology Transfer (IPRTT) Committee and seek assistance before the details of the invention are included in any grant application or published or disclosed to an industrial party.
- Any waiver of the Institute's rights shall only be effective in writing duly signed by the Chairman of the IPRTT Committee and ratified by the ED, AIIMS Bhopal before it is operable.
- AIIMS Bhopal shall own all intellectual property (IP) developed by its personnel while they are employed or pursuing their academic career, as well as any IP that is commissioned by AIIMS Bhopal or created in accordance with a research grant or contract the organization has with a third party.

IX. Types of IP:

The intellectual properties can be broadly listed as:

- a) **Patents:** All the original work related to inventions are covered under this category as per the provisions of the Indian Patent Act 1970 and other relevant applicable rule/law, depending upon the scope of the research.
- b) **Copyrights:** All the original work related to literary, dramatic, musical and artistic works, cinematograph films, computer programs and sound recording are covered in this category as per the provisions of the Copy Right Act 1957 and other relevant applicable rule/laws, as amended from time to time.
- c) **Trade marks:** The matter related to proprietary right to use the trademarks i.e. 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 and also in relation to goods or services for the purpose of indicating or so as to indicate a connection in the course of trade between the goods or services, as the case may be, are covered in this category as per the provisions of The Trade Marks Act,1999 and other relevant applicable rule/laws, as amended from time to time.
- d) **Industrial designs:** The matter related to 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 are covered in this category as per the provisions of The Designs Act, 2000 and other relevant applicable rule/laws, as amended from time to time.

- e) **IC layout designs:** The original work related in the area of Semiconductor Integrated Circuit Layout Designs and matters connected therewith or incidental thereto are covered in this category as per the provisions of the Semiconductor Integrated Circuits Layout-Design Act, 2000 and other relevant applicable rule/laws, as amended from time to time.
- f) **Biotechnology inventions:** The work related to this category of IPR is governed in accordance to the provisions of The Biological Diversity Act, 2002 which provides a mechanism for access to the genetic resources and benefit-sharing accrued there from and other relevant applicable rule/laws, as amended from time to time.
- g) **IP generated based on Artificial Intelligence:** This category of invention is latest development of technology and its application occurs in various filed of science. At present, there is no specific laws in India to govern the subject issue in respect to the IPR created by such invention as it is a settled position of law that only natural persons shall be eligible to claim authorship and ownership of IPR. To that end:
 - i If the work is produced by Artificial Intelligence with human intervention, the intervening human shall be deemed to be the author of the intellectual property. Provided that as per Section VIII, if the person is studying in or working at AIIMS Bhopal, AIIMS Bhopal shall be entitled to the first ownership of the same.
 - ii If the work is produced by Artificial Intelligence without any human intervention, the authorship shall vest with the person who developed the Artificial Intelligence. Provided that as per Section VIII, if the person is studying in or working at AIIMS Bhopal, AIIMS Bhopal shall be entitled to the first ownership of the same.
 - iii Notwithstanding the status of such authorship and ownership, the transfer of technology shall be conducted as provided for in Section XIII of this Policy.
- h) **IP with respect to mobile apps:**
 - i The Intellectual Property of any mobile applications produced by an employee shall rest with the employee. Provided that IP protection cannot be granted if the employee uses open-source code to develop the application and copyrighting is prohibited by the associated licensing agreement.

- ii The creator of the app shall have the option of copyrighting, trademarking and patenting the app, as he/she sees fit. This shall be done in accordance with the provisions of the Copyright Act, 1957, the Trademarks Act, 1999 or the Patent Act, 1970, as the case may be. The procedure laid down in Section XIV shall be adhered to.
- iii Notwithstanding the status of such authorship and ownership, the transfer of technology shall be conducted as provided for in Section XV of this Policy.

X. Ownership of IP

There could be a number of scenarios when an IP is created. The policy will apply to them as follows:

A. Context 1: IP Generation by Inventors at AIIMS Bhopal with or without Institute Funding AND in the absence of any other external sponsor

- a) Faculty members / Scientists / Students / Project Staff / Supporting Staff / visiting fellows of AIIMS Bhopal can be a part of the invention and IP creation depending on their contribution.
- b) In case, there are more than one inventors from AIIMS Bhopal, the Principal inventor (investigator)/corresponding inventor/author must be a regular staff of the institute.
- c) All Intellectual Property (IP) rights with respect to research carried out by Faculty members/ Scientists / Students / Project Staff / Supporting Staff / visiting fellow of AIIMS Bhopal with or without intramural support shall vest in and be the absolute property of the institute.
- d) AIIMS Bhopal can protect and/or commercialize such IP with its own mechanism or by using a third-party service provider through Govt. of India approved mechanisms.
- e) Inventors of AIIMS Bhopal can also undertake protection and maintenance of IP in the name of AIIMS Bhopal after the approval of IPRTT committee with their own resources (including but not limited to learning resource allowance) for fast-track filing. However, for all other official purposes, it would be considered as IP owned by AIIMS Bhopal.
- f) Steps for commercialization can also be initiated and effected by the inventors of AIIMS Bhopal under following circumstances
 - i IPCRT committee does not agree for the commercialization of the IP.
 - ii IPCRT committee agrees for the commercialization of the IP but does not recommend the institutional financial support for the same.

- iii IPCRT committee agrees for the commercialization along with institutional financial support, but the primary inventor considers the transfer to be urgent and is unwilling to wait for the required time suggested by the IPRTT committee.
- g) In the event of successful commercialization, the inventors shall share the Revenue as provided for hereunder the Section XI with AIIMS Bhopal. The expenses towards the protection/maintenance of the IP and technology transfer shall be reimbursed by AIIMS Bhopal at the rate it would have protected and maintained the IP with its own mechanism or using a third-party service provider through Govt. of India approved mechanisms.
- h) In case of an unfavorable IPCRT committee decision not to protect or maintain the IP, the inventors would have the liberty to treat the IP the way they mutually agreed upon without any interference from AIIMS Bhopal. The institute will convey such decision to the inventor in writing.

B. Context 2: IP Generation by Inventors at AIIMS Bhopal with External Sponsor :

- a) Where IP arises out of research funded by an external Sponsor e.g. government agency or other agency/institution/private company but the work/research is conducted at AIIMS Bhopal, the IPR of inventions arising out of such research projects in the absence a written arrangement/agreement shall be owned by AIIMS Bhopal. In such cases, the principal investigator shall be the primary inventor. AIIMS Bhopal will meet the entire cost of filing and protection of IPR in the same manner as provided under Section X-A and Revenue sharing as provided under Section XI.
- b) If however, there is a written Associated Agreement between the inventor/AIIMS Bhopal and the sponsor dealing with matters of ownership of IP, the ownership will be determined by the express terms of such Associated Agreement(s) and if the Associated Agreement is silent in this regard then it will be decided by the conditions under which funding of the research work is granted.

C. Context 3: IP Generation under collaborative Research

- a) All IP jointly created, authored, discovered, or invented, during the course of collaborative research undertaken jointly by the Institute with Collaborating entities (Collaborator), shall be jointly owned (proportion would be mutually decided between AIIMS Bhopal and collaborator based on the quantum of intellectual input). The cost sharing for IPR protection and maintenance shall be as per the collaborative research agreement terms executed by the parties before initiating the work.

- b) In case the Collaborating Institutions are not willing to bear fully the cost of filing and maintenance, if considered expedient by the Institute, the Institute will share the cost equitably with the Collaborating Institutions. Where the Collaborating Institution(s) is/are not willing for filing joint IPR application, the Institute at its discretion may file the application with absolute ownership and Institute will meet the entire cost of filing and protection of IPR in the same manner as provided under Section X-A and Revenue sharing as provided under Section XI.

D. Context 4: IP Generation under Research Projects that form a part of the degree programmes/certificate courses/fellowships/ observership etc at AIIMS Bhopal

- a) Research projects that form a part of the degree programmes/certificate courses/fellowships/observership etc at both undergraduate and postgraduate level e.g. B.Sc., M.Sc., PhD, MBBS, MD, MS, DM, MCh etc., are usually initiated and proposed by faculty members of the institute. In such cases, students work on a specific project or join a team to investigate one particular aspect of a much larger research programme, thereby drawing on the considerable expertise, reputation and infrastructure of the supervising Guide and substantial use of AIIMS Bhopal resources. The IP thus created belongs to the research guide and the research team.
- b) The student shall be the co-inventor of the IP if they have contributed significantly to the development of the research project and have worked for a significant period of time on the project from which the IP is created.
- c) The ownership of the IP (except copyright as provided under the Section X) shall lie with AIIMS Bhopal and will be managed in the same manner as provided under Section X-A and Revenue sharing as provided under Section XI.
- d) The ownership rights of AIIMS Bhopal will be subject to the conditions of organizations which have awarded fellowships or scholarships to the students and AIIMS Bhopal shall enter into necessary Agreements in this regard.
- e) The research Guide shall ensure that Students/fellows sign a confidentiality agreement and all other necessary documents such as non-disclosure form (NDF), material transfer agreement, collaborative research agreement etc as applicable before commencing work on the project.
- f) This policy covers students while attending AIIMS Bhopal and after they leave.

XI. Revenue Sharing

- Costs incurred in commercialization (like costs of registration and maintenance of the IP, securing legal protection and third-party intellectual property rights, the enforcement and commercial exploitation of the IP) are to be reclaimed prior to distribution of revenue earned out of licensing fee and royalty.
- If two or more pieces of IP are combined in a single project or venture, then an agreement defining the distribution of Cumulative Net Financial Benefit to the contributing parties must be concluded before the start of the commercialization process.

The break-up of the revenue to be shared among the institute and the inventors, after deduction of the associated costs described above, will be as follows.

- 30% Institute share
- 70% Inventor(s) share

In case of more than one inventor contributes to the creation of IP, the inventor share of the Revenue will be divided in the ratio of 50% to the principal inventor/investigator and the remaining 50% among other inventors/investigators unless there is a signed written agreement to the contrary. In case there is any co-principal investigator/inventor, the share will be 40% to the principal inventor corresponding to the IPCRT, 30% to the co-principal investigator/inventor and the remaining 30% for other co-investigators/inventors.

XII. Copyright on Scholarly material

100% of the royalty will be for the author(s) or originator(s) of the scholarly material(s). However, the royalty received towards such activities must be reported to IPR and Technology Transfer Division for information and Finance department for tax calculation if applicable. In the event of joint authorship, the revenue sharing must be decided among the authors before the start of the work, even if the co-author is a student/project staff.

XIII. Publication, Non-Disclosure and Trade Secrets

- The institute recognizes the right of the researchers to publish their works if and when they deem fit. However, in case of research works having the potential of generating an IP, the institute's IPRTT Committee would issue a No Objection Certificate to the innovator(s) to publish their works after giving them an opportunity to first protect any IP that may be emanating from such works.

- In view of the risk of losing IP protection rights due to early public disclosure, innovators need to identify the possibility of any patentable IP as soon as feasible and to contact the IPRTT Committee before publicizing research outcomes with potential IP.
- The institute reserves the right to classify any confidential Information as a Trade Secret owned by the institute. In such an event, all innovator(s) will be required to maintain the confidentiality of the Trade Secret and to follow the direction for management of the Trade Secret as specified by IPRTT Committee.

XIV. Procedure of Registration and Renewal of IP

a) Procedure for the Registration

Unless otherwise stated, all the inventors of the institute need to adhere following procedure for the registration of their inventions (Figure 1).

- i All the inventor(s) needs to submit a duly filled Invention Disclosure Form (Annexure-I) to the IPRTT Committee (patent filing before publishing)
- ii Patent search and patentability assessment will be carried out by the IPRTC through an empaneled patent agent/ attorney in consultation with the applicant (Timeline of 1-2 weeks)
- iii On meeting patentability criteria and commercialization potential, provisional patent to be drafted by the empaneled patent attorney**
- iv Filing to be done by the patent agent/ attorney on behalf of the innovator and the institute (forms to be signed by the Chairman of the IPRTT Committee).
- v Committee will inform the inventor about the filing and to ensure that all the post-filing formalities are complied in time-bound manner.
- vi IPRTT Committee will be responsible for managing the prosecution, maintenance and commercialization of the created IP and coordinating with the innovator, institute, patent agents and attorneys in this regard in a time-bound manner

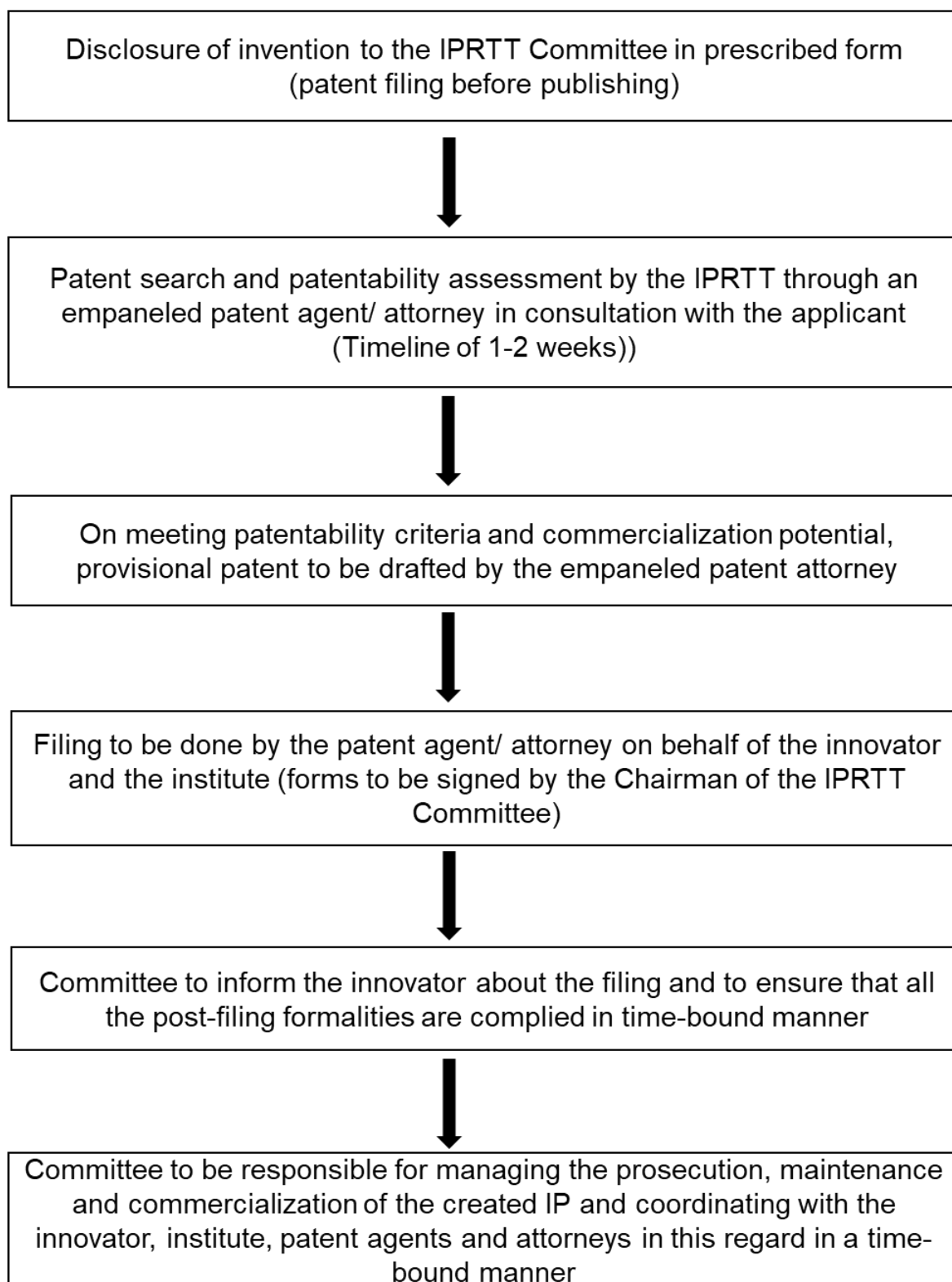


Figure 1. Flow Chart for the registration of invention by the Institute

- **Advance filing of Provisional patent by the inventor**

** In case the applicants can bear the cost of filing a provisional patent, the IPRTT Committee can give an immediate permission to proceed even before evaluation of the application. In such cases, the inventors need not disclose the details of the invention at this stage. However, if the Institute decides not to manage the IP, the applicants shall file the complete application within 12 months. In such cases, the institute shall waive off its ownership for that IP. However, if the institute decides to own the IP jointly or fully, the cost of provisional patent filing shall be reimbursed to the applicant proportionate to the ownership of the institute.

- **Renewal of patent**

- a) The Institute will pay for all prosecution and annuity costs up to the 5th year from the date of application. May be shared with joint owners (like sponsors of concerned research projects) as per the terms of any Auxiliary contract
- b) The licensee/ assignee to pay renewal fees for the subsequent 15 years from the revenue generated from the licensing and royalty in case the patent has been commercially exploited within the first 5 years
- c) In case commercialization has not taken place in the first 5 years, the institute shall discontinue its maintenance allow it to lapse through nonpayment of renewal fees.

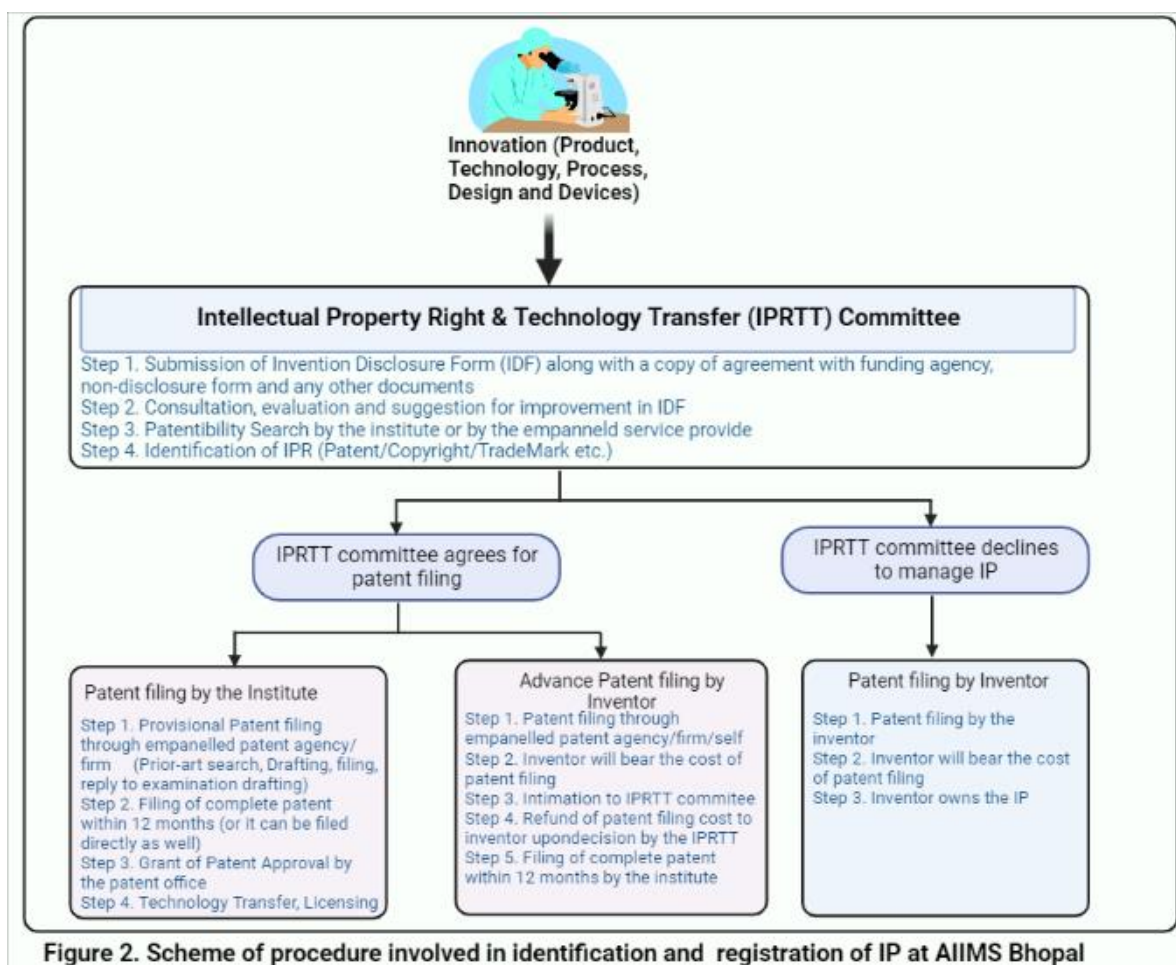
Figure 2 demonstrates scheme of procedures involved in identification and registration of IP at AIIMS Bhopal.

XV. Technology Transfer

- Whether the invention or technology or know-how developed by inventors at the institute has been formally protected by patent(s) or not, AIIMS Bhopal shall have the right to commercialize them through transfer of technology.
- To accomplish technology transfer, the IPRTT Committee or the inventors can jointly or severally identify potential licensee(s) or transferee(s) for the same.

If an industrial partner had been involved in the research collaboration leading to the development of the concerned technology, then the said partner will be given priority for commercialization of the

technology, provided the same has been included in the agreement executed beforehand between the institute and the industry partner.



- However, the institute shall be free to transfer the technology to a third party for commercialization, if the industry partner had failed to commercialize the technology within two years of executing the license or transfer of the technology.
- If the concerned technology has evolved out of collaboration with a non-commercial organization, then the institute shall reserve the sole right on the revenue generated from the commercialization unless specified otherwise in the agreement executed before the commencement of the project.
- The IPRTT Committee of the institute shall duly formalize the terms and conditions of the agreement leading to the licensing/sub-licensing for commercialization through mutual discussion between the involved parties (Inventors, AIIMS Bhopal and the Industrial partner) and get the approval of the competent authority of the institute.

- The revenue arising out of the commercialization shall be shared according to the model provided in the IPR policy of the institute.

XVI. Inventors' Code of Conduct and Binding Agreements & Contracts

- Researchers should regularly maintain a laboratory notebook while pursuing research that has a potential for commercialization. The laboratory notebook should document all relevant experimental details and results and should be regularly signed and dated by the project supervisor. This may be required to be produced as evidence in a court of law in case of any dispute.
- Collaborative research with other departments, institutes and agencies should be carried out only after the execution of a mutually consented "Collaborative Research Agreement". IPRs which are barred / exempted under the governing laws of India shall not be taken / permitted for protection by the Institute. Inventors should refer to the IP statutes and other related rules for further confirmation.
- Innovators would refrain from disclosing their innovation in public domain by any means like conference presentations or abstracts, research articles, print and electronic media, etc till the same has been secured through the filing of the provisional or final patent application.
- A "Non-Disclosure Agreement" (NDA)/ "Confidentiality Agreement" shall have to be executed by the inventors and/or the IPRTT Committee of the institute before sharing proprietary or confidential information with any third party apart from inventors.
- Transfer of tangible research materials, included within the scope of IP of the inventors and/ or its inventors, to any third party shall be governed through the execution of a "Material Transfer Agreement" (MTA) between the inventors and/ or the IPRTT Committee and the third party. The rights, obligations and restrictions for both the provider and the recipient with respect to the materials and any of its derivatives shall be specified in the MTA. In addition, the MTA must also include any confidential information exchanged with the material, conditions for publication of research results of the material by the recipient, permitted use of the material, and other associated legal issues that the provider and recipient may wish to specify in the transaction.
- The "Collaborative research agreement" should also include a "Data protection agreement", which the inventors should make to ensure protection of Sensitive Personal Data or Information ("SPDI") and specify the compensation for negligence in implementing and maintaining reasonable security practices and procedures in relation to SPDI.

- Third party use of the technology or IP shall follow the signing of the “Technology Transfer Agreement” or “License Agreement” and be bound by the conditions of the same
- The ED, AIIMS Bhopal or his authorized representative shall be the signatory to these agreements, on behalf of the institute.

XVII. Recording, Monitoring and Accounting of the IPRTT Committee:

- The IPRTT Committee shall keep the hardcopy and digital records of all intellectual property (IP) that is registered in the institute's name.
- It will also keep track of the due dates for payment of maintenance or annuity fees for protected intellectual property and, within a reasonable time frame make the payments or notify the person or department in charge of handling them.
- Additionally, the IPRTT Committee shall keep the records of income and expenses for each IP so that revenue-sharing percentages can be determined.

XVIII. Engagement of Third Party for Management of IP & Technology Transfer

- The institute, through the IPRTT Committee, may empanel service providers for IP management, after following due procedures and approval of the competent authority.
- Such third-party service providers will be governed by specific terms of license fees structure and Specific Power of Attorney and will not be assigned any IPR.

XIX. International Registration of IPR

- According to Section 39 of the Indian Patent Act 1970, it is mandatory for an Indian inventor to file patent application in India prior to filing international patent application.
- Hence, subsequent to filing of national patent, an inventor at AIIMS Bhopal can also opt for filing of international patent through either of the applicable modalities, viz. direct filing of patent application in individual foreign countries; application under the Paris Convention Treaty or application through the World Intellectual Property Organization (WIPO) for IP protection in any of the member countries subscribing to Patent Cooperation Treaty (PCT). The modalities applicable for the respective application procedures, as per the governing law, will be facilitated by the IPRTT Committee subject to the consideration of financial implication, recommendation of the IPRTT committee based on cost-benefit analysis and final approval of the competent authority.

- In case the IPRTT committee declines to support the International Patent Application, the inventors may go ahead with the process of International Patent filing using their own resources and subject to the mutual agreement of the inventors, without any interference from the Institute.
- The inventors can also use their own resources for International Patent Filing in order to expedite the filing process when the matter is still under consideration of the IPCRT committee. However, if the IPRTT committee decides in favour of managing the international IP rights of that invention it would be considered as patent owned by the institute and the expenses incurred in protecting and maintaining the IP shall be reimbursed by the institute at the rate in which it would have undertaken the process with its own mechanism or using a third party service provider through the approved mechanism of Government of India.

XX. Infringements, Damages, Liability and Indemnity

- The agreements executed by the institute with the licensee(s), while transferring technology, know-how or IP, shall have an in-built indemnity cover to secure the institute and its inventors from legal proceedings related to direct or indirect consequences of commercialization of the technology, like validation issues, manufacturing defects, production problems, batch variations, suboptimal performance in specific populations, supply chain breaches, design guarantee, up-gradation obligation, etc.
- The institute shall have the right to oppose, prosecute, engage in or desist from becoming a party in any litigation concerning IP and license infringements.
- The institute shall not be held liable for damages resulting from breaches of any auxiliary contract, irrespective of whether the contract has been approved by the institute. In case of any conflict with the provisions of such auxiliary contract, the provisions of this policy shall prevail.

XXI. Conflict of Interest

- It will be obligatory for the inventors to disclose if they or their immediate family members have a stake in a licensee-company. In such situations, execution of the commercialization license or assignment of rights for a patent to the licensee/company shall be subject to the recommendations of the IPRTT Committee and approval of the competent authority of the institute.
- The decision of the competent authority, on the existence of conflict of interest or otherwise, shall be binding on all concerned.

XXII. Dispute Resolution

- Appeals regarding disputes related to the implementation of the IPR policy and Technology management, including the apportionment of the cost and the expenses payable by the inventors and the institute, may be referred by the inventors and/ or the IPRTC Committee to the ED, AIIMS Bhopal. The ED's decision in this regard would be final and binding on both.
- The associated Agreement shall be considered to be the governing document for the resolution of disputes arising from collaborative research or from externally sponsored research out of or in relation to the construction, meaning, scope, operation or effect of IP ownership and exploitation
- In the absence of any written Agreement and if parties thereto agree, the ED AIIMS Bhopal may refer the dispute to an independent expert who shall conciliate and pass an award that shall be final and binding on all the relevant parties. The seat of conciliation shall be Bhopal and the proceedings shall be conducted in English Language.
- Researchers entering into any such associated agreement should incorporate the above stated Dispute Resolution Mechanism, therein unless the sponsor is governed by any other prescribed mode of Alternative Dispute Resolution Mechanism.

XXIII. Jurisdiction

All agreements to be signed by AIIMS Bhopal, along with any issue arising in relation to or in connection with those agreements, will be under the exclusive territorial jurisdiction of the competent courts in district Bhopal, Madhya Pradesh and shall be governed by appropriate laws in India.



All India Institute of Medical Sciences

(Ministry of Health & Family Welfare, Govt. of India)
Saket Nagar, Bhopal 462 020 Madhya Pradesh India

(Annexure 1)

INVENTION DISCLOSURE FORM

1	Title of invention:			
2	Name and Address of the Inventor(s):			
	Name	Designation	Department	E-mail/Phone No.
3	Type of Application (Check the relevant Section)	Provisional Application	Complete application	If already filed, provide patent application No.
4A	Funding Source (Check the relevant Section)	AIIMS Bhopal (Intramural)	Sponsored (Govt.)	Sponsored (Private/Industry partner)
4B	Is there a written associated agreement between AIIMS Bhopal or the Inventor(s) with the Sponsoring agency? Yes/No			
5A	Field of Invention: Check the relevant Section			
	Pharmaceutical Industry	Biotechnology Industry	Medical and Surgical Aids	Consumer
				Any other (specify)
5B	Is the invention based on Product or Process/Method/design or Composition or Others Please specify.			



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5C	Stage of Invention (<i>Check one</i>):	Only Hypothesis	Preliminary Experiments	Proof Established	Invention is ready
6	Nationality of the Inventor (s):				
7	Describe the problem that your invention is trying to solve:				
8	Brief description of invention (in 250 words):				
9	List of keywords pertaining to the invention:				
10	Existing state-of-art; patents and other publications.				
11	Drawbacks in existing state-of-art and how the drawbacks have been overcome by your invention.				
12	Objectives of the invention.				
13	Innovative features of the invention.				
14	Utility of the invention.				
15	Advantages over other known alternatives.				
16	Present status of patenting on this invention (patent and literature search)*.				
17	Detailed description (should be accompanied by labeled drawings/photographs/diagrams as in a research paper).				



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17A	Provide experimental details
17B	Provide specific genes/genetic sequences /nucleic acid sequences/details of the vectors if used in the invention
17C	Provide complete information on the specific algorithm/Codes/ UI designs (screen shots) if used in the invention
18	Test status (give details of testing and results thereof)
19	Country(ies) of filing patent.
20	When your invention was first conceived? Do you have any documentation (e.g., lab notebook) to support that first date of conception?
21	Has your invention been disclosed to someone outside the institute (e.g., Conference/ published technical article), and if so, when was it first disclosed?
22	Name & Signature of primary inventor(s). Date
	Name & Signature of Co-inventor(s). Date