INSTITUT D'INVESTIGACIÓ SANITÀRIA PERE VIRGILI (IISPV)

REGULATION FOR THE CREATION OF TECHNOLOGY-BASED COMPANIES OF IISPV

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PREAMBLE 1

The Fundació Institut d'Investigació Sanitària Pere Virgili, (hereinafter, IISPV), is a public foundation incorporated on 3 February 2005 within the framework of an institutional scientific collaboration agreement between the ICS Camp de Tarragona (Joan XXIII Hospital University, Tarragona, Primary Healthcare centre serving the Camp de Tarragona area), ICS Terres de l'Ebre (Hospital de Tortosa Verge de la Cinta, Primary Healthcare centre serving Terres de l'Ebre area), Sant Joan de Reus University Hospital, Pere Mata Group, and Rovira i Virgili University to coordinate health and biomedical research and research training in the Camp de Tarragona and Terres de l'Ebre regions.

The Board of Trustees has the majority participation of the Catalan Government, through the Department of Health and the Department responsible for research, and the participation of Rovira i Virgili University.

The IISPV is a foundation whose purpose is to promote, develop, transfer, manage and disseminate research, scientific and technological knowledge, teaching, and training in the field of life and health sciences, mainly around the Camp de Tarragona and Terres de l'Ebre regions.

With this purpose in mind, Article 17 of the Articles of Association sets out the specific regime regarding "Creation and participation in companies and companies", providing that the IISPV may set up companies and participate in them without the need for prior authorization, under the terms approved by the Board of Trustees and permitted by current legislation".

The IISPV has become an important research centre in biosanitary research and health sciences, carrying out research and teaching activities, either directly or through related entities, to generate knowledge and technologies, of high added value, which allow not only to improve the healthcare activity of the centre, but also to promote new advances that favour society.

To fulfil its objectives, the IISPV aims to encourage the creation of spinoffs arising at the initiative of its research staff and based on the exploitation of the technology and knowledge developed through the scientific research activities of the IISPV and the researchers themselves.

¹ This preamble is intended to be purely indicative, so it must in any case be in line with the characteristics, needs and guiding principles of the IISPV and its technology transfer policy.

The recent reform of the regulation of public research pushed through upon the approval of the new Law 14/2011, of 1 June, on Science, Technology and Innovation, has affected the framework of the creation of companies in the environment of Research Centres, in particular Articles 17 and 18 thereof, establishing mechanisms that favour the mobility of researchers.

Likewise, with the approval of Law 7/2011, of 27 July, on fiscal and financial measures established by the legal regime of the Research Centres of Catalonia (CERCA), it has established a legal framework applicable to these centres that has allowed to promote research, development and innovation as key elements of the new model of transformation and economic cohesion, with the aim of consolidating Catalonia as a benchmark for the advancement of knowledge and providing these Centres powers with to approve the creation of companies.

Therefore, with the aim of advancing the IISPV's promotion of research activities within its field, it is considered necessary to define an appropriate legal framework for the creation of companies in the environment of the IISPV.

In view of this new legal framework, the IISPV has considered it appropriate to establish a regulation to regulate the procedures for the creation of companies around the IISPV promoted by IISPV staff, as well as the applicable requirements for participation, of this staff as well as of the IISPV itself in these companies. All of the above with the aim of achieving a framework that promotes and supports the creation of such companies as well as their transfer of research results to the productive and social fabric.

I. INTRODUCTION

CHAPTER I. PURPOSE, SCOPE, AND DEFINITIONS

Article 1. Purpose and scope of the Regulation

The purpose of this Regulation is to establish the legal regime applicable to business projects arising from the IISPV environment, as well as the establishment of the formulas for the participation of both the IISPV itself and the IISPV research staff in these business projects, and the relational framework with them.

Article 2. Definitions

For the purposes of these regulations, the following definitions shall apply:

Spinoff: company promoted by IISPV research staff whose purpose is to exploit the results of IISPV research, whether participated in by the IISPV or not.

a) Research Personnel: IISPV staff who, in possession of the qualifications required in each case, carry out a research activity, understood as the creative work carried out systematically to increase the volume of knowledge, including that relating to human beings, culture and society, the use of this knowledge to create new applications, their transfer and dissemination.

Research Results: all technology, knowledge or processes that have been developed under the framework of the research activities carried out at the IISPV.

II. LEGAL FRAMEWORK GOVERNING SPINOFFS

CHAPTER II. PROCEDURE FOR CREATING SPINOFFS OF THE IISPV AND PARTICIPATION IN SPINOFFS ALREADY CREATED

Article 3. Application for authorization

3.1. IISPV Research Staff who are interested in: (i) the creation of a Spinoff for the commercial exploitation of IISPV Research Results, or (ii) participation by IISPV in an already incorporated company whose purpose is the commercial exploitation of IISPV Research Results, must submit the corresponding Application, which must include the following information:

- a) Presentation of the partners/entrepreneurial team, indicating their link with the IISPV, and the statement that they will not engage in the business project in breach of the regulations governing incompatibility.
- b) Applications for compatibility authorization for the provision of services in society, for leave of absence and/or the non-application of regulations governing incompatibility, made by those members of the entrepreneurial team who are Research Staff of the IISPV and who wish to participate in the Spinoff.
- c) Draft Business Plan, which includes the following aspects:
 - Technical feasibility study, including aspects related to matters such as health and safety, environmental management, etc, in accordance with current legislation and specific regulation.
 - Study of economic-financial feasibility where the economic potential of the project is evaluated, possible viable alternatives of financing, foreseen necessary investments as well as of the sales and expenses and of the cash flow expected in the first years, including the expected rate of return.
 - Strategic feasibility study, which includes the competitive advantages of the proposed project to successfully achieve its implementation in the target market.
 - d) Proposal, if applicable, for the use of IISPV or Institutional Trustees' facilities, where appropriate.
 - e) If the Spinoff is already constituted, in addition:
 - Articles of Association of the company and Agreements signed by and between its partners.
 - Certificates issued by the Tax Agency and the General Treasury of the Social Security accrediting that the company is aware of its obligations to both Administrations.
 - Annual Accounts and Report for the last four financial years, if any.
 - f) Descriptive report of the IISPV Research Results to be exploited in the framework of the development of the Spinoff project, or a copy of the Research Results transfer contract previously signed with the IISPV, when applicable.
- 3.2. For the preparation of the above-mentioned documentation, applicants may receive the advice of the Intellectual Property Area of the IISPV.

Article 4. Analysis of the IISPV Spinoff project

- 4.1. Once the Application has been submitted, the IISPV will proceed to analyse the viability of the business project, the technological, market and financial aspects, and will issue a report which must include the following aspects:
 - a) Research results that are intended to be exploited and the activity to be carried out by the company.
 - b) Proposal for participation by the IISPV, if applicable.
 - c) The considerations it deems most appropriate.
 - d) Proposal, where applicable, for the installation of the business project at the facilities of the IISPV or of Institutional patrons.
- 4.2. The IISPV may request additional information from applicants for this analysis.
- 4.3. Subsequently, the Application, together with the report issued by the IISPV, will be sent to the IISPV Board of Trustees.

Article 5. Spinoff Authorization Procedure

- 5.1. The Board of Trustees, in view of the documentation received, will decide on the request to create the Spinoff and the legal regime that will govern its constitution, as well as the applicable royalties/fees.
- 5.2. The IISPV Board of Trustees will inform of its decision to both the applicants and the direction and management of the IISPV, so that they can develop all formal aspects necessary for the implementation of the agreement that is adopted, for due purposes.
- 5.3. The IISPV Direction will sign the documents in which the agreement is entered into, and in particular the contract for the transfer of the Research Results and, if applicable, the contract between partners, in accordance with the provisions of Articles 8 and 9 of this Regulation.
- 5.4. If the IISPV Board of Trustees does not approve its participation in the share capital of the Spinoff, it will notify IISPV direction and management so that it may proceed, if necessary, with the possible signature of the corresponding contract for the transfer of Research Results between the IISPV and the Spinoff, subject in any case to the applicable property regulations.

Article 6. Participation of the IISPV in the share capital of the Spinoff

- 6.1. The authorization of the Board of Trustees for the participation of the IISPV in the share capital of the Spinoff will establish the terms and conditions under which the acquisition of the participation will take place.
- 6.2. The contribution of the IISPV for its participation in the share capital of the Spinoff may consist of:
 - a) Direct monetary contributions.
 - b) The contribution of goods and/or rights, such as the IISPV Research Results necessary for the development of the Spinoff activity, valued on the basis of their market value.
- 6.3. The IISPV shall notify the 'Protectorat' (foundations supervisory commission) within thirty days of the acquisition and holding of shares or participations that either directly or indirectly empower it to control limited liability companies.
- 6.4. Companies in which the IISPV participates must submit their accounts, as well as a management report, and any other documentation determined legally, to the IISPV management annually.

Article 7. Participation of the IISPV in the governing body

- 7.1. The participation of the IISPV in the share capital of a Spinoff may involve the presence of representatives of the IISPV in its governing body.
- 7.2. The IISPV shall have the power to appoint and, where appropriate, replace and/or remove representatives of the IISPV from the governing body of the Spinoff. In accordance with current regulations, such designation shall constitute an authorization of compatibility. In each case, the suitability of participation in the governing body of the companies will be assessed, in accordance with the strict system of responsibilities assumed by the directors of commercial companies, in accordance with the applicable regulations.

Article 8. Contract between Partners

8.1. All the members of the Spinoff in which the IISPV participates must sign, before or upon the start of participation by the IISPV, a contract between the partners,

which will set forth, among others, the rules of administration and governance of the Spinoff in accordance with the provisions of these Regulations and the agreement of authorization of the Board.

- 8.2. The partner agreement will establish the obligation for new members to adhere to it, unless the IISPV expressly agrees otherwise.
 - The IISPV may reserve in the contract between partners the right to totally or partially leave the IISPV Spinoff, hence the remaining partners assume in writing their commitment to acquire the participations held by the IISPV at the time that this institution expresses its will to totally or partially divest in the IISPV Spinoff. This may be caused by a breach of contractual obligations with the IISPV, the abandonment of the activity, the performance of an activity contrary to the ethical principles established in the IISPV Statutes, or the mere will of the IISPV to disassociate itself from the Spinoff.
- 8.3. For the purposes of the previous section, the mechanism for determining the acquisition price of the IISPV shares must be set out in the contract between the partners. In addition, the transfer contract must regulate the recovery of the transferred results, the obligation to immediately cease to use the term "IISPV Spinoff", as well as the use of the IISPV corporate image.

Article 9. Contract for the Transfer of Research Results

- 9.1. The transfer of the rights of use and commercial exploitation of the IISPV Research Results will be carried out in accordance with the applicable procedure in accordance with current regulations.
- 9.2. In any case, said transfer will involve entering into a contract for the transfer of the Research Results, which will regulate the terms in which the transfer will take place in favour of the Spinoff, as well as the corresponding consideration to which the IISPV will be entitled, in accordance with the conditions that may have been established by the IISPV.
- 9.3. The contents of the Contract for the Transfer of Research Results will follow the applicable regulations and good practices in upholding the usual public interest in this type of contract.

III. PARTICIPATION OF IISPV RESEARCH STAFF IN SPINOFFS

Article 10. Application for leave of absence to carry out activities in the Spinoff

- 10.1. Permanent Research Staff with a minimum of five years of seniority who wish to join the activities of a Spinoff may apply to the IISPV to be granted temporary leave of absence for a maximum period of five years.
- 10.2. Leave of absence must be requested for the performance of any of the activities referred to in Article 17.4 of Law 14/2011, on Science, Technology and Innovation, which must be carried out in all cases on an employment basis.
- 10.3. The granting of leave of absence will be subject to the needs of the service and the interest that the IISPV has in performing the activities to be carried out in the Spinoff and a favourable report from the IISPV's Intellectual Property Area.
- 10.4. The maximum period of temporary leave of absence will be five years, it not being possible, once this period has expired, to request further temporary leave for the same reason until at least two years have elapsed since re-joining active service, or incorporation into the workplace from previous leave.
- 10.5. During the period of leave, no remuneration will be payable for the place of origin, but the interested party will be entitled to keep their job on hold and have their research activity, if any, evaluated.

Article 11. Authorization for the provision of services in the Spinoff

- 11.1. IISPV Research Staff may request authorization for the provision of services in an IISPV Spinoff, through a part-time, fixed-term employment contract, as established in Article 18 of Law 14/2011, on Science, Technology and Innovation.
- 11.2. The application must be accompanied by a report justifying the applicant's participation in an action of interest to the IISPV.
- 11.3. The recognition of compatibility granted, where applicable, will be in accordance with the provisions of legal regulations, specifically as set forth in Article 18.2 of Law 14/2011.

Article 12. Regime of participation of the Research Staff of the IISPV in the Spinoff.

- 12.1. The participation of IISPV Research Staff in the share capital and the governing body of the Spinoff will be in accordance with the provisions of the regulations on incompatibilities of staff at the service of the Public Administration.
- 12.2. Research staff participating in a Spinoff set up or with participation in accordance with the rules provided for in these Regulations may request exemption from the application of Articles 12.1.b) and d) of Law 53/1984, as established in Article 18 of Law 14/2011, on Science, Technology and Innovation.

Article 13. Protection of IISPV Research Results

- 13.1. IISPV Research Staff participating in a Spinoff, including those who take advantage of any of the possibilities set forth in this Section, must protect the Research Results of the IISPV and its research teams, in accordance with the general intellectual and industrial property regulations of the IISPV, and the agreements and conventions signed by this entity.
- 13.2. The IISPV will establish the necessary measures to protect its position in the event of any conflict of interest.
- 13.3. In relation to IISPV Research Staff who are covered by the regime provided for in Article 11, it will be presumed that the Research Results developed by them during the compatibility period will be subject to the regime of creations or inventions developed under an employment relationship with the IISPV, unless otherwise agreed or proven. To this end, the necessary measures for the purposes described in this clause shall be contractually established.
- 13.4. The IISPV Spinoff must keep the IISPV permanently informed of developments and improvements in the results subject to transfer in their research and development activities.
- 13.5. In view of its nature and origin, the IISPV Spinoff must seek to reinvest part of the profits obtained, as a result of the exploitation of the results of the IISPV, in the funding of activities of R&D&I in collaboration with the IISPV.

IV. SPINOFF SUPPORT SERVICES

Article 14. IISPV training and aid programme

- 14.1. The IISPV, to encourage the creation of Spinoffs, to the extent possible, will develop a policy to promote entrepreneurship, which may include both programmes to support the implementation of entrepreneurial projects and the promotion of aid to these companies.
- 14.2. These support services will be coordinated by the Intellectual Property Area of the IISPV, which may, among others, offer the following services:
 - a) Incubation of companies.
 - b) Assistance in drafting the Business Plan.
 - c) Technological advice.
 - d) Advice on the search for capital and grants, as well as in the negotiation of agreements and arrangements with private investors or venture capital organizations.
 - e) Training.
 - f) Internationalization.
 - g) Strategic alliances.
 - h) Search for funding.
- 14.3. The IISPV may, with its budgets or agreements with other public or private entities, set up a seed capital fund that facilitates the creation and financing of companies.

Article 15. Use of facilities

IISPV spinoffs may request to join the business incubator. To this end, an agreement must be entered into between the companies and the IISPV regulating the conditions and terms under which the services and facilities of the business incubator will be contracted by the companies and the applicable considerations.

Article 16. Collaboration agreements

16.1. The IISPV and the Spinoffs may sign collaboration agreements with other entities, always respecting the founding principles set out in the IISPV Statutes.

16.2. In the preparation of these agreements, the appropriate mechanisms will be established to avoid potential situations of conflicts of interest, as well as the obligation of the Spinoffs to establish the necessary procedures so that the personnel involved in their activities does not disclose the trade secrets and intellectual property of those who have become aware of them due to their membership of the IISPV or of these companies, not only during their tenure, but also after termination of their contractual relationship with it.

V. MISCELLANEOUS

Article 17. IISPV Spinoff Register

- 17.1. The Intellectual Property Area will be in charge of the IISPV Spinoff Registry, which will include the following items:
 - a) Applications for the creation of IISPV Spinoffs submitted.
 - b) Spinoff applications that have been processed by the IISPV.
 - c) The participation of the IISPV in its share capital and in the administrative body, where applicable.
 - d) The acquisitions and transfers of shares in these companies by the IISPV.
 - e) The IISPV Research Results of which the company owns the rights, as the case may be, for their use and commercial exploitation.
 - f) The registered office of the Spinoffs.
- 17.2. IISPV Spinoffs, or as the case may be, the IISPV, must notify the Spinoffs Registry of any changes to the items described above for their updating.
- 17.3. The Registry will keep the Spinoff information up to date as long as the IISPV maintains a shareholding or contractual link, as the case may be, with the said company.

Article 18. Corporate image of IISPV spinoffs

18.1. The IISPV shall grant to the IISPV Spinoffs incorporated or recognized in accordance with the regime provided for in these Regulations, a licence for the non-exclusive, non-sub-licensable and non-transferable use of the corporate image and name, "IISPV Spinoff", solely for the purposes of using them to identify themselves as such in the market.

- 18.2. IISPV Spinoffs must use the aforementioned corporate image and name in association with their own corporate image.
- 18.3. The use of the corporate image and the name indicated will under no circumstances authorize the companies to act in the name of the IISPV, even if the latter may endorse its business activities.
- 18.4. The IISPV may at any time require the termination of the use of the name and corporate image indicated in this article. In this case, the company will have to stop using it immediately.

Article 19. Preferential recruitment of Rovira i Virgili University students

- 19.1. The IISPV Spinoffs, during the course of their activity, will try to preferentially hire students who have studied at Rovira i Virgili University, helping them to enter the labour market.
- 19.2. The IISPV Spinoffs will try to use, preferentially, the job bank of the IISPV and of Rovira i Virgili University to source the professionals they seek for the performance of their activities.

Article 20. Reference to the bodies provided for in these Regulations

In the event that any of the bodies referred to in these Regulations ceases to hold any of the responsibilities or attributions provided for herein, their position within these Regulations will be assumed by the entity designated by the IISPV to carry out such responsibilities or attributions.

VI. FINAL PROVISIONS

ADDITIONAL PROVISION. ADJUSTMENT TO THE APPLICABLE REGULATIONS

The IISPV will endeavour, as soon as possible, to adapt the provisions set out in these regulations to any possible modification of the applicable legal regulations, in particular those relating to incompatibilities and the creation of companies.

FINAL PROVISION. ENTRY INTO FORCE

These Regulations will enter into force on the day following their approval by the Board of Trustees of the Fundació Institut d'Investigació Sanitària Pere Virgili.

Board, 10 July 2020