

REGULATION

TO SUPPORT THE CREATION OF BUSINESSES

OF THE

HSCSP RESEARCH INSTITUTE FOUNDATION

INSTITUT DE RECERCA HOSPITAL DE LA SANTA CREU I SANT PAU



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Preamble

The Research Institute Foundation of the Hospital de Santa Creu i Sant Pau (hereinafter, “Research Institute”) was established in 1992 as a separate legal entity. The Research Institute is participated in by the Government of Catalonia, the HSCSP Health Management Foundation (HSCSP-FGS), the Autonomous University of Barcelona (UAB), the HSCSP Private Foundation (Board of Governors; MIA), the Institute of Cardiovascular Sciences (ICC), the Puigvert Foundation, the Blood and Tissue Bank, the Public Health Agency of Barcelona (ASPB), the Barcelona-Sardenya Primary Care Centre (EAP Sardenya) and the Iberoamerican Cochrane Centre.

One of the foundational objectives of the Research Institute is to promote, develop, transfer, manage and disseminate research, scientific and technological knowledge, teaching and training in the life and health sciences.

To this end, Article 5 of the Bylaws indicates that the Research Institute shall: *“promote and strengthen relations and the exchange of knowledge between researchers and research groups belonging to the different biomedical centres and entities comprising the HSCSP Biomedical Campus; promote collaboration with other institutions and organizations, awarding priority to the implementation of joint projects; raise funding for research activities of interest to the above-mentioned biomedical centres and entities; and manage resources as assigned for research by various institutions and organizations.”*

In order to fulfil its objectives in accordance with Article 17 of the Bylaws relating to the creation of, and participation in, companies and businesses, the Research Institute desires to promote the creation of spin-offs based on exploitation of technologies and knowledge developed through the scientific research activities of its researchers.

The reform of public research legislation by means of the adoption of new legislation in the form of Law 14/2011, of 1 June, governing science, technology and innovation (hereinafter, “Law 14/2011”), has had an impact in terms of business creation by research centres, specifically Article 18, which establishes mechanisms to enable and encourage the mobility of researchers.

Furthermore, with the approval of Law 7/2011, of 27 July, governing taxation and financial provisions as established under the legal regimen governing research centres in Catalonia (Catalan Research Centre Institute; CERCA), the aim is to promote research, development and innovation as key elements of the new model of economic transformation and cohesion, with a view to consolidating Catalonia as a landmark in the advancement of knowledge and authorizing research centres to create businesses.

Therefore, in order to create the environment for promotion of research in its field by the Research Institute, it is considered necessary to define a suitable legal framework for the creation of businesses as spin-offs from the Research Institute's activities.

Given this new legal framework, the Research Institute has seen fit to establish rules to regulate the procedures for business creation by Research Institute staff, as well as the requirements for participation by researchers and the Research Institute in these businesses, with the aim of developing a framework that fosters and supports the creation of businesses and the transfer of research results to the productive and social fabric.

NOTE: These rules apply to the HSCSP Research Institute Foundation.

For the HSCSP Health Management Foundation, specific regulations should be drawn up or the possibility of extending the scope of this Regulation should be explored.

TITLE I. INTRODUCTION

CHAPTER I. PURPOSE, SCOPE AND DEFINITIONS¹

Article 1. Purpose and scope

This Regulation aims to establish the legal regime applicable to business projects arising from the Research Institute and to establish the forms of participation and framework for links between the Research Institute and its research staff and these business projects.

Article 2. Definitions.

Defined for the purposes of this Regulation are the following:

- a. Spin-off:** a business that exploits the research results of, and is participated in, by researchers from the Research Institute.
- b. Researcher:** Research Institute employees who possess the relevant qualifications and who implement research — understood as systematic, creative research that adds to knowledge, including research related to humans, culture and society — and who use this knowledge to create, transfer and disseminate new applications.
- c. Research results:** any technology, knowledge, process or other outcome of research developed or obtained as a result of healthcare and related research activities undertaken by Research Institute researchers.

TITLE II. LEGAL FRAMEWORK FOR SPIN-OFFS

CHAPTER II. PROCEDURE FOR CREATING SPIN-OFFS AND PARTICIPATING IN EXISTING SPIN-OFFS

Article 3. Authorization request

3.1. Research Institute researchers interested in either the creation of a spin-off for the commercial exploitation of Research Institute research results, or in participation in an existing business for the purpose of commercializing research results, should apply to do so to the Research Institute Transfer and Innovation Unit, providing the following:

- a.** Details of entrepreneurial partners/team and of their affiliation with the Research Institute.

¹ Note regarding the general scope of the Regulation. This Regulation applies only to spin-offs participated in by Research Institute researchers according to the definition established in Law 14/2011. Thus, staff members who are not researchers are not covered by this Regulation or the above-mentioned law. but will be governed by the laws applicable to their centre of origin. Regarding the research results, this Regulation, pursuant to the above-mentioned law, refers to results obtained by researchers at the centre and not those generated by other entities, which should conform to regulations specifically applicable to them.

- b. A request for authorization to either provide services to the spin-off or obtain researcher leave to participate in the spin-off.
- c. A draft business plan based on the model prepared for this purpose by the Transfer and Innovation Unit, reflecting the following:
 - Technical feasibility study covering aspects such as health, safety, environmental issues, etc that complies with current legislation and specific regulations.
 - Financial feasibility study evaluating the financial potential of the project, possible financing options, forecasts of investments, sales, costs and cash flows and rates of return on investment expected in the initial years.
 - Strategic feasibility study covering the competitive advantages of the proposed project that would indicate successful implementation in the targeted market.
- d. Proposed use of incubator facilities, if applicable, in accordance with the provisions of Article 15 of this Regulation.
- e. In the case of existing spin-offs, additionally:
 - Bylaws of the business and complementary/supplementary agreements entered into between partners
 - Certificates issued by the taxation and social security authorities stating that the business is up-to-date with its obligations to both these bodies
 - Annual report and accounts for the last four years, if these exist.
- f. Descriptive report of Research Institute research results to be exploited through the spin-off project or a copy of the research results transfer agreement previously entered into with the Research Institute, as appropriate

3.2. Applicants will be responsible for the preparation of the documents mentioned above, although they may avail of the advice and guidance of the Transfer and Innovation Unit.

Article 4. Spin-off project analysis

4.1. Once the request has been submitted, the Transfer and Innovation Unit will analyse the viability of the business plan, in particular the technological, market and financial aspects, and will issue a report reflecting the following:²

- a. The authorization procedure applicable.

² Is it the Research Institute or the entrepreneurial team which should take responsibility for these contrasting aspects?

- b. The technological basis for the spin-off, depending on the nature of the research results to be exploited and the activities to be undertaken by the spin-off.
 - c. Relevance to the research results.
 - d. Proposal for participation by the Research Institute, if appropriate.
 - e. Model of the relationship with the Research Institute.
 - f. Most appropriate form of payment.
 - g. Proposal, if appropriate, for installation of the project in the designated entrepreneurship area, in accordance with the provisions of Article 15 of this Regulation.
- 4.2. To carry out its analysis, the Transfer and Innovation Unit may request additional information from the applicants.
- 4.3. The request and the Transfer and Innovation Unit report will subsequently be submitted to the Research Institute (scientific management and administration, if applicable).
- 4.4. If favourably assessed by the Research Institute, the request and the Transfer and Innovation Unit report will be sent to the Research Institute Board.

Article 5. Spin-off authorization procedure

- 5.1. The Research Institute Board, in light of the documentation received, will decide regarding the request for the creation of the spin-off and the legal system to regulate its creation, as well as the payments applicable.
- 5.2. The Research Institute Board will inform the applicants and Research Institute and Transfer and Innovation Unit managements of its decision so that all aspects necessary for formal implementation of the agreement adopted for this purpose can be implemented.
- 5.3. The Research Institute Director will be responsible for signing the documents making up the agreement, and in particular, the research results transfer agreement and, if applicable, the partnership agreement, in accordance with the provisions of Articles 8 and 9 of this Regulation.
- 5.4. Should the Research Institute Board decide not to approve participation in the share capital of the spin-off, this decision will be transmitted to the Research Institute and Transfer and Innovation Unit management. The Research Institute, as appropriate, may itself sign a research results transfer agreement with the spin-off, in all cases subject to the applicable regulations.

Article 6. Research Institute participation in spin-off share capital

- 6.1. The authorization of the Research Institute Board regarding participation in the spin-off share capital shall establish the terms and conditions regarding acquisition of a stake.

6.2. The Research Institute participation in the spin-off share capital may consist of:

- a.** Direct monetary contributions.
- b.** Contributions of assets or rights, at their market value, such as Research Institute research results necessary for the development of the spin-off activities.

6.3. The Research Institute shall notify the Board of Trustees within thirty days of the acquisition of shares or stakes that confer it with direct or indirect control of businesses with limited liability for partners.

6.4. Companies participated in by the Research Institute must provide the Transfer and Innovation Unit with an annual report and accounts along with any other documentation as legally determined,.

6.5. The Research Institute has the right to perform an annual audit or review in businesses in which it holds a stake. The Research Institute shall appoint and bear the cost of the person or company to be responsible for the review or audit.

Article 7. Research Institute participation in the governing organ

7.1. The participation of the Research Institute in the spin-off share capital may lead to the presence of representatives of the Research Institute in the spin-off governing organ.

7.2. The Research Institute reserves the right to appoint and, if applicable, replace or remove representatives of the spin-off governing organ. In accordance with the provisions of the regulations in force, appointment will be governed by compatibility.

Article 8. Partnership agreement

All partners in the spin-off participated in by the Research Institute must sign, before or during the creation of the spin-off, a contract between partners that covers, among other issues, the rules governing management of the spin-off in accordance with the provisions of this Regulation and the Research Institute licensing agreement. The partners shall also establish the obligation in the agreement for new partners to sign said agreement, unless the Research Institute expressly agrees otherwise.

Article 9. Research results transfer agreement

9.1. The rights to use and commercialize Research Institute research results shall be transferred in accordance with the procedure provided for in the current regulations.

9.2. In all cases, the afore-mentioned transfer shall require a research results transfer agreement to regulate the terms governing the transfer in favour of the spin-off and the corresponding payment to the Research Institute, in accordance with conditions as established by the Research Institute.

9.3. The contents of the research results transfer agreement will reflect applicable regulations and

good practices in protecting the public interest as is usual in this type of agreement.

TITLE III. RESEARCH INSTITUTE RESEARCHER PARTICIPATION IN SPIN-OFFS

Article 10. Application for leave to develop spin-off activities

10.1. Researchers who have been employed on a permanent contract for at least five years who wish to obtain leave to develop spin-off activities may apply to the Research Institute for a temporary leave of absence for a maximum of five years.

10.2. Researchers can apply for leave, using the standard form, to the Transfer and Innovation Unit in order to perform any of the activities referred to in Article 17.4 of Law 14/2011, which activities shall, moreover, be performed under an employment contract.

10.3. The Transfer and Innovation Unit will submit this application for consideration and a final decision as to approval or rejection by management. The granting of leave is subject to the Research Institute's own needs and its interest in the activities of the spin-off. Required in all cases is a favourable report from the head of the research group of the applicant.

10.4. The temporary leave of absence shall be five years maximum. Once this period has elapsed no further temporary leave of absence may be granted unless at least two years have elapsed since return to the original position in the Research Institute or since the end of a previous leave.

10.5. During the period of leave, no remuneration may be received for the original position, although the researcher's rights to their post and to research evaluation will be retained, as appropriate.

Article 11. Authorization for provision of services in a spin-off

11.1. Research Institute researchers may request authorization to provide Research Institute services through a spin-off by means of a part-time paid employment contract for a term established between the Research Institute and the spin-off, pursuant to Article 18 of Law 14/2011.

11.2. The application must be accompanied by a report that justifies the applicant's participation in an activity that is related to scientific and technical priorities as established in the Spanish Science and Technology Strategy or the Spanish Innovation Strategy.

11.3. The authorization granted by the Research Institute may not change workdays or hours and will be automatically rendered void in the event of any change of post in the public sector.

Article 12. Research Institute researcher participation in a spin-off

12.1. Researchers who participate in a spin-off, in accordance with the arrangements provided for in this Regulation, may request authorization (1) to belong to the governing organ of the spin-off and (2) to participate in the capital of the spin-off in a percentage exceeding 10%.

12.2. Research Institute staff not classified as researchers may participate in the share capital of a spin-off in a percentage not exceeding that permitted by the applicable legislation. Such staff may not participate in decision making or in configuring the Research Institute's intentions regarding matters in which their participation may lead to a conflict of interest. If their participation is necessary as a consequence of the exercise of their responsibilities to the Research Institute, they must explicitly notify the bodies making the final decision regarding this potential conflict.

Article 13. Protection of Research Institute research results

13.1. Research Institute researchers participating in a spin-off, including persons benefiting from any of the possibilities provided for in this Title, shall protect Research Institute research results and those of their research group, in accordance with the Research Institute's general intellectual and industrial property rules and agreements entered into by the Research Institute.

13.2. The Research Institute shall establish the necessary measures to protect its own position in possible conflicts of interest.

13.3. In regard to Research Institute researchers benefiting from the regime provided for in Article 11, it shall be presumed that research results obtained during their period of service provision to the spin-off will be the result of the regime applicable to creations or inventions developed under employment with the Research Institute, unless an agreement or evidence to the contrary exists. In this regard, the necessary measures shall be established by means of an agreement referring to the indications of this clause.

TITLE IV. SUPPORT SERVICES TO SPIN-OFFS

Article 14. Research Institute training and grants programme

14.1. The Research Institute, for the purpose of encouraging the creation of spin-offs, shall develop an entrepreneurship promotion policy which may include programmes to both support entrepreneurial projects and provide funding.

14.2. Support services as follows shall be coordinated by the Transfer and Innovation Unit:

- a.** Business incubation.
- b.** Help with business plan writing.
- c.** Technical and technological advice.
- d.** Advice on capital and grants and the negotiation of agreements, including with private investors and venture capital companies.
- e.** Training.
- f.** Internationalization

g. Strategic alliances.

14.3. The Research Institute may create a seed capital fund to facilitate spin-off creation and financing via the Research Institute’s own budget or agreements with other public or private bodies.

Article 15. Use of facilities

If the Research Institute or other entities affiliated with the Sant Pau Biomedical Research Institute (IIB Sant Pau) designate premises for the promotion of entrepreneurship (hereinafter, “incubator”), space in these premises may be requested for the spin-off through the Transfer and Innovation Unit. For this purpose, an agreement must be signed between the companies and the business incubator management regulating the terms, conditions and cost of the provided services and facilities.

Article 16. Collaboration agreements

16.1. The Research Institute and spin-offs may sign collaboration agreements with other organizations provided these respect the foundational principles enshrined in the Research Institute Bylaws.

16.2. In preparing these agreements, appropriate mechanisms shall be established to avoid potential conflicts of interest, with the spin-offs obliged to establish the necessary procedures to ensure that their staff do not divulge any secrets or intellectual property they have knowledge of by reason of their connection to the Research Institute or its spin-offs, not only during the period spent there, but also after termination of the contractual relationship.

TITLE V. MISCELLANEOUS

Article 17. Research Institute spin-off registration

17.1. The Transfer and Innovation Unit shall be responsible for registering the Research Institute spin-offs, specifically the following details:³

- a.** Submitted applications to create spin-offs
- b.** Research Institute participation in spin-off share capital and in the governing organ, as applicable
- c.** Research Institute acquisitions and transfers of shares in the spin-offs
- d.** Research Institute research results over which the spin-off exercises rights of use and commercialization, as appropriate
- e.** The registered address of the spin-off.

17.2. Research Institute spin-offs must update the spin-off registry regarding any change that occurs in relation to the above-mentioned issues.

17.3. Information on spin-offs shall be kept up-to-date in the register for as long as the Research

³ Validate issues to be taken account of in registration.

Institute continues to hold a stake or be connected via any agreement with the spin-off.

Article 18. Corporate image for Research Institute spin-offs

18.1. The Research Institute will, on a non-exclusive, non-transferable and non-sublicensable basis, give spin-offs complying with the arrangements provided for in this Regulation permission to use the corporate image and logo, “HSCSP Research Institute spin-off” for the exclusive purpose of identification as such in the market.

18.2. Research Institute spin-offs are required to use the abovementioned corporate image and logo in conjunction with their own corporate image.

18.3. The use of the corporate image and logo shall not in any circumstances indicate that the spin-off acts on behalf of the Research Institute or that the Research Institute endorses its business activities.

18.4. The Research Institute may at any time request the spin-off to cease using the above-mentioned corporate image and logo, in which case, the spin-off shall cease to use it immediately.

Article 19. Entities referred to in this Regulation

If any of the entities referred to in this Regulation cease to hold the responsibilities or duties described, they shall be substituted in this Regulation by the entity designated by the Research Institute to carry out the former’s responsibilities or duties.

TITLE VI. FINAL PROVISIONS

ADDITIONAL PROVISION. Compliance with applicable legislation

The Research Institute shall, in the shortest time possible, amend the provisions of this Regulation to any future modification of the applicable legislation.

FINAL PROVISION. Entry into force

This Regulation shall enter into force on the day following its approval by the Research Institute Board.