

**HOSPITAL DE SANTA CREU I SANT  
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**INTERNAL RULES REGARDING PATENTS  
AND OTHER FORMS OF INTELLECTUAL  
PROPERTY**

January 2012

The object of this internal Regulation is to regulate confidential information and the ownership of patents and other intellectual property rights, and also the procedure for recognizing and registering inventions and for managing patents arising from work performed or services provided, whether by staff employed by the Health Management Foundation and the Research Institute Foundation of the Hospital de la Santa Creu i Sant Pau (hereinafter HSCSP), or by other persons carrying out activities under contracts with either of these two foundations, in accordance with the provisions of Law 11/1986, of 20 March, governing patents (hereinafter, the “Patents Law”) and similar laws, such as those governing the ownership of industrial designs, plant derivatives, software and supplementary protection certificates.

The Health Management Foundation and the Research Institute Foundation of the HSCSP (hereinafter, the “HSCSP Foundations”) have the following missions:

- The HSCSP Health Management Foundation implements care, teaching and research activities.
- The HSCSP Research Institute Foundation fosters, manages and disseminates biomedical research for the HSCSP and has also been entrusted with managing research performed by HSCSP staff.

## **SECTION 1. PATENTS AND OTHER INDUSTRIAL PROPERTY RIGHTS**

### **Article 1. Confidentiality regarding projects, studies and research**

The information and results arising from projects, studies and research carried out by staff or contracted third parties of either of the HSCSP Foundations are confidential to the extent that they contain elements that are secrets in themselves, or as a whole, or in relation to other information or results. The secret nature of information and results is not conditioned by the fact that they may be considered an invention.

The staff or contracted third parties of either of the HSCSP Foundations shall respect the confidentiality of information and results of projects, studies and research with which they are associated. Violation of this obligation represents an act contrary to good faith both in the performance of their contractual obligations and in their relationship with the HSCSP Foundations.

The need to respect the confidentiality of projects, studies and research and the corresponding information and results shall remain in force both during and after termination of employment or service with the HSCSP Foundations for as long as such information is secret.

Any publication or communication to third parties of the above-mentioned information or results must be previously agreed to in writing by the HSCSP Foundations.

## **Article 2. Ownership of industrial property rights**

In accordance with the provisions of the Patents Law regarding inventions while in employment, and wherever this law is applicable, ownership of intellectual property rights is defined as follows:

- The HSCSP Health Management Foundation owns the intellectual property rights for the inventions and creations of its researchers and workers during the term of their employment or contracts with the HSCSP Health Management Foundation, and also those of administration and service staff and of any class of grant-aided students.
- The HSCSP Research Institute Foundation owns the intellectual property rights for the inventions and creations of its researchers and workers during the term of their employment or contracts with the HSCSP Research Institute Foundation, and also those of administration and service staff and of any class of grant-aided students.

According to the cooperation agreement between the HSCSP Health Management Foundation and the HSCSP Research Institute Foundation, signed on 8 January 2009, ownership of inventions and patents developed by employees of the HSCSP Health Management Foundation is ceded to the HSCSP Research Institute Foundation. The HSCSP Research Institute Foundation is therefore the owner of all inventions and patents developed by its own employees and the employees of the HSCSP Health Management Foundation.

## **Article 3. Application for patent or other intellectual property right protection**

The Transfer and Innovation Unit of the HSCSP Research Institute Foundation is hereby designated as the only body which may receive, manage and transfer possible scientific or technical inventions or results with potential for patenting or for registration as another kind of intellectual property.

Any inventor who considers that a research project is likely to lead to a result that should be protected by patent or by intellectual property rights legislation should notify the Transfer and Innovation Unit, which will furnish the necessary information and documents in order to assess the potential for protection of a patent or intellectual property right.

The inventor undertakes to complete the invention proposal form supplied by the Transfer and Innovation Unit, which will only consider proposals that are properly proposed and fully described in this standard document. The Transfer and Innovation Unit will assign a priority number to the proposal and will undertake to protect the confidentiality of the invention and inventors before publication of the formal application for registration of an intellectual property right.

The Transfer and Innovation Unit will study the invention and issue a report to the inventor regarding the possibility and feasibility of protection based on market criteria such as an unmet medical need, sales potential, the existence of competition, the availability of a potential licensee, etc, as well as any other criterion applicable to any given invention.

If the Transfer and Innovation Unit favourably assesses an invention, it will send a registration request to the HSCSP Research Institute Foundation manager authorized to approve and subsequently process the request for registration. HSCSP Research Institute Foundation management will notify, through the Transfer and Innovation Unit and within a reasonable time period, the inventor and their research group or department of its decision regarding the invention and the outcome. The Transfer and Innovation Unit will be responsible for registering the invention with the appropriate national or international patents and trademarks office.

In the event of an unfavourable assessment, the Transfer and Innovation Unit will proceed as established in Article 10, describing policy regarding transfers to inventors.

#### **Article 4. HSCSP Research Institute Foundation obligations**

Regarding patents and other intellectual property rights considered viable and of interest to the HSCSP Research Institute Foundation under agreements made in accordance with the previous article, the HSCSP Research Institute Foundation shall be required to do the following:

- a) To proceed with and process the request for protection through the Transfer and Innovation Unit. In cases where the patentable invention corresponds to a project that has not made provision for the processing of intellectual property rights, the HSCSP Research Institute Foundation will bear the costs of processing the patent application.
- b) Through the Transfer and Innovation Unit and paying any necessary fees, to maintain and keep properly updated the protection of rights arising from the corresponding applications.
- c) To manage use or transfer according to criteria of maximum profitability and responsible use.
- d) To adequately publicize and communicate HSCSP Foundation inventions and developments in suitable media and arenas.
- e) To recognize the authorship rights of the inventor.

#### **Article 5. Inventor obligations**

Regarding patents and other intellectual property rights considered viable and of interest to the HSCSP Research Institute Foundation, inventors shall be required to do the following:

- a) To refrain from publishing or in any other way communicating information regarding the invention before the patent application date or the date on which the HSCSP Research Institute Foundation directly authorizes the publication of a communication or article.
- b) To actively participate in filing the patent application in terms of defining the state of the art, accurately composing the text of the patent (both description and claims) and describing the allegations that defend its patentability.

- c) To actively participate in the search for funding aimed at continuing the line of research initiated by the invention and to develop the invention beyond the patenting stage.
- d) To work with the Transfer and Innovation Unit in identifying opportunities and presenting and negotiating with potential partners interested in developing and commercializing the patented invention.
- e) To cooperate with the Transfer and Innovation Unit, when deemed necessary by the HSCSP Research Institute Foundation, in the technical defence of the patent in the event of a third-party lawsuit to invalidate the patent or bring action for infringement of the rights of third parties.

#### **Article 6. Co-inventors and multiple ownership**

If there is more than one inventor, the Transfer and Innovation Unit will require the inventors to sign an agreement regarding the contribution of each inventor to authorship. This document must be signed prior to the patent application. If no agreement is reached between the inventors, the Transfer and Innovation Unit will decide the proportion corresponding to each inventor on the basis of an assessment performed in accordance with Article 2 above. Ownership and use of rights deriving from the activity of persons not employed directly by the HSCSP Research Institute Foundation, but attached to founding and other research institutions associated with it, shall be governed by a specific agreement signed between the HSCSP Foundation Research Institute and the institution of origin of such persons. If no such specific agreement exists regarding the inventor of an invention developed as a result of an employment or contractual relationship with the HSCSP Foundations, then this Regulation shall apply.

Collaboration in a public or private partnership with any entity other than the HSCSP Foundations shall be formalized in a cooperation agreement that will cover authorship and ownership of knowledge, any possible inventions, responsibilities regarding the filing of patents and the distribution of profits arising from the use and possible transfer of patents.

#### **Article 7. Transfer agreements**

Once a partner interested in developing and commercializing an invention has been identified, the Transfer and Innovation Unit, following the instructions of the HSCSP Research Institute Foundation, will negotiate the most favourable conditions for the granting of a license or transfer of rights, all the while coordinating with and remaining in constant communication with the inventors. Approval of the agreement will be the responsibility of the HSCSP Research Institute Foundation management.

#### **Article 8. Distribution of profits between two or more owners**

The Transfer and Innovation Unit, in coordination with the HSCSP Research Institute Foundation management, will collect any net profits resulting from use or transfer of a patent filed by the Transfer and Innovation Unit, and will distribute said profits to patent holders, including the HSCSP Research Institute Foundation, according to ownership

percentages. The HSCSP Research Institute Foundation management will also distribute net profits corresponding to inventors who are employed or contracted by either of the HSCSP Foundations.

For inventors attached to either of the HSCSP Foundations but hired by other entities, profits will be distributed by those entities in accordance with the corresponding policies described in agreements signed between the two entities.

#### **Article 9. Distribution of profits between entities and inventors**

Net profits from the use or transfer of a patent corresponding to staff of either of the HSCSP Foundations shall be distributed as follows:

- a) 30% for the inventor(s), in accordance with the shares corresponding to each as described in Article 6 above referring to authorship of the invention
- b) 20% for the research group(s) to which the inventor(s) belong(s) as of the date of application to the relevant authority, applying the same criterion as to shares as above
- c) 20% for the entity to which the inventor belongs, whether the HSCSP Health Management Foundation or the HSCSP Research Institute Foundation or both.
- d) 30% for the HSCSP Research Institute Foundation as the managing body.

This distribution refers exclusively to profits corresponding to the HSCSP Foundations in accordance with their ownership share in the patents.

Net profits from the use or transfer of a patent shall be the sum resulting after deducting an amount equal to twice the costs incurred in relation to application and processing prior to use or transfer, such as market research, patentability research, filing and maintenance costs and legal costs associated with use or transfer agreements, etc. Once these prior costs have been covered, the net profits from use or transfer of a patent shall be the sum resulting after deducting costs associated with the maintenance of the patent, together with any other costs related to protection and legal advice that may be incurred during the life of the patent.

The profits payable to the inventor(s) shall be considered, for tax purposes, as capital gains and shall therefore be subject to the corresponding personal income tax.

#### **Article 10. Transfer to the inventor**

Should the HSCSP Research Institute Foundation not wish to protect or maintain ownership of an intellectual property right belonging to it, it may transfer this in writing for use by the inventor(s). Once a first patent application is agreed and is processed, the HSCSP Research Institute Foundation will, as a general rule, commit to ownership for 18 (eighteen) months following filing of the application. After this period, the Transfer and Innovation Unit, together with the inventors, will assess the status of the patent. Depending on the existence of genuine transfer opportunities, the Transfer and Innovation Unit will either extend this period or, if no interest has been expressed in the invention, transfer the right to the inventor(s).

A decision to expand geographical coverage of the intellectual property right (e.g., via the Patent Cooperation Treaty or the Europe Patent Office), or the conclusions of a patent search report issued by a national or international agency patents body regarding the validity and state of the art of the patent, may likewise lead to a review of the situation in relation to the availability of potential partners. The HSCSP Research Institute Foundation is not obliged to assume responsibility for entry to the national phase of the patenting procedure.

The HSCSP Research Institute Foundation may decide to transfer the patent to the inventor(s) if it is concluded that this would ensure effective and appropriate use of the invention.

If transfer is to the inventor(s), the HSCSP Research Institute Foundation may reserve a non-exclusive, non-transferable, free licence on behalf of itself and/or the HSCSP Health Management Foundation and/or any body attached to the HSCSP.

The agreement covering the patent transfer to the inventor(s) shall define the HSCSP Research Institute Foundation's share of any potential future profits from use of the invention. If, prior to transfer to the inventor(s), the HSCSP Research Institute Foundation has incurred expenses in regard to filing the intellectual property right, initial profits from the invention shall be earmarked to cover these expenses.

The inventor(s) will assume the cost of transfer whereas the Transfer and Innovation Unit will be responsible for processing.

The HSCSP Research Institute Foundation may, at any time, halt a patent application or registration procedure or decide to no longer support a granted patent if the lack of expectations does not justify the cost.

#### **Article 11. Withdrawal of the inventor**

Inventors who leave the employ of the HSCSP Foundations shall maintain their rights as an individual to net profits arising from the use or transfer of a patent, in accordance with the provisions of Article 9 (a).

For inventors who leave the employ of the HSCSP Foundations, the rights of the research group to the net profits arising from the use or transfer of a patent, in accordance with the provisions of Article 9 (b), shall remain in force as long as the research group continues to be associated with the HSCSP Foundations.

If the research group to which the inventor belongs closes down or becomes disassociated with the HSCSP Foundations, the net profits arising from the use or transfer of a patent, in accordance with the provisions of Article 9 (b), shall go to the HSCSP Research Institute Foundation as the rightful owner.

If the research group to which the inventor belongs is taken over by another group in either of the HSCSP Foundations, the net profits arising from the use or transfer of a patent, in accordance with the provisions of Article 9 (b), shall go to the newly created group.

In other cases affecting the inventor(s), such as the division of a group or the creation of an emerging group, the parties shall decide, by mutual agreement, the distribution of net profits arising from the use or transfer of a patent, in accordance with the provisions of Article 9 (b). If the parties have not reached an agreement within two (2) months, the

HSCSP Research Institute Foundation management in conjunction with the Transfer and Innovation Unit will base a decision as to profit distribution on the arguments and documentation submitted by the parties.

#### **Article 12. Confidentiality agreement**

If an invention has not been made public, a confidentiality agreement must be signed before third parties (interested companies, other researchers, etc) are informed of it, irrespective of whether or not the invention has been patented. This agreement must always be signed by a person duly authorized to do so by the HSCSP Research Institute Foundation. The aim is, if no patent application has as yet been filed, not to lose the right to patent the invention or, if a patent application has been filed, not to miss out on the possibility of either halting the process in order to file another application or maintaining the information as know-how (modified or otherwise).

The Transfer and Innovation Unit shall compose and distribute a model confidentiality agreement to be signed by the HSCSP Research Institute Foundation representative and third parties.

#### **Article 13. Transfer and Innovation Unit arbitration**

The HSCSP Foundations shall provide for arbitration mechanisms as necessary, in order to ensure strict compliance with the provisions of this Regulation. The Transfer and Innovation Unit is hereby appointed as responsible for resolving any doubts as to application.

#### **Article 14. Use of patents and other intellectual property rights through spin-offs**

This Regulation shall not apply if a patent or intellectual property right is used by means of participation, by either of the HSCSP Foundations, in a spin-off company held in partnership by the inventors, with each HSCSP Foundation holding a right to its share of profits in the form of dividends, capital gains, etc. In this case, HSCSP regulations regarding the creation of, and participation in, spin-offs shall apply.

### **SECTION 2. CLINICAL ASSESSMENT SCALES AND OTHER INTELLECTUAL PROPERTY**

All the articles in SECTION 1 of this Regulation, referring to PATENTS AND OTHER INTELLECTUAL PROPERTY RIGHTS, shall equally apply to clinical assessment scales and other intellectual property rights, with the exception of Articles 2 and 9, which are replaced by Articles 15 and 16, respectively.

#### **Article 15. Intellectual property ownership**

The ownership of computer programs, databases and other intellectual property created by the staff of the HSCSP Foundations as a result of their healthcare, teaching or research activities belong to the HSCSP Research Institute Foundation, in accordance with Article 97 paragraph 4 of Royal Decree 1/1996, of 12 April, approving the consolidated copyright law.



The ownership of clinical assessment scales and associated materials created by the staff of the HSCSP Foundations as a result of their healthcare, teaching or research activities correspond to the HSCSP Research Institute Foundation.

However, in the cases expressly provided for in the above-mentioned law, the intellectual author shall be the person or group of persons responsible for the creation or the entity considered to be the holder of the copyright.

#### **Article 16. Distribution of profits between entities and authors**

Net profits from the use or transfer of clinical assessment scales or any other intellectual property corresponding to staff of either of the HSCSP Foundations shall be distributed as follows:

- (a) 30% for the inventor(s), in accordance with the shares corresponding to each as described in Article 6 above referring to authorship of the invention
- (b) 40% for the research group(s) to which the inventor(s) belong(s), applying the same criterion as to shares as above
- (c) 10% for the entity to which the inventor belongs, whether the HSCSP Health Management Foundation or the HSCSP Research Institute Foundation or both
- (d) 20% for the HSCSP Research Institute Foundation as the managing body.

This distribution refers exclusively to the profits corresponding to the HSCSP Foundations in accordance with their ownership share of the patent.

Net profits arising from the use or transfer of a clinical assessment scale or any other intellectual property shall be the sum resulting after deducting costs associated with registration of the intellectual property.

The profits payable to the inventor(s) shall be considered, for tax purposes, as capital gains and shall therefore be subject to the corresponding personal income tax.

Article 11 of this Regulation shall apply to any inventor who leaves the employ of the HSCSP Foundations.

#### **Final Disposition**

This Regulation, approved by the HSCSP Health Management Foundation Steering Committee on 29 September 2011 and by its Board on 26 January 2012, shall come into force on 27 January 2012.

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| <b>On behalf of the HSCSP Research Institute Foundation</b><br><br>Jaime Kulisevsky Bojarski | <b>On behalf of the HSCSP Health Management Foundation</b><br><br>Jordi Varela Pedragosa |
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