University of Alkafeel

Alkafeel Research Center for Pharmaceutical Medical Science (ARCPMS)

Research Agreement Principles: Intellectual Property Rights and Expensive Scientific Research-equipment

Version 1

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1. Introduction

Research within the health sector is increasingly being based on collaborations, state-of-the-art technology, and the creation of intellectual property. **ARCPMS** understands the paramount nature of the creation of clear, transparent and enforceable policies that regulate the intellectual property rights (IPR) and the handling of high-cost scientific equipment. These principles serve to give a coherent framework to guarantee the safeguarding of the research products, the fair use of the resources, and the adherence to the national and international norms.

The key aims of this guidance are to guard intellectual inputs, make research infrastructure utilization responsible, and encourage collaboration within the University and with other partners. Formalization of the principles and procedures of IPR management and high-cost equipment usage can help the **ARCPMS** maximize the effectiveness of research, promote innovation, and ensure ethical and legal compliance. The guidelines are supposed to be applicable to any type of research performed in the Centre, both internal research, collaborative research, partnership with other universities, collaboration with government and non-government bodies and sponsored research programs with the industry partners.

The document is consistent with best practices defined by international organizations, such as the World Intellectual Property Organization (WIPO), the Organization for Economic Cooperation and Development (OECD) Principles on Access to Research Data, and policies of major world research universities worldwide. Its stipulations are meant to make sure that intellectual property and scientific equipment are utilized effectively, safely, and ethically to promote knowledge and benefit the health of the population.

2. Intellectual Property rights (IPR) Operational Framework in Research Collaboration

2.1 The Essentials of Intellectual Property Rights.

The intellectual property rights play a central role in acknowledging and securing the creativity and innovation of the researcher. At ARCPMS, the policies on IPR have been based on **equity**, **openness**, and **accountability**.

2.1.1 The concept of **equity** guarantees that both principal and co-investigators, students, and technical employees will be rewarded in the research results and will receive the benefits of the research.

2.1.2 **Openness** involves that rights, responsibilities, and obligations be written in written agreements and hence decreasing disputes and enhancing trust in the collaborators.

2.1.3 The notion of **accountability** demonstrates the desire by the Centre to apply intellectual property in a way that, it contributes to society, specifically in the health sector where the ethical ramifications of accessing medical innovations might be immense.

To promote intellectual property protection, the **ARCPMS** promotes the establishment of proper legal safeguards like patents, copyrights, trademarks, and trade secrets. The University is the primary owner of IP generated with its resources unless otherwise stated. Inventors are however known as authors or inventors and entitled to receive part of the revenues that could come out of exploitation, according to internal policies. Such balance of institutional rights and individual acknowledgment results in a culture of innovation and keeps the interests of the University.

2.2 Allocation of Rights in Research Results and Outputs

The rights of research products are defined according to the manner in which funding was attained, how partnership was formed and the manner in which institutional resources were exploited.

2.2.1 In the case of research wholly financed by the University, the intellectual property generated in the process of the work belongs to the University. This will ensure that any findings done can be taken care of, preserved and utilized to the benefit of the research fraternity and the population at large. Researchers who get engaged in such projects still get their contributions recognized and could even share in revenue in case the outputs are commercialized.

2.2.2 In collaborative research where external partners are involved, ownership is established based on the contribution of the parties. The ownership, right to use, and responsibilities should be written and stated before the research is conducted. This involves the determination of how any resulting IP is to be managed, licensed or commercialized.

2.2.3 Where sponsored research is concerned, supplied by third parties, the University may grant the sponsor limited rights such as first-option licenses, but retain the right to publish results, to use findings in instruction, and to do additional research. Such agreements should always be made officially in order to be clear and prevent any future disputes.

2.3 Copyright, Patent, Trademark and other related rights

The University safeguards a wide range of intellectual property created by research processes.

2.3.1 **Protection of Copyrighted Works** is used to protect written works, teaching materials, software, and databases; the protection guarantees the rights of the creators.

2.3.2 **Patents** protect inventions, methods used in the laboratory, and even medical devices and provide legal remedies to prevent illegal commercial exploitation.

2.3.3 **Trademarks** guard branding of university-innovated goods, equipment or applications.

The **ARCPMS** seeks that new inventions, software, and other creative work be reported to **Technology Transfer Office (TTO)** that evaluates their commercial potential and secures legal protection.

Patenting can be done internationally where it is warranted particularly where the discoveries are of worldwide health concern. Exploitation is not the only reason to protect IP by patent or other legal means; it also guarantees the University the freedom to work with industry and governmental partners without fearing infringement, as well as the right to share knowledge and engage in academic freedom.

2.4 Privacy, disclose and Non-Disclosure Obligations

2.4.1 **Privacy** is not only required to protect intellectual property, but it is also ethically imperative.

2.4.2 **Non-**Disclosure Agreements (NDAs) will be signed by the researchers, their collaborators and external partners before accessing sensitive information about the research or proprietary methodology. NDAs provide official guidelines that the confidentiality of information shall not be revealed to unauthorized entities.

2.4.3 Inventions or initial discoveries should be **disclosed** in a cautious manner. Publications, communications, or presentations in public may also be considered as a threat to patent rights when they are made without protection. Hence, it is the obligation of researchers to arrange disclosures with TTO and to act according to the policies of the University regarding the protection of intellectual property.

The preservation of confidentiality also builds trust between the University and other partners that is critical in the development of long-term collaborations. Publications should not take place until patent applications (where appropriate) have been submitted in order to protect rights.

2.5 Authorizing, Exploitation, and Revenue Sharing

2.5.1 Intellectual property **authorization** is a significant tool in knowledge and technology transfer to the broader community. By issuing licenses (non-exclusive and exclusive) to third parties, the University can assure that the outputs of research are used responsibly and on an ethical and commercial basis. Licensing agreements should specify the terms of use, royalty, requirements to perform and reporting requirements.

2.5.2 The concept of **revenue sharing** is one of the principles that motivate researchers and maintain the institutional support of innovation.

2.5.3 The University has developed policies that distribute the revenue obtained by IP **exploitation** to inventors and departments, as well as central research funds. This will support innovation in an environmentally friendly manner to sustain the **ARCPMS** and the wider research program financially.

2.6 Disagreement settlement

Even with the best efforts, there could occur disputes on intellectual property. To adequately address such cases, the University has a levelled disagreement settlement process. The first consists of direct negotiation between the parties involved. When no resolution can be reached, then the issue is referred to the IPR Committee of the University which mediates and makes binding recommendations. Litigation or arbitration in a court of law is used as the last option. This systematic process lessens the exposure of the research activities and allows settling conflicts fairly and openly.

3. Research Collaboration Agreements and Regulations

3.1 Collaborative Research Agreements (CRA)

Collaboration involves research in which research partnerships are very important in the development of the health sciences. These collaborations need to be formalized by conventions which outline the scope, purpose, duty, and role of each party. Well-defined agreements assist in controlling expectations and avoid conflict over the ownership of IP, rights of publication and exploitation.

The policies on data management, such as data collection, storage, sharing, and publication of research findings, should also be stipulated by these agreements. They should outline how the results should be reported, how the contributors are to be rewarded and how conflicts need to be resolved. These arrangements make the University assure that the collaborative research work is done ethically, transparently, and productively.

3.2 Funded Research Agreements

Research can be funded by external agencies (e.g. partners in the industry or government) and explicit contractual arrangements are necessary. These contracts should specify the right of the sponsor to exploitation without any infringement on the right of the University to publish, to use the results to make instruction, and to continue research.

Funded research agreements should provide an agreement on the funding terms, schedule, deliverables, reporting requirements, and intellectual property ownership. Clear language on the rights to publish materials secure the continuation of academic freedom and that research results will be used to benefit the general population while addressing the profitability issue.

3.3 Scientific Material Transfer Agreements (SMTA)

Publicity of actual scientific studies that comprise biological materials, reagents, or cells is that related with official agreements to uphold right of possession, usage, and ethics-conformity. SMTAs are used to clarify what can be permitted, what should not be used in

business and what should be done to give credit to the source of materials. They also promote adherence to biosafety, import/export limits and institutional rules.

3.4 Data Sharing Agreements (DSA)

Health research is often based on personal or clinical information that is sensitive. Data sharing contracts offer a legal and ethical framework in handling such information. They define access permissions, permitted usage, a stipulation to maintain confidentiality, and integrity data requirements. In case of necessity, DSA must confirm that they live up to the national privacy legislation and international regulations, such as General Data Protection Regulation (GDPR). The basic aspects of these agreements involve anonymization, secure storage and controlled access procedures.

3.5 Memoranda of Understanding (MOU)

MOUs create initial agreements between the University and third parties with regards to research cooperation or joint usage of expensive equipment. They have to be consistent with university policies regarding intellectual property and equipment management and will not form binding obligations or convey rights. All MOUs should expressly indicate that certain conditions on IP ownership, funding or access to equipment will be detailed in later formal agreements as per these directives.

4. High-tech Research Instrumentation

4.1 Purchasing and Procurement Policies

The purchase of expensive scientific equipment should be well planned and justified. The procurement process should be transparent and in line with research requirements, possible impact, and cost-effectiveness. Orders of new equipment must include specifications, envisioned use, operation needs, and maintenance and lifecycle management plan.

4.2 Investment Strategy and Cost Distribution.

The costly equipment can be financed by university funds, government grants, or industry assistance. Cost sharing with third parties should have clear ownership, rights of use, and responsibilities in terms of operating and maintenance expenses. The financial arrangements are to be recorded in written form to avoid conflict and provide fair access.

4.3 Proprietorship, Availability, and Utilization Guidelines

The University owns equipment and is not to be deemed as an implicit alternative unless otherwise. The access policies are used to make sure that the equipment is utilized efficiently to aid research goals. Internal research projects are often accorded the first priority though there is an option to give external collaborators the chance to utilize equipment under an approved contract. Utilization should be planned, observed and recorded to streamline efficiency and responsibility.

4.4 Procedures of Scheduling and Access Control

High-demand equipment needs to be managed through a centralized scheduling system. Equipment should be reserved and adhered to by the researchers. Critical research projects can be assigned priority utilization, which could include projects of urgent public health

importance or projects that have been financed by competitive grants. The scheduling machine should provide equity, transparency, and traceability of utilization.

4.5 Training, Certification and Safety Compliance of the User

High-cost equipment may be handled by only trained and certified personnel. The training programs should include technical operation, safety measures, adherence to ethical principles, and good documentation. As a way of ensuring that all users are up to minimum competency standards, certification minimizes chances of accidents, equipment damage and errors in research.

4.6 Maintenance, Upgrading and Replacement

Maintenance and calibration are necessary to maintain accuracy, reliability and durability of expensive equipment. The University is obliged to have service contracts in place, to have detailed maintenance records, and to offer technical assistance to users. The proactive maintenance saves the time, guarantees the maintenance of the research quality, and secures the institutional investment.

Equipment replacement or upgrade decisions must take into consideration the technological relevance, operational efficiency and cost-benefit analysis. The disposition of out-of-date machines has to adhere to regulations on safety, environmental, and institutional policies. The significance of proper disposal is to safeguard employees, site, and safety of the people, and to have a sound stewardship of the University resources.

5. Administrative Structuring and Control Systems

Powerful administration of the intellectual property and costly machinery needs distinct administration frameworks. The ARCPMS has set up an oversight committee to give strategic leadership, oversee compliance, and settle conflicts. Distribution of responsibilities is among the leadership of the ARCPMS, the Technology Transfer Office, and departmental administrators.

The oversight committee oversees compliance with institutional policies, ethical standards and legal requirements. Accountability and transparency are achieved through regular audits, reporting and performance assessments. In order to preserve trust, fairness, and integrity in research, conflicts of interest should be proactively disclosed and managed.

The external partners, collaborators, and researchers must adhere to the University policies of managing intellectual property and equipment before embarking on any project. These guidelines have to be formally accepted by all parties by filling in the Acknowledgment and Acceptance Form (See Annex I).

To help coordinate or sponsored projects, any activity that involves the use of the University resources or equipment should be registered through the Research Project / Equipment Access Record (See Annex II). A Usage and Responsibility Record should also be filled where equipment is of high cost (See Annex III).

6. Conclusion

The ARCPMS is dedicated to the excellence, innovation, and accountable management of resources. Intellectual property laws and the management of high-cost equipment should have clear guidelines to encourage ethical, efficient, and impact research. The application of such principles means that by conducting research, the Centre is sure that the results will help the academic community, as well as the society, though remain compatible with the international standards and best practices.

These guidelines will be adopted to promote collaboration, protect intellectual property, maximize utilization of research infrastructure, and strengthen the role of the University as the leading institution in health sciences research.

Annex I: Acceptance and Recognition of guidelines

The present document establishes that the undersigned parties have read the Guidelines of Research Agreements: Intellectual Property Rights and High-Cost Scientific Research Equipment of the ARCPMS and approved them.

Name of Approving Authority	Title / Position	Institution / Department	Signature	Date

Optional: Add the annex II and III to the operational records in case the document will also address certain projects or allocations of equipment.

Appendix II: Research Project / Equipment Access Form.

Project Title	Research Coordinator /Leader	Sponsoring Entity	Agreement Classification (MOU / Sponsored / Collaborative / MTA)	Authorization Code	Date of Authorization

Annex III: Record of High-Cost Equipment Usage and Responsibility.

Name	Title/Position	Department	Signature	Date	Comments