

Intellectual Property Rights (IPR) Guidelines of National Institute of Pharmaceutical Education and Research, Raebareli (NIPER-R)

1. INTRODUCTORY REMARKS

National Institute of Pharmaceutical Education and Research, Raebareli (NIPER-R) recognizes that creativity and inventions resulting from innovative teaching and research supported by central facilities, equipment, or grants of or administered by the institute may be recognized and relevant intellectual properties can be protected. It believes in the vision to expedite such inventions and copyrightable works for societal benefits. NIPER-R preserves the primary spirit of academics on one side and on the other side, keeps the pace with the evolving global scenario by increasing awareness about 'knowledge asset'. The institute desires to foster the creativity and publication of innovative works by faculty/students/project staff/supporting staff/visitors through Intellectual Property Rights (IPR) protection policies that look out to reconcile such inventions on behalf of the public, the institute, the inventors, and authors. The guidelines on the one hand addresses outreach of institutional novel innovations and technologies and on the other hand, motivates the faculty, students, and researchers to initiate technology transfer using rights gained over a novel invention.

The material put forward in this document aligns with IPR laws of India, such as the Trade and Merchandise Marks Act, 1958, Patent Act, 1970, Copyrights Act, 1957, and Designs Act, 2000, and theory amendments.

2. Fundamentals to the innovation process and technology transfer for the development of Intellectual Property (IP)

To clarify and understating the process of IP development, the following flowcharts (Fig. 1 & 2) are included for reference.

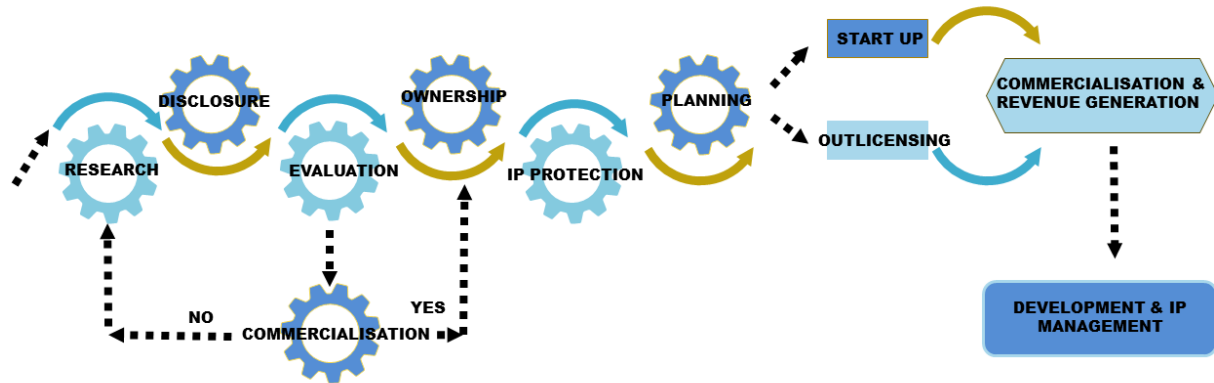


Fig. 1: Flowchart depicting the technology transfer process

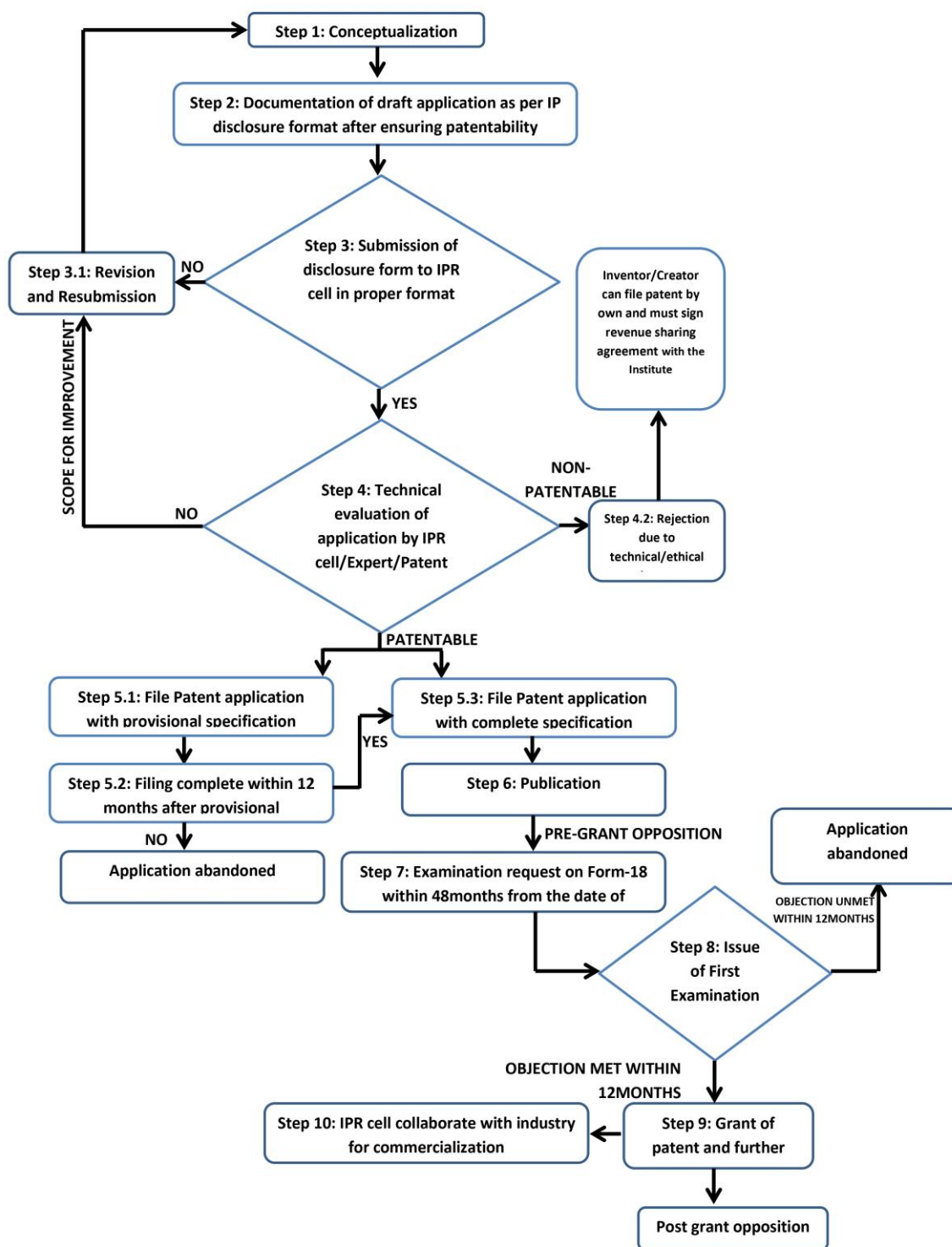


Fig. 2: Flow diagram of IP conceptualization to patent filing

3. Essential elements of Institutional IPR guidelines

NIPER-R is a research-driven institute and therefore, institutionalizing invention processes are essential. This document details all issues related to the generation of IP in the form of patents, copyright, trademarks, designs, etc. It also identifies issues raised for licensing IP rights to third parties for commercialization. This document highlights the institute's guidelines towards the publication of research outcomes as copyrightable work (such as journal or book articles, poster presentations, or lectures in conferences). It establishes ownership of IP created by its faculty, staff, students, and co-ownership when the research is funded by a third party or conducted in collaboration. It deals with the enforcement of IPR guidelines reflected in employment contracts, agreements on research grants, and collaborations with other organizations. This document also outlines the establishment of an institutional committee to manage all aspects of IP, including generation, protection, licensing of innovations, and other administrative support on demand. The document should be critically reviewed at regular intervals (yearly) and ensure amendments upon need and experience obtained. All the personnel of the institute are required to abide by institutional IPR guidelines.

4. Core Objectives

The objectives of this guidelines document are entitled below:

1. To nurture, stimulate and encourage creative works in areas of interdisciplinary science such as Chemistry, Pharmaceuticals, Pharmacology, and Biotechnology.
2. To promote outreach of Institute's intellectual property in order to ensure practical utilization of IP for societal benefits along with securing interests of creators or licenses of such 'knowledge assets'.
3. To provide guidelines to protect the legitimate interests of creators/inventors such as faculty/staff/students of NIPER-R in a rational manner for public benefits.
4. To set up and maintain a dedicated cell to provide IPR-related services and to supervise the fair distribution of returns in accordance with this guidelines and its amendments.
5. To defend and protect both creators' and Institute's interests against illegitimate use of IP.

6. To create appropriate mechanisms for legal support from Institutional panel of attorneys/lawyers as per the scope of work.
7. To promote the generation of revenues for Institute/Stakeholders by encouraging licensing and commercialization of IP and providing legitimate revenue sharing among innovators.

5. Key Terms

a) Intellectual Property: Intellectual property (IP) is a type of property created out of intellect. It is the creation of a mind bestowed with the status of property because of its potential commercial value. In the present context, it shall include knowledge that is patentable, copyrights articles such as original publications in books, research journals, magazines, perspectives, monographs, software design, process design, registered designs, trademarks/logos, etc.

IP generated shall be of the following types:

- i. NIPER-R as an Institute, its employees or other stakeholders (through proper agreement) hold ownership and licensing rights wholly/partly of IP generated through R&D projects run in-house.
- ii. Licensing on IP generated through contract research would be in compliance with the statutes adopted by NIPER with respect to third-party stakes in such licensing.

b) Patent: A patent is a document which is issued upon application, by a government office. The patent creates a monopoly right for an invention. Patentable inventions are solutions to specific problems in technology. It is a product or a process that provides a novel and original way of doing something. Patentability is designated to an invention that falls under patentable subject matter. A patentable subject matter is established by statute in which materials belonging to natural origins and settings are not patentable. It is granted under the provisions of the Indian Patents Act, 1970, and later amendments as well as those issued by international patent agencies/authorities/organizations.

c) Copyright: It deals with the rights of intellectual creators, which is particularly concerned with protecting creativity and ingenuity. The protection afforded to all forms of public knowledge includes original printed publications, photographs, drawings, cartoons, graphical art, artistic works, movies, and podcasts.

d) Trademark/Service Mark: It defines any sign that individualizes the goods of a given enterprise and distinguishes them from the goods of its competitors. The mark can be represented in graphical form.

e) Biotechnology Inventions: These inventions include recombinant plasmids, nucleotide sequences, and microorganisms.

f) The “Institute”: Wherever the word institute is referred to, it would represent NIPER-Raebareli.

g) IP Rights: It means ownership of IP, with identification of members contributing to the creation of such IP.

h) Creator: Any employee of NIPER-R that includes those who are on probation, employed on a temporary/contractual basis either in the Institute or in projects such as research scholars or students, project staff who are accountable for the creation of IP using the facilities provided by the Institute.

i) Inventor (s): A person or a group of people responsible for creating an IP. In cases where IP creation is associated with more than one inventor, one of them would function as a Lead Inventor through mutual consent.

j) Owner: The owner has the right to decide who may or may not use the patented invention for the period in which the invention has been protected. The Institute will be the owner of the IPR.

k) Sponsor: An Organization/Agency/Private Partner that commits itself to providing funds, (recurring and non-recurring) for basic/applied research, consulting assignment and training program.

l) IPR Committee (IPRC): The committee constituted by the competent authority of the Institute from time to time to coordinate the functioning of the IPR cell and make recommendations regarding IP-related concerns.

m) IPR Cell: A dedicated office to document, disseminate information and synchronize between the creators, IPR committee, external patent attorney, and other IPR-related proceedings.

n) Technical Evaluation Committee (TEC): A sub-committee nominated by the Competent Authority on a case-to-case basis to examine and approve the filing of IPR.

o) Licensing: It is a major aspect of IP where an agreement is built up through a partnership between the owner as the licensor, and one who is authorized to use IP rights by the name of the licensee. It grants the licensee the right to utilize the IP for using the resulting product for commercial purposes or otherwise agreed to. The licensing agreement creates new business opportunities in exchange for consented royalty.

p) Revenue: Any fund received by the Institute according to the agreement for the legal use of IPR.

q) Outsourced work: A kind of work commissioned by NIPER-R to the creator or groups of creators who either could be an employee of NIPER-R or invited from outside the Institute to pay for the same work. Such work will be outside the scope of IPR claims. For example: Design work, Software, Epidemiological survey reports, Artistic works and Videography.

r) Non-Disclosure Agreement (NDA)/Confidentiality Agreement: A legally bound contract that establishes a confidential relationship among parties involved in executing an NDA.

s) Analogous agreement: The document built upon the mutual consent of involved parties that defines the rights, roles, and responsibilities of either party for example, Memorandum of Understanding (MoU), Memorandum of Association (MoA), Memorandum of Cooperation (MoC), Research Agreement, Consultancy agreement, etc.

6. Administrative cell/committees

a) Structure of IPR cell

The IPR cell of the institute will be the nodal agency responsible for coordinating the IPR filing process including seeking necessary approvals for technical committee formation acting as a liaison between with IPR attorney and the inventor, recordkeeping, and networking for the market potential of the invention. The creators/inventors of the IP shall dispense all necessary information to the IPR cell in order to ascertain whether the Institute is incline to own and manage the IP. This cell will be managed by a qualified person in IPR having proficiency and experience in IP management for smooth management of the IPR filing process such as drafting and vetting of agreements, MoUs, MoCs, etc. for facilitating commercialization and licensing activities. Wherever required IPR cell, upon recommendation of the competent authority, can get assistance from professional bodies/agencies/firms for support in the drafting, filing and, commercialization process. The IPR cell will maintain all statutory and necessary documentation related to IPR activities for official records.

b) Intellectual Property Rights Committee/IPR committee (IPRC)

IPRC shall consist of a five-member committee constituted by the competent authority for three years tenure. Among the five members, one will be the chairperson, and one member will be the coordinator. All members of the committee should be from diverse areas/disciplines representing pharmaceutical sciences, chemical sciences and life sciences of which one member may preferably have experience in IPR. In specific cases, experts including practicing patent attorneys from other organizations can be co-opted. The IPRC will examine the IP application and make specific recommendations regarding the patentability/registration of the proposal by the institute. IPRC will work for encouraging IP creation, primary evaluation of an invention seeking national and/or international patenting, get inputs for violation/infringement tracking through professional sources, facilitating commercialization, and framing terms and conditions. In all these endeavors, the confidentiality of the IP shall be strictly maintained.

c) Technical Evaluation Committee (TEC)

For expert review of the invention draft the IPRC will request the competent authority for the formation of a technical evaluation committee to scrutinize and recommend filing of IPR in both disciplinary and interdisciplinary IPR cases. The TEC will submit the evaluation report after analyzing the technical competence of the patent and provide recommendations to IPRC. In all these endeavors, the confidentiality of the IP shall be strictly followed. The inventor/creator shall complete the non-disclosure agreement with the committee members and submit a copy to the IPR cell.

7. Working and costing of IP

NIPER Faculty may undertake contract research and provide consultancy and technical services as under:

a) Contract Research:

Contract research shall comprise all R&D undertaken through specific contractual arrangements agreed upon for the purpose and shall cover the following:

1) Sponsored projects: Projects with full funding by the client that have specific R&D objectives and culminate to the generation of IP. These projects can be multi-client with shared funding and research outcomes.

2) **Collaborative projects:** A collaborative research project involves both parties incriminated in planning the project and research plan. These projects are partially funded by the client and supplemented by institutional provisions such as manpower, infrastructural facilities, etc. There shall be well-defined project outcomes. Collaborative projects could be for upscaling/proving laboratory level know-how, technology development, or IP generation.

3) **Grant-in-Aid Projects:** These projects are for supporting basic or exploratory research or for maintaining or creating testing and infrastructural facilities. These projects shall involve grants by way of financial inputs and assistance e.g., equipment and training to supplement NIPER-R's efforts in ongoing or new R&D projects or for creating new facilities.

b) Costing of Contract Research Projects: *(extracted from NIPER statutes APPENDIX-A)*

The charges for contract research shall include expenses on account of :

- I. Cost of man-days of staff deployed
- II. Cost of consumables/raw materials/components with 25% overhead
- III. Cost of physical inputs/services/utilities with 25% overhead
- IV. Equipment usage cost/cost of equipment procured specifically for the project
- V. Any external payment envisaged
- VI. TA/DA
- VII. Contingencies

Total expenses = sum of I to VII.

c) Intellectual Fee: Minimum of 33.3% of total expenses as of 7.b.

For any sponsored research, rights for licensing intellectual property shall rest with NIPER. In the case of collaborative research, such rights shall be held by NIPER and the collaborator. Licensing for commercial exploitation of the intellectual property generated out of contract research shall be held jointly. NIPER shall charge an adequate amount as a fee. This could be a lump sum and or recurring royalty.

Wherever feasible the sponsor shall be given a non-exclusive license fee with an exclusive license for a limited period of time normally exceeding 5 years, for commercial exploitation of the intellectual property.

Project charges=Total expenses+ Intellectual fee + License fee

c) Sharing of the monies by Staff

Forty percent of the intellectual fee or net surplus (remaining after accounting for all direct or indirect project expenditure) whichever is lower arising from R & D contracted is to be shared with the staff.

The pattern of sharing for staff is as follows:

Staff	Share
Innovators and Principal Contributors	40%
S&T (supporting staff)	35%
Remaining supporting staff of the NIPER	20%
Welfare fund	5%

d) Consultancy

All consultancy services in the NIPER shall be institutional. There shall be two categories of consultancy as follows:

Advisory Consultancy

These consultancy services rendered outside NIPER-R would involve any kind of professional advice including scientific, technical and engineering bestowed upon clients based on the available expertise and experience of individuals. This may not envisage the use of any facilities of NIPER-R and should not involve any kind of survey, detailed study, or report preparation/submission.

General Consultancy

These consultancy services shall comprise scientific, technical, engineering, or other professional advice /assistance based on the available expertise of NIPER-R. This consultancy is intended for only minimal use of laboratory facilities for essential experimentation that could meet the objectives of the assignment. This consultancy may cover:

- Preparation of prior art search, state-of-art/project/technology forecasting reports
- Analyzing and validation of test results and data, risks, and hazard/environmental impact analysis

- Engineering of design
- Assistance in erection, commissioning, operation, fabrication/tendering and purchase of equipment, trouble-shooting, productivity improvements, pollution abatement/control measures, energy conservation, waste utilization and technology assessment/evaluation.

The consultancy assignment, which does not strictly fall under the category of Advisory Consultancy, shall be taken up as General Consultancy.

e) Costing of Consultancy project

The charges of the consultancy project shall include expenses on account of

- I. Cost man-days of staff deployed
- II. Cost of physical inputs/services/utilities/consumables/raw materials/components with 25% overhead
- III. Equipment usage cost
- IV. External payment is envisaged *e.g.* to outside consultants, for obtaining data and hiring infrastructural facilities.
- V. TA/DA
- VI. Contingencies

Total Expenses = sum of I to VI.

f) Intellectual fee

This should be commensurate with the quality of inputs provided and the likely benefits to accrue to the client because of the consultancy. While there is no ceiling on the upper limit of intellectual fees to be charged, it should not be less than the estimated manpower charges.

g) Distribution of Honorarium

For Advisory Consultancy

Distributable amount up to a maximum of 2/3rd of intellectual fee as follows:

Nature of duties	Share
Team of consultants	95%
Welfare Fund	5%

For General Consultancy

Distributable amount up to a maximum of 2/3rd of intellectual fee or 300% of the manpower charges levied, whichever is less as follows:

Staff	Share
Team of Consultants	65%
Other S&T Staff	15%
Remaining Supporting Staff	15%
Welfare Fund	5%

h) Licensing of Intellectual Property

Licensing of intellectual property

8. Pricing of intellectual property

The estimated price for IP may be determined based on the nature of work; however, the following factors will be kept in view during the approximation:

- a) Development Cost
- b) Net benefit to be derived by the licensee
- c) Capacity of potential licensees
- d) Possibilities of IP being pirated
- e) Opportunity value

Development cost can be determined on the inclusion of the following elements:

- a) Scientific & Technical Manpower deployed on the project
- b) Consumables with 25% overhead
- c) Physical input for the project with 25% overheads
- d) Usage of equipment
- e) External payments (if any)
- f) Cost of securing the IP
- g) Maintenance of the IP

9. Ownership and Licensing of Intellectual Property

- Various definitions for ownership of IP of different types are described as follows:

- a) IP will be owned exclusively by NIPER-R under the following circumstances:

- It has been solely developed utilizing the funds/facilities provisioned in NIPER-R or in the amalgamation of funds/facilities of the Institute and external agencies but without any formal associated agreement.
- It has been developed employing funds/facilities of external agencies that include sponsored research and consultancy projects in the absence of any agreement of association.
- It has been developed under any contract that includes “work-on hire” basis, work commissioned/outsourced by the Institute.
- It has been developed in compliance with a written MoU where ownership has been granted to NIPER-R.
- It has been developed over a period of time with contributions from personnel from various disciplines of /for NIPER-R

b) IP will be owned either in conjunction or exclusively by third party/parties

- It has been developed with external funding such as sponsored research, consultancy projects, and other collaborative projects in compliance with a formal agreement.
- It has been developed out of work carried out by faculty/staff/students during their stay in third-party organizations.

➤ Summary of ownership of the Creator/Inventor of IP generated from different activities is as follows:

	OWNERSHIP	CREATOR/ INVENTOR	BENEFIT SHARING
Academic Research	Institute	Faculty/Students/ Staff	Faculty/Students/ Staff
Fully funded Govt. research	Institute	Faculty/Students/ Staff	Institute/Faculty/ Students/Staff
Fully funded Non- Govt. research	Institute and Agency	Faculty/Students/ Staff	Institute and Agency. Transfer on mutual consent to third-party through MoU
Partially funded Non-Govt. research	Institute and Agency	Faculty/Students/ Staff	Institute and Agency. Transfer on mutual consent to third-party through MoU

- The following guidelines should be aided in case of sponsored research and consultancy projects or any other activity involving collaboration:
 - In cases where the funding agency allows ownership to NIPER-R, Institute can share its rights with other third party/parties with due consideration of their contribution.
 - The ownership shall be decided at the time of approval of the activities in compliance with the pre-determined clauses of the government funding agency.
 - In cases of non-governmental funding, the ownership can be shared between the Institute and the agency or can be waived on recommendation by Inventor(s) or Lead Inventor based on reasonable compensation to the Institute.
 - In cases of international/inter-institutional collaborations, an explicit agreement will be prepared that will define the ownership of IP generated considering the direct involvement of their human/other resources among the collaborators. IP involving indigenous biomaterials, the ownership agreement must be prepared to keep into account the restrictions mentioned in 'Biological Diversity Act 2002' of India.
- The following guidelines are to be followed for copyrightable works:
 - The copyrights are owned by the authors of textbooks, research books, and articles and teaching-learning resource materials unless restricted by an MoA. Revenue generation if any from defined activities should be reported to the Institute.
 - The Institute owns the copyright if the work is created out of a contract.
 - Copyrights of thesis, dissertations, term papers, the laboratory records will be possessed by the student unless restricted by an associated agreement. Further, for ownership of such copyrights, the student(s) has/have to declare that the thesis is beyond any information that needs IP protection by the Institute.
 - Faculty/staff/students of NIPER-R can be engaged in developing software or other IP using software which is exclusive to certain suppliers after its procurement for education and research purposes. However, for software which is restricted on IP creation and commercial use, it is essential for establishing a settlement with the owner/supplier of the software before beginning the process of IP protection. Otherwise, that software which is for general use should be procured with a proper license.
- The following guidelines have to be followed for trademarks/ service marks/logos:
 - Trade and service marks related to goods and services involving NIPER-R will be owned by the Institute.

- NIPER-R would allow the use of its signature and trademarks owned by it to the third party/parties with whom IP has been licensed whenever there is intentional use of IP for the benefit of society. The third-party/parties should sign the undertaking that IP will be used keeping in mind environmental safety and good manufacturing practices designated by the Government of India and its regulatory bodies. The aforesaid undertaking should also mention that the promotion of IP will be based on truthful claims and information avoiding any kind of deceptiveness to society. Moreover, the undertaking must include that the institute does not hold any liability in case of misuse of IP or accidental damage due to IP use. Under no circumstances, IP will be used against the interest of the Union of India.
- The licensee must take prior approval from NIPER-R detailing the demeanor in which the name of NIPER-R and its trademarks are to be used in both printable and electronic media for promotion.
- Licensing of IP to a third party is the general process for technology transfer with commercialization chances in the future. Licensing of IP generated by NIPER-R can be discussed under the following two headings:

Sponsored projects: The rights for licensing will be kept to NIPER-R in all cases where the Institute has ownership. The sponsor shall be bestowed with the first right for commercial exploitation of IP after sharing a written communication detailing the specified period of time (already mentioned in the contract) of commencement of the commercialization process for IP. Failure of the abovementioned will lead to Institute reserving the right to license the IP to third party/parties and money generated from such arrangements shall be shared equally between NIPER-R and the sponsor. NIPER-R will be charging an appropriate amount as a license fee as a lump sum or a recurring royalty. NIPER-R shall have the right to license IP to any other party non-exclusively or with limited exclusivity upon the expiry of the exclusivity period. In such cases, the money accrued by NIPER-R is non-distributable to the sponsor. Nevertheless, the exclusive license granted to the sponsor, NIPER-R shall have the right to license its IP during the period of license if the Government of India desires NIPER-R to disclose IP for use in national interest. In such cases, the royalty accrued shall be shared between the sponsor and NIPER-R on the basis of MoA.

Collaborative projects: The rights of licensing shall be held between the Institute and the collaborator. The first right for commercial exploitation of IP shall be granted to the collaborator by a written disclosure to the Institute within a pre-decided period of time commencing from the receipt of the final report. The terms will be mutually decided between

NIPER-R and the collaborator. In exceptional cases, where the collaborator fails to commercially exploit the IP within the pre-specified period as per contract, the Institute reserves the right to license the IP based on the mutually decided terms and conditions. NIPER-R shall have the right to license IP to any other party non-exclusively or with limited exclusivity upon the expiry of the exclusivity period. In such cases, the money accrued by NIPER-R can be shared with the collaborator on a mutually agreed basis. Nevertheless, with the exclusive license granted to the collaborator, NIPER-R shall have the right to license its IP during the period of license if the Government of India desires NIPER-R to disclose IP for its use in the national interest. In such cases, the royalty accrued shall be shared between the collaborator and NIPER-R on the basis of MoA.

10. Terms and conditions for revenue sharing

- i. A proper legally validated MoA should be framed for IP licensing and the Institute should be notified in a written document about the cost accounting.
- ii. The Institute should be contended about its obligations in the assignment and whether it has been executed in line with the MoA.
- iii. All the stipulated monies/fees should be received in their entirety.
- iv. The client has not opposed NIPER-R's contentment with its obligations as defined in the MoA.
- v. Innovators/ Primary contributors may comprise faculty and staff who have significant contributions in framing the creation; developing design and are on the payroll of either NIPER-R or on the contractual roster.
- vi. Other staff may comprise personnel who have provided direct support for the specific activity that includes research scholars, lab assistant(s), etc.
- vii. The remaining staff may comprise individuals who have not been enlisted in the immediate above two criteria and this group may involve IPR staff who assisted in the generation and commercialization of IP and also involved in future business development.
- viii. A standing committee appointed by the competent authority will consider and decide on the share of monies based on the recommendations of the Project Leader and after pondering on the project records. The recommendations framed by the standing committee shall be intimated to all the contributors and the same shall be displayed on the notice board. Objections/representations of any kind if not received within fifteen days from the notification date, the same shall be submitted for consideration and approval by the competent authority.

- ix. In case of any kind of representation against the recommendations within the specified time period, the standing committee should take them into consideration and frame fresh recommendations. The latter should be presented with detailed representations to the competent authority for contemplation and approval.

11. Fostering the growth and monetization of innovative concepts and technology

Commercialization of intellectual property involves converting the intangible creations of the human intellect into marketable products or services that generate revenue. IP commercialization has numerous benefits, including nurturing innovation, driving economic growth, and enhancing the competitiveness of the national economy. The exercises mentioned below can encourage IP commercialization procedures:

- I. Streamline the patent process
- II. Increase grants for research and development
- III. Provide incentives for commercialization
- IV. Boost technology transfer
- V. Provide legal and regulatory support
- VI. Increase public outreach
- VII. Encourage collaboration

The Indian government has recognized the importance of intellectual property (IP) in driving innovation and economic growth, and has taken several measures to stimulate IP licensing and commercialization. Here are some of the key initiatives taken by the Indian government:

- **Startup India initiative:** It was launched by the Indian government in 2016 to promote entrepreneurship and innovation nationwide.
- **National Intellectual Property Rights (IPR) Guidelines:** The National IPR Guidelines launched in 2016 by the Indian government promotes the creation, protection, and commercialization of IP.
- **Technology and Innovation Support Centers (TISCs):** The Indian government has established a network of Technology and Innovation Support Centers (TISCs) across the country to provide provisions to inventors and entrepreneurs. The TISCs also provide training and capacity-building programs to inventors and entrepreneurs to help them protect and commercialize their intellectual property.

- **Atal Innovation Mission**-The Atal Innovation Mission was launched by the Indian government in 2016 with the aim to create a network of incubation centers, accelerators, and innovation laboratories and to confer resources to startups and entrepreneurs.

To encourage intellectual property (IP) commercialization and licensing, NIPER-R believes in strategic directions that involve the following processes:

1. **Recognize and protect IP:** The Institute must identify innovative ideas and technologies developed by its researchers and protect them by filing for patents or copyrights.
2. **Appraise marketability:** The Institute should assess the commercial potential of the IP by conducting market research, analyzing the competitive landscape, and identifying potential customers.
3. **Set up partnerships:** The Institute must initiate building up partnerships with industry investors, and startups to leverage their expertise, resources, and networks for IP commercialization.
4. **Develop an entrepreneurship plan:** The Institute looks forward to developing a business plan that outlines the commercialization blueprints, identifies potential revenue streams, and disposes financial and operational goals.
5. **License the IP:** The Institute must arrange for IP licensing to companies or investors who have the potential to develop, manufacture, and market the product or technology.
6. **Monitor and enforce IP rights:** The Institute must keep track of the use of its IP and prosecute its rights by taking legal action against infringers.

12. Procedures for keeping records

A critical aspect in the course of the creation of IP is the record-keeping process, which helps to establish the originality and ownership of the intellectual property.

- The first step in this process is to document all research activities, including experiments, data analysis, and any other relevant information in Institute's laboratory notebooks, storage disks marked "PRIVATE & CONFIDENTIAL" with proper dates, page numbers, and avoiding mutilations. This information should be stored in a secure location (lead inventors/principal investigator/concerned faculty) and each document should be earmarked with a unique identifier to facilitate tracking and retrieval.
- Such documents should be properly authenticated by creator's initials and date.
- Explicit descriptions of all the methods used during experimentation should be provided and suggestions should be demarcated from the work actually executed.

- No non-standard abbreviations or terms should be used unless clearly defined either at the front or back of the record book.
- Rectifications should be made by drawing a line through the deleted matter and report as “canceled” beside it. The corrected input should be demarcated below and authenticated by the creators’ initials and date.
- Images of a new product formed either from the established protocol or a new protocol should be preserved and inscribed by the creator with the date.
- Establish a system for tracking deadlines and important dates in the proceedings.
- Maintain accurate and complete records of all correspondence, pleadings, and other documents related to the proceedings.
- Ensure that all records are stored securely and are accessible only to authorized personnel.
- Regularly review and update the case file to ensure that it reflects the current status of the proceedings.
- When the proceedings are concluded, archive the case file and related documents in accordance with applicable laws and regulations.

Overall, a robust record-keeping process is essential for the successful development and management of intellectual property assets. By exhibiting clear procedures for documenting and managing research work, inventors can protect their IP, maximize its value, and alleviate the risk of infringement or legal disputes.

13. Standards for Disclosure and Maintenance of Confidentiality

The personnel and students of the institute are required to sign appropriate documents regarding the confidentiality of information as defined by the institute. The Invention Disclosure Form provided in Annexure should contain a complete and thorough disclosure of all details, including the nature and specifications of the IP, the identification of all inventors, and a statement indicating whether the inventor(s) believe they own the IP or not, along with reasons for their belief. The inventors of the Intellectual Property must provide all necessary and relevant information to the IPR Cell to ascertain the patentability of their IP. The inventor must also provide any additional information and sign any documents as needed to ensure the effective protection and maintenance of the Institute's proprietary rights to the IP. If there are multiple inventors for different components that make up a system, they must be identified separately along with their respective contributions.

If an inventor creates any type of IP, they must agree to keep all relevant details of the invention confidential until the Institute initiates the process of securing IP protection by filing an application under the relevant laws. Without written permission from the Institute, the inventor is not permitted to disclose any such information, either in full or part, to any person or entity. Additionally, when seeking permission to disclose information, the inventor must clearly define the intended purpose of such disclosure. If the protection of the invention is through confidentiality, then the inventor must keep the same information secret and confidential for as long as the IP has commercial value. Every member of the IPR cell must sign an undertaking in compliance with this.

Inventors and/or Institute personnel must take care not to disclose any confidential details of Institute-owned IP in their publications, speeches, or other communications with the outside world, except after filing the IPRs.

All Institute personnel must treat all information related to IP as confidential until the information is publicly known only through and by the Institute.

Institute personnel are prohibited from directly disclosing or using, for their own purposes or the benefit of any third party, any confidential information about the Institute's IP, during or after the period of their appointment; unless that information is public knowledge or they are required by law to disclose it.

The Institute is responsible for keeping inventors of IP informed about the progress regarding the filing of the patent, commercialization, and/or disposition of the IP. The Institute and inventors must maintain transparency and share information at all stages of the process. The inventors are required to keep the Institute informed of any updates or developments related to the IP that have tangible effects on the property.

In cases where the IPRC needs help with searching for prior art and filing the application, experts may be called upon for assistance. However, the confidentiality of the intellectual property shall be strictly maintained.

14. Statement Regarding Infringements, Legal Responsibility, and Compensation by Inventors

The guidelines requires IP inventors to ensure that their work does not violate any existing copyrights or legal rights of third parties to the best of their knowledge. In case any part of the work is not original and belongs to someone else, inventors must either provide proof of

permission from the rightful owner or justify that such permission is not required under fair use. Additionally, inventors must confirm that the work does not contain defamatory material or invade the privacy of others.

If a third party accuses an inventor of violating their rights and the Institute's IPRC discovers that the inventor made false claims, the Institute will dissociate itself from the intellectual property immediately. Agreements between the Institute and the inventors should have provisions that indemnify the Institute against damages arising from such litigation.

NIPER-R is dedicated to establishing an efficient administrative entity that will examine any violation or infringement issue and recommend solutions to the competent authority. In case any third party is found to infringe upon NIPER-R's IPR, the administrative body will investigate the issue and suggest appropriate actions, including legal recourse.

Annexure I

INVENTION DISCLOSURE FORM

Elementary Information:

1. Full Name; address; designation; and nationality of the applicant/s:
2. Full Name; address; designation; and nationality of the inventor/s:
3. How would you describe the connection between the inventor and the applicant (employee/consultant)?
4. Contact details including the name, position, phone number, fax, and email address for correspondence.
5. Enumerate the countries where patent filing is required through PCT/Conventional Route.

Particulars pertaining to the invention:

1. Title of your invention:

2. The fundamental characteristics of invention:

(The description should be concise yet convey an accurate idea of the invention's essence without delving into its specific details) Kindly address the following aspects:

(a) Prior Art Status

- i. What is the current state of the art in the relevant field?
- ii. Has a literature search been conducted on this invention? Yes/No.
- iii. Has a prior art/patent search been performed on this invention? Yes/No.

(b) Novelty

(Identify the aspects mentioned above that distinguish the invention from others and make it innovative)

(c) Uniqueness

(Based on the prior art status mentioned in (a), state the unique features of the invention? If so, please explain how)

(d) Advantages

(What are the advantages of the invention over the existing contemporaries?)

Funding details:

(Did the invention receive financial support from external sources in the form of research grants or contract funds?)

Give details as per following:

- I. Sponsor/Funding agency
- II. Grant/Contract No.
- III. Period of grant/contract
- IV. Principal Investigators/Co-investigators *(This pertains to individuals who, while not classified as inventors under the scope of this document, may have contributed to the invention and are not entitled to recognition or royalties)*
- V. Have you notified the sponsor/funding agency of the invention? *(Please indicate whether such disclosure is mandatory under the conditions of the grant or contract award)*

Revenue potential:

Please provide the following information regarding the commercial potential of IP:

(a) Potential applications and/or products that could incorporate aspects of technology.

(b) Potential end-users.

(c) Potential for commercialization *(should include commercial suggestions such as necessary inputs; capacity for production, if relevant; requirements for raw materials; method of transfer; companies and countries targeted; economic information; potential for sustained commercial success; use additional sheets if necessary)*

(d) Have you shared information about the invention with industry representatives or any third parties? Has anyone expressed commercial interest in the technology, and if so, what type? Please provide the name of individuals with their designation and industrial affiliation.

Following questionnaires demands accurate data is required, as prior disclosure may affect patentability:

- Has the date when the idea or concept for the invention was first formed been recorded and documented? If yes, please provide details such as the page number of the lab notebook where it was recorded, the date of recording, and the signature(s) of the inventor(s) as well as any witness (es).
- Has this invention been presented at any seminars or discussions that were not required as part of the student's degree program? If yes, please provide the details about the date of submission for such presentation.

Declaration

I/we affirm that all the information provided in this document is accurate to the best of my/our knowledge. Furthermore, I/we acknowledge and agree that all rights, title, and interest in the invention shall be assigned to the Institute. I/we will execute any required documents to transfer my/our rights in any patent filed on the invention to the Institute and cooperate with the Institute to protect and commercialize the invention. In the event that any royalty income is generated from the invention, the Institute will share it with the inventor(s) in accordance with the prevailing IPR policy. Alternatively, if the work was carried out without significant use of Institute's resources, the Intellectual Property Rights will belong to me/ourselves.

_____	_____	_____
Inventor's Signature	Date	Place
_____	_____	_____
Inventor's Signature	Date	Place

Terms and Termination:

This document holds great legal significance as it serves either of the following purposes:

- (a) It forms the foundation for determining the patentability of an invention and drafting a patent application, or
- (b) It is essential for establishing a claim in cases where the invention is in the conception stage and the inventors seek support from third parties for reducing it to practice and/or further development before patenting.

A patentable invention must not be obvious to a person with average skills in the relevant technology and must not have been previously described in a printed publication or available in the public domain. Patents confer the right to an inventor to exploit a commercial invention for a limited period of time. However, patents can be lost if the details of the invention are disclosed to the public before filing. Patents are not automatic rights like copyright. To obtain a patent, the proposed invention must be novel, inventive, and industrially applicable. Once the patent is sealed, the patentee can sue anyone who attempts to exploit the patented invention without their consent. The IPR policy provides examples of patentable innovations. If, for any reason, patenting is not feasible for an innovation, it can be protected to some extent by limiting the publication of information about it (secrecy).

Please submit the completed disclosure form to the IPRC of the Institute.

Annexure II

REFINED STRUCTURE FOR EVALUATING PATENT PROPOSALS

Title of Invention:

Inventor(s):

Department(s):

Disciplinary/Interdisciplinary (Tick):

Own/In Collaboration with Industry/In Collaboration with other Institute(s)

Funding approx. expenditure required:

Evaluation of the patent proposals should be based on the following salient points:

1. Theme or idea or topic is product/process/method:

Comments of committee members:

2. Confidentiality of patent maintained by inventors (Yes/No)

Comments of committee members:

3. Whether meeting following patentability criteria (Yes/No):

- novel
- non-obvious to person skilled in art
- industrial applications/utility
- Stability

Comments of committee members:

4. Prior art/literature survey done by inventor(s) personally (Yes/No):

Comments of committee members:

5. Invention Disclosure Form (IDF) sufficiently explains patents with diagrams (Yes/No):

Comments of committee members:

6. Draft of patent given (Form 2) (Yes/No):

Comments of committee members:

7. Provisional or Complete Specification (Provisional/Complete)

Comments of committee members:

8. How many inventor(s) are involved in patent work? (One/Two/Three or more)

Comments of committee members:

9. Inventors and applicant are same or different? If different, mention

Comments of committee members:

10. Whether lab notebook/storage disks as proof of patent is maintained (Yes/No):

Comments of committee members:

11. Whether inventor(s) are interested in patent commercialization/technology transfer (Yes/No). Mention if parallel development of patent and product (Yes/No)

Comments of committee members:

12. Whether inventor(s) wish to develop product/process/method on their own/in collaboration with industry/in collaboration with institute. Mention the share fees if external person or industry involved

Comments of committee members:

Committee expert's/members' confidence level on patent topic (Rating:1= narrow applicability; 5=broad applicability)

Committee members' Signature with date

Following documents to be submitted to IPRC:

- Annexures I-IV,
- Form 2 Complete Specifications,
- Prior art/literature survey,
- MOU/MoA

Chairperson final comments/suggestion/decision to IPR Cell: Forwarded and recommended,
Forwarded with comments, Rejected with reasons/comments

Approximate expenditure of patent:

Reasons/comments:

(Signature with Name of Chairperson with Date)

- ✓ To ensure a comprehensive evaluation of patent topics, the committee must use above rubric questionnaire as a guide to assess the technical competence of the patent.
- ✓ The committee will provide recommendations and comments to the competent authority, which will be recorded by the IPRC.
- ✓ Inventor(s) are required to deliver a concise presentation to the committee, focusing on the rubric points. They may also present signed hard copies of draft patent documents, including invention disclosures, product/process/method designs, and data sheets.
- ✓ In addition, the inventor must complete a Non-Disclosure Agreement with the committee members and provide a copy of the agreement to the IPRC.

Annexure III

REVENUE SHARING AGREEMENT FORM

To
The Director,
NIPER-Raebareli

I/We, _____, from the Department of _____ at NIPER-Raebareli, who are responsible for the creation of the invention titled " _____ "under IP Application No. _____, hereby agree to comply with the revenue sharing clause of the IPR Regulations of NIPER-Raebareli.

Please find below the details of the all inventor(s) involved in the creation of the invention. We have attached our signatures below as a sign of our agreement to the terms and conditions set forth in the IPR Regulations of NIPER-Raebareli.

Sincerely,

Name(s) of the inventor(s):

[Name]

[Place]

[Signature with date]

Annexure IV

Inter-Institutional Collaborator Disclosure Authorization Form

To be filled and submitted by Collaborators from External Institutes before IP filing through NIPER, Raebareli

[Name of the Institute]_____, solemnly affirm our commitment to the guidelines outlined by the National Institute of Pharmaceutical Education and Research, Raebareli (NIPER-R), regarding intellectual property (IP) management and commercialization in the collaborative research project titled [Title]_____. The institute acknowledges and categorizes projects as sponsored/collaborative/grant-in-aid, and pledges to adhere to NIPER-R's comprehensive costing structure encompassing various expenses.

In full comprehension of NIPER-R guidelines, the institute acknowledges the distribution of intellectual fees among staff members, agrees to comply with licensing conditions for intellectual property, and accepts terms for revenue sharing as per our mutual decision is this_____.

Our institute is fully aware of measures for commercialization and recognizes the paramount importance of meticulous record-keeping in this regard.

Our institute confirms its unwavering commitment to upholding standards for disclosure and confidentiality, understanding the significance of these measures. Additionally, the institute declares its responsibility to prevent infringements diligently.

By affixing the authorized signature below, we hereby certify that we have thoroughly read, comprehended, and willingly agreed to comply with the guidelines established by NIPER-R. Furthermore, it is hereby affirmed that all information provided in this declaration is accurate to the best of our knowledge.

[Name]

[Institute]

[Signature]

[Date]

[Official Seal of the Institute]

Annexure V

Certificate of No Objection for the filing of Intellectual Property Rights

To be filled upon NIPER, Raebareli's request for complete ownership

**Reference: Application for Filing IPR titled _____
from the National Institute of Pharmaceutical Education and Research (NIPER) Raebareli**

[Institute Name] _____ hereby confirms that there are no objections to file the Intellectual Property Rights (IPR) for the specified application, as indicated above, from the National Institute of Pharmaceutical Education and Research (NIPER) Raebareli. The proposed IP is unrelated to the official duties or roles within our Institute, and no institutional resources have been utilized in its creation. Consequently, we grant permission to independently own, protect, or license the IP to NIPER, Raebareli.

It is important to note that this approval is contingent upon adherence to our Institute's policies. The Institute acknowledges and expresses gratitude for NIPER, Raebareli for their commitment to managing the formalities associated with filing the IP for rights.

Authorized Signature: _____

Name and Designation: _____

Official Seal: _____

Date: _____