



KING EDWARD MEDICAL UNIVERSITY

Policy on Intellectual Property Rights

Objectives:

- I. To establish a clear and sound framework for the encouragement of invention, innovation, creative work and technological development;
- II. To protect the rights of researchers/students with respect to the products of their intellectual endeavors;
- III. To set out a framework to protect the creative efforts of the University and its employees and students, and economic and other investments made by the University;
- IV. To protect the interests of the University, including ensuring that the use of the University name and insignias is accurate and appropriate, and ensuring that the University receives appropriate value in the commercial development of its intellectual property.

1.0 Definitions:

1.1 **Intellectual Property:** includes Works and Inventions as defined below.

1.2 **University:** means **KING EDWARD MEDICAL UNIVERSITY**.

1.3 **University Personnel:** includes all full-time and part-time employees of the University, fellows and residents, interns, volunteers and any non-employees who receive University Support, including visiting faculty, in respect of their work at the University.

1.4 **Students:** includes all full-time and part-time students of the University, including visiting students.

1.5 **University Support:** means financial or any other support including but not limited to salaries, personnel, facilities, equipment, data, materials or technological information, regardless of origin, which is used in the discovery or development of Intellectual Property and is provided through University channels.

1.6 **Work(s):** shall include any copyrightable material, such as printed material, procedure manuals, computer software or databases including pedagogical software, audio and visual material, , pictorial or graphic works and material related to teaching, including but not limited to lectures, course outlines, programme proposals and descriptions, case studies, and other learning materials including textbooks.

1.7 **Invention(s):** include any discovery, process, composition of matter, article of manufacture, know-how, design, model, technological development, biological material, strain, variety, culture of any organism, or portion, modification, translation or extension of these items, and any mark used in connection with these items.

1.8 **Inventor/Author:** means a member of University Personnel or Student who creates a Work or Invention.

1.9 **Patent:** is an exclusive right granted by the Government allowing the applicant to exclude all others from making, using, or selling his/her invention within a particular territorial limit for a limited number of years.

1.10 **Trademark:** or a service mark is a distinctive word or a graphic symbol identifying the source, producer or distributor of goods or services.

1.11 **Copyright:** a legal right of the author(s)/creator(s)/owner(s) of copyright to exclusive publication, production, sale and distribution of their work both domestically and internationally regardless of how it is published. Copyright protects the "expression" of an idea, not the idea itself.

1.12 **Computer programme/software:** any computer programme regardless of form of expression or object in which it is embodied, together with any users' manuals and other accompanying explanatory materials and any computer database.

1.13 **Contract:** is a legally binding agreement between two or more parties in which an exchange of value occurs, and which ties each party to certain liabilities covering that exchange. Those signing such an agreement must be authorized to bind the entity that they represent.

1.14 **Tangible Research Property (TRP):** means any tangible items produced in the course of research projects either through University Support or by external sponsors and includes but is not limited to biological materials, cell lines, data sets, computer software, computer databases, prototype devices and equipment.

1.15 **Net Income:** income remaining after deducting all costs incurred for obtaining, protecting, marketing and licensing the Intellectual Property by the University.

1.16 **Scholarly Work:** means a copyrightable work created by any University Personnel as evidence of academic advancement or academic accomplishment including, but not limited to, scholarly publications, journal articles, research-based bulletins, monographs, books, (excluding case-studies and textbooks and other works of commercial value), plays, poems and musical compositions.

2.0 Application

2.1 This Policy is applicable to all Intellectual Property developed or created in the course of work or study at the University with University Support. This Policy extends to all University Personnel and Students and applies to all programmes supported by the University, including all campuses, hospitals, institutions, owned, controlled, managed and/or operated by the University.

3.0 Ownership, Creation, Development and Protection of Intellectual Property

3.1 The University owns all rights, title and interest in and to Intellectual Property developed as a result of University Support. By accepting employment with or enrolment in the

University, University Personnel and Students hereby assign and agree to assign to the University all of their rights, title and interest in and to Intellectual Property developed as a result of University Support unless otherwise agreed.

3.2 Ownership of Intellectual Property emerging from all sponsored research including clinical trials and partnerships will be negotiated separately taking this Policy and the interests of the University into account.

3.3 Patents

3.3.1 All potentially patentable inventions conceived, designed or created by University Personnel and Students in the course of their University responsibilities or with University Support shall be disclosed on a timely basis to the University.

3.3.2 All University Personnel and Students are expected and obliged to notify and to disclose to the University any discovery or invention which may be useful, patentable, or otherwise protectable, including potentially useful biological materials, devices, and software, even if not patentable.

3.3.3 The University shall have the first right, either directly or through an outside agent, to evaluate and seek patent protection of the Invention, and to undertake efforts to introduce the Invention into public use. The Inventor is expected to cooperate (at no expense to the Inventor) with the University and/or the outside agent, including assigning to the University any ownership rights the Inventor may have in order to permit the University or the outside agent to evaluate the Invention, to seek a patent, and/or otherwise to introduce the Invention into public use.

3.3.4 Royalties or other income resulting from the Invention will be shared among the Inventor, the University in accordance with section 4.4 as well as other applicable University policies and any relevant terms of any agreement between the Inventor and the University.

3.3.5 If the University does not want to seek patent protection of the Invention, it will inform the Inventor who can then pursue patent protection if he/she so wishes independently and at no cost to the University. Under such circumstances, the agreement shall include an apportioning of some appropriate share of resulting revenue to the University.

See Annexure A for further information on filing patents.

3.4 Copyright

3.4.1 The University shall own copyrightable works as follows:

(a) Works created pursuant to the terms of a University agreement with a third party;

(b) Works created as a specific requirement of employment or as an assigned

University duty that may be specified, for example, in a written job description or an employment agreement;

(c) Works specifically commissioned by the University. The term "commissioned work" refers to a copyrightable work prepared under an agreement between the

University and the creator when (i) the creator does not fall under the category of University Personnel or (ii) the creator is a University employee but the work to be performed falls outside the normal scope of the creator's University employment. Contracts covering commissioned works shall specify that the author convey by assignment, if necessary, such rights as are required by the University

(e) Works by Student(s): Unless provided otherwise by written agreement, copyrightable works prepared by students as part of the requirements for a

University degree programme shall be the property of the student but are subject to the following provisions:

i) The original data and materials (including software) researched for a graduate thesis or dissertation are the property of the University but a copy may be retained by the student at the discretion of the student's principal department.

ii) The University reserves the right, as a condition of awarding the degree, to retain, use and distribute a limited number of copies of the thesis, royalty free, together **with the right to require its publication for archival and/or educational use.**

3.4.2 Video-recording, Computer Software, Pedagogical Software: Courses developed and used for teaching at the University belong to the University. Any courses, which are video-recorded or recorded using any other media, are University property, and may not be further distributed without written permission from the Department Head.

3.4.3 Textbooks and case-studies intended primarily for instructional uses and to be distributed commercially.

3.4.4 Unless provided otherwise by written agreement, the University shall not claim ownership of Scholarly Works.

3.5 Trademarks

3.5.1 The University owns all rights, title and interest in any Trademarks (registered or otherwise) that relate to the University or relate to a programme of education, service, public relations, research or training by the University.

3.6 Computer Programmes

3.6.1 All Intellectual Property rights to computer programmes and applications shall vest with the University if:

- (a) it was created or developed by University Personnel or Students with University Support;
- (b) it was made or developed pursuant to a sponsored research agreement in which case unless the agreement explicitly determines ownership, the ownership and the Intellectual Property rights of such computer programmes shall vest with the University.

3.7 Other Intellectual Property

3.7.1 All rights, interests and title to any and all Intellectual Property created or developed by or at the University shall vest with the University.

3.7.2 For the purposes of this section, Intellectual Property rights created or developed by or at the University include,

(a) Intellectual Property rights resulting or arising out of the activity of the creator, author or inventor's employment or engagement with the University; or

(b) Intellectual Property rights created or using resources or facilities of the University.

3.7.3 Developed by University Personnel or Students using University Support will be the property of the University subject to agreements with appropriate funding sources.

See Annexure B for more information on TRP.

4.0 Administrative Procedures

4.1 **Research Office:** The University Research Office shall be responsible for the management of this Policy, including all activities pertaining to the evaluation, patenting and licensing of new Inventions and discoveries made at the University.

4.2 The Research Office shall serve as a point of reference for all members of the University for:

i) providing educational resources on Intellectual Property issues and guidance for the creation and development of Intellectual Property;

ii) generating collaborations with industrial partners for new sources of research sponsorship;

iii) protecting Intellectual Property while protecting academic priorities, interests and values;

iv) evaluating whether the research results and/or Inventions are patentable and navigating it through the patenting process with the assistance of the Legal Office of the University;

v) effectively transferring discoveries and inventions from the classroom and laboratory into commercial development;

vi) monitoring research and license agreements to ensure the development and commercialization of the technologies;

vii) managing the Intellectual Property portfolio of the University.

4.3 Signing Authority

4.3.1 Research Office, through its duly authorised personnel, shall have the signing authority on behalf of the University for various agreements, such as licenses, material transfer, industrial contracts and others pertaining to the ownership and management of Intellectual Property once all such agreements have been reviewed by the Legal Office. University Personnel and Students are not authorized to sign any agreements or documents that obligate the University to assign or license intellectual property rights to another entity.

4.4 Income Sharing

4.4.1 The formula of distribution of Net Income arising from the commercialization of any Intellectual Property will be negotiated on a case-by-case basis as a function of particular circumstances, including the extent of University support for the development of the Intellectual Property. Normally each of the following will be apportioned a share of the revenue with the larger share flowing to the Inventor:

- (a) The Inventor(s);
- (b) The Department(s) of the University in which the Inventor(s) involved in the creation of the Intellectual Property is/are deployed;
- (c) The Research Office; and
- (d) The University, to be used at the discretion of the President

Negotiations on behalf of the University will be conducted by the Dean of Research and Graduate Studies or designate in consultation with the head of the academic unit of the Inventor.

4.4.2 Person(s) whose Work or Invention is owned by the University as commissioned work are not entitled to royalties under this Policy.

5.0 Dispute Resolution

5.1 Disputes between members of University Personnel research teams: If a dispute or concern arises with regard to ownership of the Intellectual Property, efforts should be made to resolve it within the University Personnel research team. If the dispute persists, and if all the University Personnel belong to the same department, the aggrieved party shall approach the Departmental

Head for resolution of the dispute. If members of the research team are from different departments, the aggrieved party may refer the dispute for resolution to the **Director Research/ORIC**, through their Head of Departments and Chairpersons.

5.2 If the aggrieved party is not satisfied with the decision of the Departmental Head or the Dean of Research, they may approach the VC to settle the dispute. The VC may appoint a sub-committee led by a member of the **University Research Council** to look into the dispute. The decision of the sub-committee will be final and binding on all parties.

5.3 Any dispute between University Personnel and the University with respect to the application of this Policy shall be referred to the VC whose decision shall be final and binding on all the parties.

5.4 Any dispute between University Personnel and Students or between Students relating to the ownership of Intellectual Property shall be referred to the Department Head. If the matter is not resolved through the intervention of the Department Head, the matter shall be referred to the VC whose decision shall be final and binding on all the parties.

Related documents and policies:

1. Annexure A - Assessment of Invention and Criteria for Filing Patents (page 10)
2. Annexure B - Access and Control of Research Data and TRP (page 12)
3. HR/PP-14 Conflict of Interest Policy (HR Policies on the KEMU intranet)

References

1. Intellectual Property Policy, The Agha Khan University, 2013
2. Intellectual Property Policy, The Johns Hopkins University, October 5, 2011.
3. Guidelines on Developing Intellectual Property Policy for Universities and R&D

Organizations, World Intellectual Property Organization, Geneva, Switzerland, December 2004.

4. Statement of Policy in regard to Intellectual Property. Office of Technology Development, Harvard University, May 1, 2012.
5. Policy on Intellectual Property Rights. Office of Research Support, Duke University, May 11, 2000.
6. Intellectual Property: Inventions, Patents, and Licensing. Stanford University, USA.
7. Revised Intellectual Property. University of Illinois, Urbana-Champaign Senate, February 9, 1998.
8. Intellectual Property Organization of Pakistan.

Annexure A

ASSESSMENT OF INVENTIONS AND PROCESS AND CRITERIA

FOR PATENT FILING

Patentability

1. A patent is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. In order to be patentable, the invention must fulfill certain conditions.
2. An invention must, in general, fulfill the following conditions to be protected by a patent:
 - #It must be of practical use;
 - #it must show an element of novelty, that is, some new characteristic which is not known in the body of existing knowledge in its technical field. This body of existing knowledge is called "prior art";
 - #it must show an inventive or non-obvious step which could not be deduced by a person with average knowledge of the technical field; and
 - #its subject matter must be accepted as "patentable" under the applicable law.

3. In general, an application for a patent must be filed with the local Patent Office, and a patent shall be granted and enforced, in each country in which the University seeks patent protection for its invention, in accordance with the law of that country. In some regions, a regional patent office, for example, the European Patent Office (EPO) or the African Regional Intellectual Property Organization (ARIPO) which accepts regional patent applications, or grants patents, which have the same effect as applications filed, or patents granted, in the member States of that region.

4. It is important to file a patent application before publicly disclosing the details of the invention. In general, any invention which is made public before an application is filed would be considered prior art. The applicant's public disclosure of the invention prior to filing a patent application would prevent him/her from obtaining a valid patent for that invention, since such invention would not comply with the novelty requirement.

5. In patent law, the word "publication" is interpreted much more broadly than when used in the typical research community. A publication or public disclosure is anything that is made readily available to the public (a journal paper, a conference presentation, a publication on the World Wide Web, even a dissertation indexed at the library) that describes the basic ideas in enough detail that someone else would be able to make and use the invention; i.e., those ideas that are new. Showing or telling these ideas may also constitute disclosure, as does selling or offering for sale a prototype of the invention.

April 2014 IPR Annexure A Completion of Checklist

6. A checklist can be obtained from the Legal Office which requires the inventor to provide information about a potential patent, what was invented, circumstances leading to the invention, and facts concerning subsequent activities. It provides the basis for a determination of patentability and the technical information for drafting a patent application.

7. Inventors must complete and submit the checklist to the Legal Office for each potentially patentable invention conceived or first actually reduced to practice in whole or in part in the course of their University responsibilities or with more than incidental use of University resources. The Legal Office requires a minimum of two (2) weeks to review the information provided and shall then contact the inventor for further information and next steps.

Licensing Strategy

8. The University recognizes that protection of proprietary rights in the form of a patent or copyright are often necessary, particularly with inventions derived from basic research, to encourage a company to risk the investment of its personnel and financial resources to develop the invention.

9. In order to commercialize intellectual property, the fundamental mechanism is licensing, i.e. the granting of permission, under certain terms and conditions, for the commercial business or company to use the intellectual property. Licensing take many different forms and can be for particular fields of application, geographical areas, and periods of time.

10. In some cases an exclusive license may be necessary to provide an incentive for a company to undertake commercial development and production. Non-exclusive licenses allow several companies to exploit an invention.

11. The research and teaching missions of the University always take precedence over patent considerations. While the University recognizes the benefits of patent development, it is most important that the direction of University research not be established or unduly influenced by patent considerations or personal financial interests.

12. The Research Office shall handle the evaluation, marketing, negotiations and licensing of University-owned inventions with commercial potential in accordance with the Royalty Sharing provisions under Article 4.4.

Annexure B

ACCESS AND CONTROL OF RESEARCH DATA AND

TANGIBLE RESEARCH PROPERTY

1. Research data and any tangible research property ,including but not limited to medical records or biological samples (TRP) generated, observed or collected by University Personnel shall be

the property of the University, which can be held accountable for the integrity of the data even after the University Personnel have left the University.

2. It is the University's policy to promote the prompt and open exchange of TRP and research data with scientific colleagues outside the investigator's immediate laboratory.

3. It is the responsibility of the principal investigator (or department chairperson, if the TRP is not developed as a sponsored research project) to control the development, storage, use, and distribution of data and TRP made in the course of research activity, subject to provisions of applicable grants or contracts and University policy.

4. Such control includes determining if and when distribution of the TRP is to be made beyond the laboratory for others' scientific use within the University or shared with researchers outside the University. When distributing TRP to research colleagues outside the laboratory, costs of the raw materials and handling may be recovered from the recipient, with the income returned to the account, which funded those costs. If any costs are charged for TRP distribution, adequate documentation must be maintained for audit purposes.

5. In case of any biological samples being shared externally, the principal investigator must ensure that a proper Material Transfer Agreement (MTA) is executed between the University and the external researcher in order to protect and secure the University's rights over such TRP.

6. If software owned by the University has commercial value or if it is considered desirable to control subsequent use, distribution for research purposes must be coordinated with the Research Office and must be accompanied by an appropriate agreement with the recipient. The Research Office may coordinate with the Legal Office for any trademark and copyright registration if needed. KEMU Legal Office will also provide wording for the distribution agreement as necessary to preserve commercial value of the software and provide coordination with existing or prospective commercial licensing activities.

7. University Personnel, outside the research group, should be allowed access to research data only after approval from the Department Head after going through a due process that should confirm data safety and integrity. If there is any possibility that a copyright or patent application might emerge from a group project, the Research Office must be notified in writing.

8. University Personnel who leave the University may be entitled to take a copy of the research data they have collected to another institution provided it is for the sole purpose of continuing and/or completing the research they had commenced at the University. A formal written agreement on disposition of research data shall be entered into prior to the use of the data outside the University.

9. Where two or more of University Personnel have jointly generated research data they may incorporate the data in their thesis, for which they will have the copyright, with the permission of the other co-owners. The grant of permission to use data in their thesis, shall not give the University Personnel the right to use such data for any other purpose without permission from the University.