

# Enforcement Rules for the Management and Use of Research and Development

## Results from Taipei Medical University and its Subsidiary Bodies

Drafted and passed by the school council (4/27/2005)

Passed by the university board (5/30/2005)

Amended by the school council (5/20/2009)

Amendment passed by the university board (6/16/2009)

Amended by the school council (12/21/2011)

Amendment passed by the university board (1/10/2012)

Amended by the school council (10/16/2013)

Amended by the school council (10/7/2015)

Amended by the school council (4/3/2019)

Amended by the school council (9/11/2019)

All thirteen articles amended in accordance with TMUS Memo 1080003452 (10/1/2019)

Article 1     These *Enforcement Rules for the Management and Use of Research and Development Results from Taipei Medical University and its Subsidiary Bodies* (hereinafter referred to as “these Rules”) are prescribed in accordance with the *Regulations on the Ownership, Management, and Utilization of Research and Development Results from Taipei Medical University and its Subsidiary Bodies* to effectively manage, promote, and use the University’s and its subsidiary bodies’ research and development results, as well as to expand the scope of the use of these results.

Article 2     The terms used in these Rules are defined as follows.

1.   The *research and development results, revenue from research and development results, inventor or creator, expenditures relating to the research and development results, and subsidiary bodies* referred to in these Rules are defined as per the *Regulations on the Ownership, Management, and Utilization of Research and Development Results from Taipei Medical University and its Subsidiary Bodies*.
2.   *Patent fees*: The application fees, certificate fees, annual fees, patent agency fees, and other fees required by law throughout the patent application process.
3.   *Net equity income*: The net amount after the following are deducted: taxes, payment to the agencies funding the program that yielded the research and development results, miscellaneous costs (including, but not limited to, the aforementioned patent fees), and other costs arising from contractual obligations (including, but not limited to, promotional fees paid to non-University units) governing the revenue from the research and development results.
4.   *Office of Business Development operational costs*: operational costs arising from **1**) industrial–academic collaborations and **2**) the management and use of research and development results (include staffing, business, and promotional costs); these operational costs are set at 15% of the net equity income.
5.   *Derived new enterprise*: Enterprises that **1**) the University holds equity in in

exchange for technology or 2) has invested in or 3) was established by the University using the research and development results.

Article 3 The Office of Business Development shall be the Responsible Unit for the management and use of the research and development results.

Article 4 Application and review process for patenting research and development results

1. Applying for patent review

- a. An inventor or creator at the University submitting a patent application for their research and development results shall log in to the *Patent Application and Management System* and enter the proposal information. An inventor or creator at a University subsidiary body shall submit paper and electronic copies of the documents listed in Subparagraph b of Article 4.
- b. In addition to the proposal information, the inventor or creator shall provide the following documents.
  - i. Information on technology retrieved earlier (including theses, patents, and literature).
  - ii. The contract or a list of approved program funds from the funding agency for the results of government-funded research and development; the documents need to note the principal investigator of the project.
  - iii. *Declaration of Research and Development Results for Taipei Medical University and Subsidiary Bodies*
  - iv. To avoid loss of novelty, the inventor or creator must submit an application prior to the patent review and shall attach the *Taipei Medical University and Subsidiary Bodies Affidavit of Payment of Patent Application Fees*.
- c. The Office of Business Development will notify the inventor or creator if their application is incomplete. If the application is still incomplete by the deadline, with or without the supplements, the application will not be processed.

2. Patent review

- a. Patent review shall be conducted by the Office of Business Development in accordance with Paragraph 3 of this Article and may be coordinated with internal and external examiners, as necessary.
- b. Review panel qualifications: Members of the review panel should have relevant experience in intellectual property, technology transfer, law, and medical biotechnology.

3. Review principles and method
  - a. In accordance with the requirements prescribed in the *Patent Act*, applications from the inventor or creator shall be reviewed based on novelty, progressiveness, and industrial applicability.
  - b. The inventor or creator shall provide a complete supplemental explanation in accordance with the findings of the aforementioned review.
  - c. The Office of Business Development shall submit the compiled documents to the Research and Development Results Management Committee for deliberation.
4. If the Research and Development Results Management Committee decides to subsidize the patent application, the Office of Business Development shall commission a suitable patent agency to handle the application; if the patent is co-owned by an inventor from a department that is neither of the University nor of one of its subsidiary bodies, the application shall include an *Agreement of Intellectual Property Co-ownership*, or *Surrender of Joint Ownership*, or another set of similar agreements.
5. Patent applications that the Research and Development Results Management Committee have agreed to subsidize must be completed within 3 months. If the deadline is not met, the Office of Business Development may not hire a patent agency to handle the application unless the application is reviewed again.

Article 5 Obligations of the inventor or creator

1. If there are two or more inventors or creators, the entire body of inventors or creators shall elect one person to be the body's representative. The representative shall decide on matters relating to the patent application and execute all the rights and obligations prescribed in these Rules.
2. The inventor or creator shall write the proposal with academic expertise and integrity. If the proposal contents are found to be untrue or to infringe on the rights of others as a result of untruthfulness, plagiarism, forgery, or stolen trade secrets, the inventor or creator shall bear all liability.
3. The inventor or creator shall cooperate with the patent agency to draft and provide the necessary information for the patent application. In the event of an administrative appeal or administrative litigation, the inventor or creator shall—to retain their rights—fully cooperate in the plea, furnish answers with regard to the research and development result, and keep the patent contents confidential until their public disclosure is allowed by law.
4. The whole body of inventors or creators shall clearly understand and shall not

dispute that the patent application's rights, patent rights, and other relevant intellectual property rights of the research and development results belong to the University or its relevant subsidiary body. In the event of a dispute, the representative shall be responsible for negotiating a settlement; if the dispute causes injury to the University, the representative shall pay damages to the University or subsidiary body.

5. The inventor or creator shall cooperate with the Office of Business Development to promote and use their research and development results and patent.
6. In the event that 1) claims are made that the research and development results or the received patent of which is ineffectual or 2) objections or revocations are raised by a third party, the inventor or creator has an obligation to assist the University or its subsidiary body, without compensation, with regards to the necessary response or defense. If the patent rights have been infringed upon by other persons, the inventor or creator has an obligation to assist the University or subsidiary body, without compensation, in explaining the technology and analyzing the violation.

#### Article 6 Undertaking the patent fees

1. If the patent application that the Research and Development Results Management Committee has agreed to subsidize is part of a MOST-funded project, MOST shall be responsible for 90% of the patent fees, and the inventor or creator shall be responsible for the remaining 10%. If the patent application is not part of a MOST-funded project, the University shall be responsible for 50% of the patent fees, and the inventor or creator shall be responsible for the remaining 50%.
2. Patent applications with multiple inventors or creators shall fill out the *Taipei Medical University and Subsidiary Bodies Research and Development Results Fees and Revenue Allocation Agreement*.
3. For 7.5 or 5 years starting from the issue date for US and non-US patents, respectively, the University or subsidiary body shall be responsible for the maintenance fees, excluding the subsidized portion in accordance with MOST regulations.
4. Subsidies for patent application appeals, supplementations, revisions, and responses shall be capped at three occurrences; the inventor or creator shall take full responsibility in the fourth, or a further, occurrence.
5. In the event that the patent fees are paid by other units, the intellectual property rights shall be handled in accordance with the *Regulations on the Ownership, Management, and Utilization of Research and Development Results from Taipei*

*Medical University and its Subsidiary Bodies.*

Article 7 Patent maintenance

1. Patents maintained by the University and its subsidiary bodies shall be entered into the ledger for management; the existing technology and patent scope of applications shall be assessed periodically for the purpose of promoting and expanding technology or patent licensing.
2. The Office of Business Development shall assess, after a reasonable period of time, the benefits and value of the unlicensed use or technical service of the aforementioned patents. The Office of Business Development may submit their findings to the Research and Development Results Management Committee to review the necessity of maintaining the patent. The maintenance or termination of the patent shall then be handled in accordance with the regulations of the agency that funded the research and development results or the terms of any other agreements.

Article 8 Promoting and licensing research and development results

1. To adhere to the principles of fairness, transparency, and impartiality, that pertaining to use, license region, relicensing, retransfer or assignment, and other appropriate technology transfer or licensing restrictions shall be stipulated in writing. If sensitive technology, dignity of life, or professional ethics are implicated, the technology transfer and licensing restrictions shall be handled in accordance with the MOST Manual on Safety and Control for Government-Funded Research into Sensitive Technology.
2. The University may license the use of research and development results under its management to government agencies, manufacturers, and other groups or persons, so long as the licensed use is compensated, non-exclusive, and prioritizes domestic use.
3. Technology transfer, licensing, or assignment that are uncompensated, exclusive, or that occur overseas shall first be reviewed by the Research and Development Results Management Committee and then reported to either the principal or the highest ranking officer of the subsidiary body for approval. Such technology transfer, licensing, or assignment must then be handled in accordance with the regulations of the agency that funded the project through which the research and development results were obtained.

Article 9 Procedure for technology transfer, licensing, or assignment of research and development results

1. The Office of Business Development shall determine a reasonable price for

technology transfers, licensing, and assignments. The Office of Business Development shall, after a period of time, conduct matchmaking selection and negotiate the contract terms. The principle of confidentiality shall be upheld throughout the process; if the technical information has not been disclosed, a nondisclosure agreement shall be signed before disclosure to protect the research and development achievements of the University.

2. The inventor or creator or licensed party shall submit their application, with relevant documents attached, to the Office of Business Development. The Research and Development Results Management Committee shall deliberate on the application. The relevant documents to be attached are as follows.
  - a. *Technology Licensing of Research and Development Results: Self-Evaluation of Creator for Taipei Medical University and its Subsidiary Bodies*
  - b. *Technology Licensing of Research and Development Results: Criteria for Manufacturers Participating in Open Selection by Taipei Medical University and its Subsidiary Bodies*
  - c. *Technology Licensing of Research and Development Results: Manufacturer Application for Taipei Medical University and its Subsidiary Bodies*
  - d. *Technology Licensing of Research and Development Results: Manufacturer Development Plan for Taipei Medical University and its Subsidiary Bodies*
3. The minutes of Research and Development Results Management Committee meetings shall be submitted to the principal for approval. A copy of resolutions relating to a subsidiary body shall be sent to the subsidiary body.
4. Collaborations involving the holding of technology shares shall be conducted in accordance with the *Taipei Medical University Equity Enforcement Regulations for Research and Development Results*.

Article 10 Patent assignment

The University and its subsidiary bodies may assign the patent to an assignee. If the patent is for government-funded research and development results, the assignment of the patent right shall be handled in accordance with the regulations of the funding government agency. If the patent is for the University's or its subsidiary bodies' research and development results, the prospective assignee shall apply for the assigning of patent rights in accordance with the procedure prescribed in Article 8 of these Rules.

Article 11 Application and review process for derived new business

1. Derived new business application: The following documents must be provided prior to establishing the company.

- a. Business plan application
  - b. Business plan
  - c. Investment agreement
2. Review of new derived business
    - a. The Office of Business Development shall hire experts and scholars to conduct a preliminary document review.
    - b. A Research and Development Results Management Committee meeting shall be convened to conduct a secondary review. The applicant must attend the review to give a representation on their application.
    - c. In the event that the application is rejected, the applicant may resubmit their application within a month.
    - d. If the reapplication is rejected, the applicant may not resubmit a similar application within six months.
  3. Review criteria
    - a. Innovativeness, market competitiveness, product commercialization time, feasibility, and other possible efficacy factors of the major technology, product, service, or operational model
    - b. Feasibility and development prospects
  4. Technology transfer agreements for new business that are derived based on the technology shall be drafted and signed in accordance with the *Regulations on the Ownership, Management, and Utilization of Research and Development Results from the Taipei Medical University and its Subsidiary Bodies*.
  5. The University's allotment of the profits of the new derived business shall be determined according to the *Taipei Medical University Equity Enforcement Regulations for Research and Development Results* and according to the negotiated terms between the University and the individual new business.

Article 12 Allocation of income from research and development results

The net equity income (including equity) from technology transfer, licensing or assignment, or industrial–academic collaboration (based on the research and development results that were completed using University or subsidiary-body resources), after the Office of Business Development's operational costs are deducted, shall be allotted in accordance with the following terms.

1. Results not protected by patents

a. Results of the University's research and development

<b>Allotment recipient</b>	University	Inventor or creator	Award for Promoting Industrial–Academic Collaboration and its Research and Development Results	Inventor or creator's university campus and department
<b>Percentage</b>	15%	70%	7.5%	Campus: 2.5% Department: 5%

b. Results of subsidiary body's research and development

<b>Allotment recipient</b>	University	Inventor or creator	Award for Promoting Industrial–Academic Collaboration and its Research and Development Results	Inventor or creator's level-1 or level-2 department
<b>Percentage</b>	15%	70%	7.5%	Level 1 department: 2.5% Level 2 department: 5%

2. Results protected by patents, where the patents had 50% of their application and maintenance fees covered by the University or its subsidiary body

a. Results of the University's research and development

<b>Allotment recipient</b>	University	Inventor or creator	Award for Promoting Industrial–Academic Collaboration and its Research and Development Results	Inventor or creator's university campus and department
<b>Percentage</b>	15%	70%	7.5%	Campus: 2.5% Department: 5%



b. Results of subsidiary body's research and development

<b>Allotment recipient</b>	University	Inventor or creator	Award for Promoting Industrial–Academic Collaboration and its Research and Development Results	Inventor or creator's level-1 or level-2 department
<b>Percentage</b>	15%	70%	7.5%	Level 1 department: 2.5% Level 2 department: 5%

3. Results protected by patents, where the patents had 80% of their application and maintenance fees covered by the University or its subsidiary body

a. Results of the University's research and development

<b>Allotment recipient</b>	University	Inventor or creator	Award for Promoting Industrial–Academic Collaboration and its Research and Development Results	Inventor or creator's university campus and department
<b>Percentage</b>	18.5%	65%	7.5%	Campus: 3% Department: 6%

b. Results of subsidiary body's research and development

<b>Allotment recipient</b>	University	Inventor or creator	Award for Promoting Industrial–Academic Collaboration and its Research and Development Results	Inventor or creator's level-1 or level-2 department
<b>Percentage</b>	18.5%	65%	7.5%	Level 1 department: 3% Level 2 department: 6%

4. Patents with the University or its subsidiary body as the patent right holder, where the inventor or creator is reimbursed for application and maintenance fees paid in advance

a. Results of the University’s research and development

<b>Allotment recipient</b>	University	Inventor or creator	Award for Promoting Industrial–Academic Collaboration and its Research and Development Results	Inventor or creator’s university campus and department
<b>Percentage</b>	12%	75%	5.5%	Campus: 2.5% Department: 5%

b. Results of subsidiary body’s research and development

<b>Allotment recipient</b>	University	Inventor or creator	Award for Promoting Industrial–Academic Collaboration and its Research and Development Results	Inventor or creator’s level-1 or level-2 department
<b>Percentage</b>	12%	75%	5.5%	Level 1 department: 2.5%

5. University-assisted technology transfers, licensing, or assignments of inventions developed outside of work duties

a. The inventor or creator is University staff

<b>Allotment recipient</b>	University	Inventor or creator	Award for Promoting Industrial–Academic Collaboration and its Research and Development Results	Inventor or creator’s university campus and department
<b>Percentage</b>	6.5%	85%	4%	Campus: 1.5% Department: 3%

b. The inventor or creator is subsidiary body staff

<b>Allotment recipient</b>	University	Inventor or creator	Award for Promoting Industrial–Academic Collaboration and its Research and Development Results	Inventor or creator’s level-1 or level-2 department
<b>Percentage</b>	6.5%	85%	4%	Level 1 department: 1.5% Level 2 department: 3%

6. If there is more than one inventor or creator, the profits shall be allocated in accordance with the *Agreement on the Allocation of Fees and Revenue from Research and Development Results from Taipei Medical University and its Subsidiary Bodies*.
7. Any aforementioned stakeholder that fails to pay any patent fees they are responsible for shall lose their right to the allocation of the income from the research and development product; their portion shall be transferred to the party that bore the costs.
8. The Award for Promoting Industrial–Academic Collaboration and its Research and Development Results shall be allocated in accordance with the *Taipei Medical University BioMED Revenue and Expenditure Regulations*.

Article 13 These Rules and any amendment thereto shall be examined and approved by the executive council prior to their announcement and implementation.