

REGULATIONS ON INVENTIONS, PATENTS AND INTELLECTUAL PROPERTY

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Regulations on inventions, patents and intellectual property

TABLE OF CONTENTS

Article 1	Objectives	3
Article 2	Definitions	3
Article 3	Scope of application	4
Article 4	UniCamillus Patent Board	4
Article 5	Ownership of patentable inventions	5
Article 6	First filing and reporting requirements	5
Article 7	Management and monitoring of the patent portfolio	6
Article 8	Patenting costs	6
Article 9	Technology transfer of intellectual property	6
Article 10	Obligations of the Inventor	7
Article 11	Notifications	7
Article 12	Confidentiality	7
Article 13	Student inventions	7
Article 14	Delegation of powers to the Rector	8
Article 15	Temporary and final provisions	8



Article 1 Objectives

1. The Saint Camillus International University of Health Sciences, hereinafter also referred to as 'UniCamillus' or 'University', in accordance with the principles defined in its Statute and with the strategic objectives it pursues, protects and promotes the results of its research activities, which are to be regulated by these Regulations, in accordance with Legislative Decree no. 30 of 10 February 2005 'Industrial Property Code' (hereinafter 'IPC'), as amended by Law No. 102 of 24 July 2023. The provisions of these regulations also apply to intellectual property in the broadest sense, i.e. activities aimed at protecting industrial property arising from inventions resulting from the University's research activities.

Article 2 Definitions

- 1. For the purposes of these Regulations the following terms are defined as follows:
 - a. <u>University</u>: UniCamillus Saint Camillus International University of Health Sciences.
 - b. <u>Industrial Property Rights (hereinafter also referred to as IP)</u>: all moral and patrimonial rights to inventions, utility models, scientific articles, which may result from institutional or commissioned research activities, however defined, carried out within the University and covered by the following definitions, and which may be protected by patents.
 - c. <u>Inventor:</u> any person who has an employment contract or relationship with the University, whether permanent or temporary, of any classification and at any level (researchers, tutors, technical and administrative staff involved in research projects), as well as external subjects involved in carrying out research activities under contract in various capacities, such as doctoral students, researchers, scholarship holders, trainees, contractors of any kind, who have obtained results subject to patenting as part of the research activities carried out at UniCamillus. Also included are students of the degree programmes who are involved in research activities within UniCamillus, in collaboration with or under the direction of the above-mentioned subjects and under their scientific supervision, and who have made inventive or creative contributions to the achievement of patentable results through the above-mentioned activity.
 - d. <u>Know-how</u>: unpatented technical knowledge and experience owned by the University, resulting from research carried out within the University and not subject to specific property rights.
 - e. <u>Institutional research</u>: research carried out by the entities referred to in paragraph 1, letter c) of this article, financed by internal UniCamillus resources or by resources derived from external national and/or international funds allocated to the University budget as a result of participation in research projects.
 - f. <u>Commissioned research:</u> a particular type of research financed, in whole or in part, by third parties other than the University, including non-governmental and legally recognised universities, public bodies and IRCCS, carried out in accordance with a purpose oriented by the funding body, which is interested in a specific application result or in solving a technical problem that requires a contribution in terms of innovation, skills, academic knowledge, also in combination with the knowledge of the funding body, which the latter does not possess, as defined in the Interministerial Guidelines to Law no. 102 of 24 July 2023.
 - g. <u>Invention</u>: the result of research, whether institutional or commissioned by UniCamillus, that may become the subject of industrial property rights through the filing of an invention patent or utility model application and know-how.



h. <u>Relevant office:</u> the central administrative office in charge of managing the processes of evaluation, protection, promotion and technology transfer, as well as monitoring the University's patent portfolio.

Article 3 Scope of application

1. The purpose of these regulations is to define the rules for the protection, safeguarding, promotion and economic exploitation of 'Inventions' resulting from institutional or commissioned research activities carried out by one or more of the subjects referred to in Art. 2, letter c), independently or in collaboration with third parties, including the use of University resources, equipment and facilities and/or economic resources managed by the University, unless otherwise provided by regulations or contractual agreements between the parties. It incorporates and specifies the principles and regulations defined by Legislative Decree no. 30 of 10.02.2005 on the Industrial Property Code (IPC), as amended by Law no. 102 of 24.07.2023, also applicable to non-state universities recognised by law.

Article 4 UniCamillus Patent Board

- 1. The University shall establish the UniCamillus Patent Board (hereinafter also referred to as "UPB") with the specific task of assisting in the patenting process of inventions, as well as being responsible for their evaluation and for the protection, management and valorisation of the University's industrial property.
- 2. The UPB is composed of a President assisted by 3 to 5 members with proven technical and scientific qualifications and experience. One member will be selected from among experts in legal fields with particular reference to commercial law.
- 3. All members of the UPB, including the President appointed by the Rector, shall hold office for 3 (three) years and may not serve more than two consecutive terms. The information disclosed and discussed within the framework of the activities of the UPB is confidential and protected by the obligation of secrecy and may not be disclosed to third parties, in accordance with the provisions of Article 14 below, and upon assuming office all members of the UPB must sign a confidentiality agreement, which is valid for the entire term of office.
- 4. The UPB shall meet periodically and carry out the tasks of proposal, evaluation and decision-making required for the purposes of these Regulations, adopting the following opinions
 - a) obligatory: on applications for initial filing and relative extension abroad submitted by inventors; on the maintenance of patents after initial filing, on the basis of the results of the periodic monitoring of the relative state of development and technology of the invention, as well as its concrete possibilities for use and commercial exploitation
 - b) mandatory and preparatory: with regard to negotiating agreements for the commercial exploitation of patents and cooperation agreements for the technological development of inventions in the portfolio, subject to the approval of the UniCamillus Board of Directors.
 - c) optional and advisory: on the criteria, guidelines, procedures and policies to be followed in patenting and technology transfer.
- 5. The UPB examines the applications submitted by inventors and verified by the relevant office; it evaluates them according to the criteria of patentability and the sustainability of the legal protection of the invention, the prospects of technology transfer and the actual industrial applicability. In particular, the UPB gives its opinion on the initiation of patent protection procedures based on the outcome of the assessment of the degree of maturity of the invention (search for 'known protection'), i.e. in terms of



the University's lack of interest in protecting the proposed invention. In cases that are particularly critical for the decision, the Board may call upon experts from outside the University, subject to the signing of a confidentiality agreement.

- 6. If the research submitted to the UPB for examination is incomplete, the UPB will ask the inventor to complete their work within the time limit set by the UPB.
- 7. In case of urgency in the management of the University's patent portfolio, the Rector authorises the UPB to file the patent application, delegating it to the Board of Directors, but subject to the mandatory opinion of the UPB on the evaluation of the invention.

Article 5 Ownership of patentable inventions

- 1. The persons referred to in Article 2(c) of these Regulations shall be the legal owners of the moral rights to inventions resulting from research activities. If the invention has been made with the contribution of more than one inventor, the moral rights shall be shared equally by all the co-inventors, unless otherwise agreed and declared in writing by them.
- 2. Pursuant to Art. 3 of Law no. 102 of 24 July 2023 (amending Art. 65 of Legislative Decree no. 30/2005), the patrimonial rights to patentable inventions resulting from institutional research activities belong to UniCamillus, while the right to be recognised as the author of the invention remains with the inventor.
- 3. In the case of research activities with external sponsors, the University shall negotiate in advance the procedures for the recognition of intellectual property rights by signing specific contracts/agreements/conventions, in accordance with Art. 3, no. 5) of Law no. 102 of 24 July 2023, the accompanying interministerial guidelines and the internal regulations of UniCamillus.
- 4. When inventions are made with the participation of employees of other institutions or companies, whether Italian or foreign, the inventors are obliged to inform their respective institutions immediately in writing, in accordance with the regulations in force. In such cases, the University will regulate, by means of a specific agreement, the joint management of the results obtained, the relative valorisation, the deadline for notification and the consequent sanctions in the event of late notification.

Article 6 First filing and reporting requirements

- 1. The result or results obtained at the end of a research activity shall be communicated to the relevant Office by the persons qualified as inventors within the meaning of Article 2, paragraph 1, letter c) of these Regulations in due time and/or within the time limits laid down in specific contractual agreements.
- 2. The invention must be an inventive result which, in their opinion, is patentable, by means of a formal application for the registration of a new invention, accompanied by a technical and scientific report highlighting its innovative features in relation to the 'known state of the art' and any prospects for technology transfer, using a form provided by the competent Office, including the reasons for the benefit(s) that can be obtained by the University, both economic and otherwise, and which affect future planning.
- 3. If the invention has been made by more than one person, all the inventors must sign the report and assume the burden of protecting the novelty of the invention itself and undertake to avoid any disclosure.



- 4. The relevant Office, after an appropriate preliminary examination, shall submit the patent application to the UPB for its evaluation and shall issue its mandatory opinion in accordance with and for the purposes of Article 4, letter a) above.
- 5. If, at the end of the preliminary examination, a favourable opinion is given, the Rector shall, in accordance with art. 16 below, the Rector shall authorise the filing of the patent application, as delegated by the UniCamillus Board of Directors.
- 6. If, on the other hand, the opinion is unfavourable, the University shall inform the Inventor of its lack of interest in filing the patent application: in this case, the Inventor may proceed independently, in their own name and at their own expense, with the filing of the patent application, with a notice of filing within 30 (thirty) days from the date of filing. The inventor is then free to assign or license the patent to third parties without the University having any claim to it.

Article 7 Management and monitoring of the patent portfolio

- The UPB shall be responsible for the management of the patent portfolio after the initial filing of the patent application and for each subsequent patent phase, the UPB shall be called upon to carefully assess the relevance, appropriateness, effectiveness and sustainability of the possible extension and/or maintenance of patent protection for the invention, providing the required opinions of competence as provided for in Article 4 of these Regulations.
- 2. To this end, the UPB's examination will cover various aspects, including:
 - a) the technological progress of the invention compared to the time of its first filing;
 - b) the benefits that can still be obtained by the university in terms of performance at the national planning level, as well as the prospects for technology transfer in relation to the current market interest in the use or development of the invention;
 - c) the progress of the research carried out by the inventor(s) and the results of the product research studies carried out by the relevant offices, both nationally and internationally.
- 3. At least every two years from the first filing, the UPB shall conduct a survey to monitor the state of development of patents and patent families whose priority application has been filed for more than 6 (six) years.

Article 8 Patenting costs

1. Patenting costs (including: preparation of the patent text, filing of the application, possible international extensions, pre-grant and post-grant maintenance costs, grant and validation fees and, in general, all actions useful for the continuation of the patenting process) shall be borne by the University.

Article 9 Technology transfer of intellectual property

- UniCamillus is interested in promoting its patent portfolio by means of collaborations with other public or private entities interested in the development and industrial application of inventions and know-how belonging to the University, in accordance with the University's strategic objectives of promoting the results of research, and always in compliance with the introduction to these Regulations and applicable legislation.
- 2. To this end, UniCamillus may enter into agreements with third parties for the transfer of the invention and the related intellectual property rights or for the exclusive or non-exclusive licensing of intellectual



property rights. Such agreements must be approved by the University Board of Directors, subject to the favourable opinion of the UPB.

Article 10 Obligations of the Inventor

 The inventor must inform UniCamillus or the relevant office of the making of an invention in the manner and within the timeframe provided for in article 6, paragraph 1, in order to protect its novelty, while respecting the obligation of confidentiality which they have assumed, in particular by undertaking not to make any prior disclosure, either orally or in writing, in accordance with the express provisions of Art. 12 below; they must disclose any facts or circumstances of which they are aware which may invalidate the patent application filed; they must cooperate actively and directly with the relevant Office in technology transfer activities aimed at exploiting the invention.

Article 11 Notifications

1. All notifications shall be sent by e-mail to the following address: brevetti@unicamillus.org and, in the case of multiple inventors, the person designated as 'first inventor' at the time of the original application shall be responsible for sending notifications.

Article 12 Confidentiality

- 1. In the event of the filing of an application for a new invention, all the obligations of confidentiality already assumed for the previous invention and set forth in these regulations shall remain with the inventor.
- 2. The same obligations shall remain with the inventor until the patent application has been filed with the appropriate national or international patent offices, even if the University decides to file the patent application on its own.
- 3. All staff of the relevant office and members of the UPB are obliged to maintain the utmost confidentiality with regard to inventions and related know-how of which they learn about while performing their duties.
- 4. External experts invited by the UPB to attend meetings are required to sign a confidentiality agreement in advance concerning the information they receive.

Article 13 Student inventions

- 1. Students enrolled in degree and doctoral programmes at UniCamillus shall also be considered as inventors for the results of inventive research activities carried out at the University in collaboration with the subjects referred to in Art. 2, paragraph 1, letter c) or under their scientific supervision, who have contributed with inventive or creative contributions to the achievement of patentable results, in accordance with the provisions of Art. 3, paragraph 4, letter a of law no. 102 of 24 July 2023.
- 2. The dissertation supervisor/programme director or the head of the laboratory of the student's programme shall inform the relevant office of the student inventor, specifying the actual inventive contribution made in the notification of the invention and the related patent application.
- 3. The student-inventor shall be subject to the conditions laid down in these Regulations. The dissertation supervisor/programme director must ensure maximum cooperation in all stages of patent protection, even after the student's cooperation with the University has ended.



Article 14 Delegation of powers to the Rector

1. The Board of Directors of UniCamillus approves these Regulations, in accordance with the provisions of Article 4 above, and delegates to the Rector the power to carry out all activities relating to the procedure for obtaining patents and their management.

Article 15 Temporary and final provisions

1. These Regulations are effective from the date of issue of this document and are published on the UniCamillus institutional website.