

Regulation

for the protection, management and enhancement of intellectual property

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INTRODUCTION

This Regulation is defined in compliance with and based on the following regulatory references on patent protection and intellectual property registrations:

- Legislative Decree n. 30 of 10 February 2005 and subsequent amendments (Industrial Property Code in short CPI);
 - Legislative Decree 16/10/2003 n. 288 and subsequent amendments;
 - Copyright Law n. 633 of 22 April 1941 and subsequent amendments;
- and governs the protection, use, enhancement and transfer of inventions, utility models and what is susceptible to protection under the aforementioned legislation and which has emerged within the research activity of the IRCCS Policlinico Foundation "San Matteo" of Pavia (hereinafter the "Foundation").

This Regulation is therefore a tool for guaranteeing corporate strategies in the field of Invention management and an operational tool for all the professionals of the Foundation who develop them in various capacities.

TITLE I - GENERAL PROVISIONS

ART. 1 - OBJECTIVES

In order to implement and organize scientific research in the translational and biomedical field and to transfer the results to clinical practice, in accordance with the guidelines of the Ministry of Health and the Lombardy Region, it pursues the following objectives of promotion and protection of inventive results :

- to promote and organize all translational and clinical research within the Foundation, and in particular in the field of transplantation: diseases that can be cured with organ transplantation, tissues and cells and in internal diseases of high biomedical and technological complexity in particular, but without exclusion of anything else recognized to it within the development lines of the programming of the Lombardy Region and the Ministry of Health;
- promote collaboration initiatives with public and private researchers in order to enhance the activities that favor the development of results, subject to potential protection pursuant to the aforementioned legislation, both in the regional field and in the national and international field, through collaboration with other IRCCS, Health Authorities, Universities and National and International Research Bodies;
- define organizational structures and contexts that recognize the protection of inventive research results as an integral part of their institutional activity, aimed at supporting research and enhancing its results, with the primary purpose of favoring its transfer to the NHS and access and the use by citizens who could benefit from it;
- economically exploit inventive results, through industrial development and technology transfer (TT), and possibly establish or strengthen relationships with companies, according to methods consistent with the primary purpose indicated above.

ART. 2 - DEFINITIONS

2.1 Pursuant to this Regulation, the following terms have the meanings indicated below:

- a) Intellectual Property Code (CPI): it is the industrial property code approved by Legislative Decree 10.02.2005 n ° 30 and subsequent additions and modifications.
- b) Invention: the inventions covered by art. 65 and 64 of the Legislative Decree. 10.02.2005 n ° 30 and that they are the result of the research activity carried out in the Foundation.
- c) Patent is a legal title by virtue of which a temporary monopoly of exploitation of the Invention is granted to its owner in a specific territory and for a specified period, in order to prevent others from producing, selling or using their Invention without authorization. .
- d) Know-how: is the set of knowledge and confidential technical experience, codified or not, owned by the Foundation deriving from the Foundation's activities and which are not the subject of specific Intellectual Property Rights.
- e) Moral rights: inalienable rights due to the author / inventor, deriving from the mere authorship of the work / invention

- f) Property rights: ownership of the Invention protected by international conventions, by EU law or by Italian national legislation or any other country in the world. They are transferable rights. They can also be defined as Intellectual Property Rights (IPR).
- g) Inventor: the author of an invention. In any case, the inventor has the moral rights relating to his own invention. The attribution of property rights derived from the invention is instead governed by the subsequent articles of this Regulation and by the relevant laws.
- h) Researcher: the person who, for whatever reason, carries out research activities in the Foundation
- i) Personnel: means anyone who in any capacity (employee, freelance, contractor and fellow) has established a working relationship at the Foundation.
- j) Commissioned Research: indicates research commissioned, in whole or in part, by private subjects or carried out in the context of specific research projects financed by public or private subjects and carried out by researchers of the Foundation in pursuit of the statutory purposes, in fulfillment of private law contracts and / or conventions, on behalf of the aforementioned public or private entities;
- k) Funded Research: means research carried out by researchers of the Foundation with the support of public or private sources of funding, for the performance of scientific activities which are of its own or prevailing interest for the Foundation compared to that of the funder, in accordance with the purpose of the Foundation itself;
- l) Collaborative Research: is the funded research carried out by at least two independent parties, aimed at the exchange and development of knowledge or technologies, or at the achievement of a common goal based on the division of labor, in which the parties contribute to its implementation and share the results. The provision of research services is not considered a form of collaborative research.
- m) Institutional Research: means Research other than Funded Research, Commissioned Research and Collaborative Research. In particular, for Institutional Research, it must be understood the pure and / or applied research carried out by the Foundation in the fulfillment of its statutory purposes, in its laboratories or facilities or at national and / or international affiliated external structures, by one or more researchers of the Foundation and / or using the Foundation's facilities / equipment and / or funding or economic resources managed by the latter, but not deriving from commissioned and / or funded research.
- n) Research results: these are inventions, utility models, trademarks, designs and models, plant varieties, databases and computer programs that derive from the Foundation Research and that are likely to be the subject of intellectual property .
- o) Technology Transfer Office: (hereinafter TT or UTT Office) is a structure that manages technology transfer. It is a support for the Inventor and a point of reference for third parties, individuals and scientific partners, for everything related to the protection of the Foundation's Intellectual Heritage, know-how and research results. Its purpose is the economic enhancement of the results of scientific and technological research achieved in the relative organization to which it belongs.
- p) Patent Commission: has the task of evaluating the patent proposals and expressing its opinion on the patents filed whenever decisions are necessary.
- q) Contract for the transfer of property rights: agreement under which the inventor transfers the ownership of the invention to the IRCCS (see Annex 1).

- r) Invention Report: form relating to the description of an invention, likely to be patented and / or marketed. It is a confidential document (see Annex 2).
- s) First filing: it is the first filing of a patent application. It is thus defined as its (priority) date may be claimed in subsequent patent extension applications filed within the year (priority right).
- t) Patent family: means all the applications / patents granted that refer to a single parent application for which it claims priority.
- u) License agreement: agreement under which a licensor (for example the IRCCS) grants to a third party (called licensee), in an exclusive or non-exclusive way, the right to use a patented invention in a specific field of application , territory and duration.

ART. 3 - SCOPE OF APPLICATION AND OBJECT OF THE DISCIPLINE

3.1. These Regulations apply to research results and related intellectual property titles deriving from the activity in which, for any reason, the staff of the Foundation participates.

3.2. The Inventions and / or other research findings and results for which the Patent - or similar title - and / or protection of the Invention in any form, within one year from when the Inventor (s) has ceased his relationship for any reason established with the Foundation.

3.3. The inventor has the obligation to act, in carrying out his research activity for the protection of the interests of the Foundation and in compliance with the confidentiality obligations as defined in Article 8.

3.4. This Regulation governs:

- a) inventions susceptible to patent protection or similar title, achieved in the context of Institutional Research, as defined in Article 2;
- b) inventions susceptible to patent protection or similar title, achieved in the context of Funded or Commissioned Research, as defined in Article 2;
- c) non-patentable results, inventions, utility models and any other innovation achieved in research activities and / or activities carried out with the use / aid of Foundation structures and economic resources and founding know-how of the Foundation. By way of example, but not limited to, scientific procedures, working methods, calculation algorithms, etc.

ART. 4 - OWNERSHIP OF INVENTIONS AND RIGHTS ON THE INVENTION

4.1 The Inventor has the inalienable right to be recognized as the author of the invention.

4.2 Pursuant to art. 65, paragraph 1 C.P.I., the researcher is the exclusive owner of the rights deriving from the patentable invention of which he is the author in the context of an Institutional Research activity. If the invention is likely to be patented, the inventor chooses to:

- file the patent application (first filing) in their own name; or
- transfer the rights under the invention to the Foundation or to third parties

4.3 The inventors are, in any case, required to immediately notify the Foundation of any inventive result in their opinion likely to be the subject of a patent (or similar title).

4.4 If the inventor decides to file the patent application (first filing) in his own name or to transfer it to third parties, he must proceed, within twenty days of filing or transfer, to notify the Scientific Direction - Transfer Office in writing. Technological - and to

make available, in copy, all related documentation. The inventors are also required to notify the Scientific Direction - Technology Transfer Office, within twenty days, of the stipulation with third parties of exclusive or non-exclusive license agreements, of patent transfer agreements and of any other contract, both to both a fee and a free one, which provides for the transfer of the economic exploitation rights of the invention, attaching a copy.

4.5 If the inventor intends, on the other hand, to transfer the property rights on the invention to the Foundation, he must complete the appropriate form for the transfer of ownership (Annex 1) of these Regulations which can also be found on the Foundation's website.

ART. 5 - OCCASIONAL INVENTIONS

5.1 The rights deriving from the invention of the non-research employee are governed by the provisions of art. 64 of the Industrial Property Code (C.P.I.).

5.2 Research results that do not fall within the types provided for in these Regulations, as they are conducted outside the research activity, but still fall within one of the Foundation's fields of activity, are subject to the provisions of art. 64, paragraph 3, C.P.I.

5.3 The occasional Inventor is required to contact the Scientific Direction - Technology Transfer Office - communicating the achievement of the Invention, according to the procedures set out in art. 9.

ART. 6 - COMMISSIONED, FUNDED OR COLLABORATIVE RESEARCH INVENTIONS

6.1 If the Invention originates from Commissioned, Finalized or Collaborative Research Results, it will be governed by the provisions of art. 64 of the Industrial Property Code.

6.2 The results of the Commissioned Research are owned by the Foundation. The rules on co-ownership are reserved, if the results have been achieved with the inventive, documented contribution of external personnel. The IPR on the results of the Commissioned Research can be acquired by the client through the granting, by the Foundation, of a license for consideration.

6.3 The ownership of the IPRs on the results of the Funded Research belongs in part to the Foundation, without prejudice to any different provisions established by the financing entity.

6.4 Ownership of IPRs on the results of Collaborative Research is partly due to the Foundation, when said results have been achieved within an activity carried out with one or more parties, including private parties, who have financed part of the activity.

6.5 For the purposes of regulating the situations of co-ownership of the IPR, it will be necessary to proceed with the stipulation of inter-institutional agreements for the management of the joint ownership.

6.6 The Foundation has no right to continue to use the Results subject to IPR and related knowledge for exclusively scientific, experimental and dissemination purposes.

ART. 7 - SPECIAL SOFTWARE RULES

7.1 The provisions of this Regulation apply exclusively to software that can be protected by means of an invention patent ("computer-implemented invention"), possessing the requisites and technical specifications of the Intellectual Property Code.

7.2 The software, intended as a computer program "as such", is governed by the laws on Copyright (Law April 22, 1941, No. 633 and subsequent amendments) and is therefore excluded from the scope of this Regulation.

ART. 8 - PROTECTION OF THE CONFIDENTIAL NATURE OF THE INFORMATION

8.1 The staff of the Foundation is required to pay the utmost attention in the communication of confidential research results, or contained in invention reports, or in patent applications filed and not yet published.

8.2 It is understood that, where the Inventors of the Foundation have failed to inform the same about the existence of pre-disclosures of which they are the authors, the Foundation may claim against them to the extent of the costs incurred for the protection procedures which, due to pre-disclosures, they cannot lead to the granting of the patent.

8.3 On all occasions of contact with subjects external to the Foundation that require the communication of know-how and any other knowledge, the Staff of the Foundation is obliged to use confidentiality agreements prepared for the purpose, by the Scientific Direction - Technology Transfer Office or authorized by it.

TITLE II - GENERATION OF OWNERSHIP

ART. 9 - COMMUNICATION OF THE INVENTION

9.1 Personnel who believe they have achieved results susceptible to protection through the use of Intellectual Property Rights are required to notify the Scientific Direction - Technology Transfer Office, using the model of the Invention Report prepared by the Foundation and attached to these Regulations (Annex 2).

9.2 The inventors are also required to provide timely and complete information on all the circumstances relating to the results achieved and to keep the confidential nature of the information for the time in which the Foundation will carry out the evaluation and protection activity.

9.3 Where the inventor intends to send scientific articles, communications, dissertations or anything else concerning the knowledge that are the subject of the Invention Report to editorial or organizational committees, he is required to expressly specify it in said report, also communicating the maximum times within which reasonably the review procedures should be completed.

ART. 10 - OBLIGATIONS OF THE FOUNDATION

10.1 Upon delivery of the Invention Report compiled by the inventor at the Scientific Direction - Technology Transfer Office, the aforementioned initiates the internal assessment procedure, aimed at verifying the appropriateness of protection and the existence of the requirements for the achievement of Intellectual property.

10.2 The Patent Commission expresses a mandatory, non-binding technical opinion on fundamental aspects such as patentability, industrialization and marketability of an invention.

10.3 The assessment procedures, including that of the Patent Commission, must be completed within 60 days of receipt by the Scientific Direction - Technology Transfer Office of the Invention Report compiled by the Inventor, provided that it is complete in all its parts and signed by all inventors. Where the Invention Report is incomplete, the term runs from the day the additional information is obtained.

10.4 For particularly complex cases, the term referred to in the previous paragraph can be extended once only for a period of 30 days with a reasoned opinion from the Patent Commission.

10.5 If, following the evaluation procedure, the General Management deems it not to proceed with the protection of the Research Results, the relative property right will be the exclusive property of the Inventors. The rights of the Foundation to use the relevant knowledge for further scientific research purposes are reserved.

ART. 11. - OBLIGATIONS OF THE INVENTOR

11.1 The inventors are required to promptly provide all information useful for the purposes of the evaluation and protection procedures of the Research Results.

11.2 If the General Management has decided to proceed with the Protection of Research Results, the Inventors must collaborate with the Scientific Direction - Technology Transfer Office, as well as with the professionals in charge, to carry out the prescribed activities in all phases of the administrative processes.

11.3 Inventors are obliged to do what is necessary to protect the confidential nature of the research results to the extent that this is required for the valid achievement of the Intellectual Property Rights.

11.4 For the purposes of the correct and efficient valorisation of the Research Results, the Inventors are obliged to collaborate with the Scientific Direction - Technology Transfer Office and with any third parties appointed to enhance the Invention

ART. 12 - EXAMINATION AND FIRST DEPOSIT

12.1 The Scientific Direction - Technology Transfer Office - activates the procedure for the evaluation of the reported Research Results and prepares a report to be submitted to the specific Patent Commission.

12.2 The Patent Commission, having regard to the investigation prepared by the Scientific Direction - Technology Transfer Office, must provide a technical, motivated and non-binding opinion, in favor or against the first filing (priority application) on the protection of inventive results and indications on the patent strategy to be undertaken.

12.3 The opinion of the Patent Commission is to be delivered within 20 days following receipt of the proposal. Having acquired the opinion of the Commission, the Scientific Directorate - will send the proposal to the General Management, accompanied by the opinion and its own illustrative report, indicating the possible uses and potential effectiveness of the Invention. The General Management will express itself in favor or against for the first filing (priority request). L

12.4 If the General Management decides to proceed with the first filing, in relation to an invention it owns, it will arrange at the expense of the Foundation to file the relative patent application and to maintain it, being able to avail itself, for this purpose and in compliance with the legal provisions on external assignments, external patent attorneys.

For the solution of particularly complex issues relating to the implementation of these Regulations, the General Management, on the proposal of the Scientific Direction - Technology Transfer Office, may make use, when necessary, of any intellectual work provided by companies and individual professionals as regards the practices for the filing of Patents and as regards the exploitation of the same.

TITLE III - MANAGEMENT OF INTELLECTUAL PROPERTY

ART. 13 - DECISION ON THE EXTENSION OF PATENT PROTECTION

The investigation for the extension of patent protection will be prepared by the Scientific Directorate - Technology Transfer Office, after consulting the Inventor, and subjected to the mandatory non-binding assessment of the Patent Commission.

Having acquired the opinion of the Patent Commission and having heard the Scientific Director, the General Management will take the decision to proceed or not with the extension, maintenance and exploitation.

ART. 14 - PERIODIC REVIEW OF THE PORTFOLIO

14.1 Every three years, the Scientific Direction - Technology Transfer Office periodically reviews the Foundation's intellectual property rights portfolio and prepares a report to be sent to the Strategic Direction, after consulting the Scientific Director. The report referred to in the previous paragraph accurately identifies the number of active intellectual property securities in the portfolio, including the applications filed and still under confidentiality, the number of securities which are already the subject of enhancement agreements as well as enhancement activities are in progress.

14.2 In the same report referred to in paragraph 1, the Technology Transfer Office also draws up a list of securities which, due to technology obsolescence, criticality of protection, foreseeable costs and commercial prospects, can be disposed of, having consulted the Patent Commission. The relative decisions are the responsibility of the General Management, after consulting the Scientific Director.

ART. 15 - DECISION OF ABANDONMENT

15.1 If the Directorate General, after obtaining the opinion of the Patent Commission, decides to abandon licenses granted or procedures in progress, even limited to one or more countries of extension, the inventors designated will be informed in good time in order to exercise the right to take over the ownership of the Intellectual Property Rights and assumption of future prosecution and maintenance costs.

15.2 The expenses for the takeover of the inventors in the ownership will be borne by the latter.

15.3 The Inventor must exercise the right to take over within 60 days from the communication with the stipulation of a transfer contract, the content of which must be agreed from time to time between the General Management and the inventor, also taking into account the patent costs incurred by Foundation.

ART. 16 - DECISIONS REGARDING LITIGATION

16.1 All decisions regarding active or passive litigation, including oppositions to third party rights, regarding intellectual property rights owned by the Foundation will be taken by the Board of Directors.

16.2 Legal actions to protect the paternity of the Invention are in any case the responsibility of the Inventor.

TITLE IV - ENHANCEMENT OF INTELLECTUAL PROPERTY

ART. 17 - OBLIGATIONS AND FORMS OF VALORISATION

The General Management provides, through the Scientific Direction - Technology Transfer Office and in cooperation with the other Structures, compatibly with the resources and skills available, for the economic enhancement of the Research results, ensuring that the enhancement activity does not conflict with the purpose of the Foundation.

17.1 Any decision regarding the use and commercial exploitation of confidential technical knowledge, or confidential information relating to a non-patented or patentable technology owned by the Foundation, is the responsibility of the General Management, having obtained the opinion of the Scientific Director.

17.2 The General Management has the right to assign the right of industrial exploitation of the invention to third parties, through exclusive or non-exclusive license agreements or the transfer of patentable results, of the patent application or of the patent.

17.3 All contracts concerning the transfer, permanent or temporary, of the rights referred to in the previous paragraph are for consideration. The free transfer to third parties of the rights referred to in the previous paragraph is permitted only on a non-exclusive basis for the pursuit of public or social purposes.

17.4 The consideration in favor of the Foundation for the transfer to third parties of the right of industrial exploitation of the invention is determined taking into account the economic importance of the invention and / or the value of the patent and must be constituted as follows:

- a) a single lump sum, to be paid upon signing the license or transfer;
- b) from sums (milestones) to be agreed with the licensee or transferee, to be paid upon the achievement of objectives relating to the development of the invention and at the time of commercial exploitation of the invention
- c) periodic royalties on the turnover deriving from the commercial exploitation of the invention.

17.5 All acts of disposition of the rights on patents or research results susceptible to patenting must include specific clauses that provide for the transfer by the licensee or the transferee of the charges, taxes and expenses inherent in obtaining and maintaining the relative patent, as well as a specific agreement that retains the rights of the Foundation in the event that the licensee or the transferee in turn transfers or licenses the rights acquired by the Foundation to third parties.

17.6 If the licensee or the transferee intends to make use of Foundation personnel in the development, production and sale phase of the transferred or licensed invention, the program, objectives, duration, consideration and other contractual conditions will be defined and agreed upon by the parties in specific contracts to be concluded in writing, which in any case provide for an adequate consideration for the Foundation.

ART. 18 - VALORIZATION OF THE FOUNDATION KNOW HOW

18.1 The Discipline provided for in this Regulation applies exclusively to the enhancement agreements in favor of third parties of know-how owned by the Foundation when this Know-How is accessory to the enhancement of other industrial property rights.

18.2 The enhancement of the Foundation's Research Results cannot in any case involve the exclusive and definitive compromise of the Know-how.

18.3 The enhancement agreements having as their object the exploitation of the Foundation's know-how alone will not in any case find application of the provisions of Article 19.

ART. 19 - BREAKDOWN OF INCOME ARISING FROM ECONOMIC EXPLOITATION OR ASSIGNMENT

19.1 In the case of a patent owned by the Foundation, the proceeds deriving from its exploitation will be divided according to the following formula:

a) the costs incurred by the Foundation up to the time of conclusion of the enhancement agreement, the expenses incurred for the achievement and maintenance of the Intellectual Property Rights will be subtracted from the gross consideration obtained;

b) the sum obtained on the basis of letter a) will be paid at the rate of 50% to the Inventor (or to the inventors pro quota, in the case of several Inventors), at the rate of 15% to the Structure from which the Inventor comes (or to the pro-rata Structures in the case of one or more inventors from different Structures), at the rate of 15% to the Scientific Direction of the Foundation and 20% to the Foundation for the fund intended to cover the costs related to the protection of Intellectual Property.

19.2 If the inventor opts for the filing of the patent application in its own right, the Foundation has the right to receive 50% of the proceeds deriving from the economic exploitation or from the transfer of the patented invention, less the expenses incurred for the enhancement of the invention. and for the achievement of the patent and its maintenance. The proceeds will be divided according to the formula defined in point 19.1 b.

19.3 If the inventor initially filed the patent application in his own name and then transferred it to the Foundation, in no case will the Foundation reimburse the inventor the costs for the protection of the Research Results incurred prior to the date of acquisition of the rights by the of the Entity. The proceeds will be divided according to the formula defined in point 19.1 b.

TITLE V - FINAL PROVISIONS

ART. 20 - USE OF THE FOUNDATION NAME AND SYMBOL

20.1 The Foundation name and logo (alias) are the exclusive property of the Foundation.

20.2 The use of the name and logo of the Foundation for Intellectual Property enhancement initiatives by third parties is permitted, subject to the approval of the General Management of the Foundation, as long as the dignity of the Entity is ensured.

ART. 21 - JUDICIAL ACTIONS

Any dispute relating to the interpretation, application, execution of these Regulations will be resolved at the Specialized Business Sections established at the Court of Pavia.

ART. 22 - FINAL PROVISIONS

For anything not expressly provided for in these Regulations, please refer to the provisions of Legislative Decree no. 30 of 10 February 2005 and subsequent amendments

ART. 23 - ATTACHMENTS AND FORMS

- ATTACHMENT 1 Form RA C.d.A. 44.1 Proposal for the assignment of patent ownership
- ATTACHMENT 2 Form RA C.d.A. 44.2 Invention report form

ART. 24 - ENTRY INTO FORCE

This regulation enters into force on 01/07/2020