

**AUGUST PI I SUNYER BIOMEDICAL RESEARCH INSTITUTE**

**REGULATIONS SUPPORTING THE CREATION OF SPIN-OFFS**



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## **PREAMBLE<sup>1</sup>**

The August Pi i Sunyer Biomedical Research Institute (IDIBAPS) is a leading research center focused on disease prevalence, morbidity and mortality. Founded in 1996, it is a public consortium made up of the Generalitat de Catalunya, the Hospital Clínic de Barcelona, the Faculty of Medicine and Health Sciences of the University of Barcelona and the Barcelona Institute for Biomedical Research at CSIC.

In accordance with its By-Laws, the main objective of IDIBAPS is "to develop research in the field of biomedical sciences, especially oriented to basic and clinical research activity".

Among its research activities, IDIBAPS has made great contributions to the fields of applied knowledge and innovation. Its overarching goal is to involve both patients and society at large in the advances made by these research activities, resulting in valuable products that reach the world marketplace. IDIBAPS has the expertise not only to carry out all the necessary negotiations when working with business organizations, but also to advise on the best plan of action when exploring the various options for setting up a new companies (spin-offs). In this regard, IDIBAPS has a SOP entitled "Procedure for creating a spin-off", last revised on 28/02/2019.

For this reason, and in conjunction with the regulations governing Intellectual Property Rights (IPR), approved by the Governing Board of December 17, 2014, IDIBAPS has decided to formulate its own regulations for the promotion, support, and development of new business projects by its research staff.

The reform of regulations on publicly funded research, which was promoted by the passing of Law 14/2011 (June 1) for Science, Technology and Innovation, has made an impact on the creation of companies affiliated with research centers. Articles 17 and 18 of this Law, in particular, establish mechanisms that help facilitate business opportunities for researchers.

In addition, with the approval of Law 7/2011 (July 27), fiscal and financial measures established under the auspices of the Research Centers of Catalonia (CERCA) provide a legal framework applicable to these centers. This legal framework will make it possible to promote research, development and innovation as key elements inherent to the new model of transformation and economic cohesion, with the overall aim of consolidating Catalonia's position as a leader in the advancement of knowledge, and

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<sup>1</sup> This preamble is intended to be merely a framework, and will in any case have to be adapted to the specific characteristics, needs and guiding principles of IDIBAPS and its technology transfer policy.

conferring upon these centers the autonomy to approve the creation of companies and spin-offs. In this sense, IDIBAPS is considered a CERCA center, subject to the legal framework established by Law 7/2011 governing all fiscal and financial measures, as well as by the Eighth Additional Provision of this Law, and by the rest of those specific regulations that the Generalitat of Catalonia promulgates in the field of scientific research.

In accordance with all of the above, IDIBAPS has deemed it appropriate to establish its own set of regulations governing not only the procedures for the creation of spin-offs by IDIBAPS research staff, but also the requirements of participation by said staff and IDIBAPS itself to such companies. All of this is to be carried out with the goal of establishing a framework that promotes and supports the creation of such companies and the transfer of research results to the societal and industry network.

## TITLE I. INTRODUCTION

### Article 1. Object and scope of the regulations

These regulations aim to establish the legal requirements applicable to business projects arising from IDIBAPS, and the participation guidelines for both IDIBAPS itself and its research staff in business projects, as well as the relationship framework ordering the same.

### Article 2. Definitions

For the purposes of these regulations, the following definitions will be used throughout:

- a) **Spin-off:** A company owned by IDIBAPS and its research staff that intends to make use of IDIBAPS Research Results.
- b) **Research Staff:** IDIBAPS staff who, in possession of the proper accreditation in each case, carry out research activity, understood as the creative work carried out in a systematic way to increase the body of knowledge, including those related to human beings, culture and society. This includes the use of said knowledge to create new applications, their transfer and dissemination.
- c) **Own Research Staff:** Research staff hired by IDIBAPS.
- d) **Affiliated Research Staff:** Research staff hired by a third institution that carries out their research tasks at IDIBAPS, regulated by any pertinent agreements between the two institutions.
- e) **Results of the research:** Any and all technology, knowledge or processes that have been developed within the framework of research activities carried out at IDIBAPS.

## TITLE II. IDIBAPS SPIN-OFF CREATION PROCEDURE AND PARTICIPATION OF SPIN-OFFS ALREADY CREATED

### Article 3. Authorization request

- 3.1. Research Staff (own and affiliated) who are interested in: (i) the creation of a Spin-off for the commercial exploitation of Research Results, or (ii) the participation of IDIBAPS in a company already constituted and whose purpose is the commercial exploitation of Research Results, will have to present the corresponding Application, which must include the following information:

- a) Presentation of the partners / entrepreneurial team, indicating their connection with IDIBAPS, and a statement that they will not be involved in any aspects of the business project that are in breach or incompatible with the existing regulations.
- b) Requests for authorization regarding compatibility of provisions pertaining to the company's services, of leave of absence and / or of implementation of the rules on incompatibilities, made by those members of the entrepreneurial team who are part of the Research Staff and who want to participate in the spin-off.
- c) Draft of the Business Plan, which includes the following aspects:
  - Economic and financial feasibility study evaluating the economic potential of the project, any viable financing alternatives, forecasting of the necessary investments, as well as sales and expenses, and expected cash flow during the initial years, with a stated rate of the expected return(s).
  - Strategic feasibility study, which encompasses the competitive advantages of the proposed project when successfully implemented in the marketplace sector it is targeted for.
- d) Application for use of any facilities belonging to the Business Incubator, if IDIBAPS has the necessary space.
- e) In the event that the spin-off is already constituted, there shall be in addition:
  - Company By-Laws and Shareholders Agreement signed between its members;
  - Certificates issued by the Tax Agency and the Treasury Department of the Social Security Administration proving that the company is aware of its obligations to both agencies.
  - Annual Accounts and Report(s) for the last four financial years, if any.
- f) Descriptive report of the Research Results to be exploited as part of the development of the spin-off project, or a copy of the transfer agreement of the Research Results previously signed in agreement with IDIBAPS.

3.2. Applicants will seek the advice of the IDIBAPS Knowledge and Technology Transfer (KTT) Office to prepare the aforementioned documents.

3.3. In cases where members of the entrepreneurial team are Affiliated Research Staff, their participation will be subject to the authorization granted by the entity to which they are associated, in accordance with the existing regulations and procedures stipulated by that entity.

#### **Article 4. Spin-off project analysis**

4.1. Once the application has been submitted, the IDIBAPS Knowledge and Technology Transfer Office will analyze the feasibility of the business project, in particular its technological, market and financial aspects, and will issue a report that must address the following aspects:

- a) Relation to Research Results.
- b) Details regarding the participation of IDIBAPS, if applicable.
- c) Any other considerations deemed appropriate.
- d) A proposal, when possible, for installation of the business project within the working spaces of the Business Incubator.

4.2. To carry out this analysis, the Knowledge and Technology Transfer Office may request additional information from the applicants.

4.3. Subsequently, the Request, together with the report made by the KTT, will be forwarded to the Director of IDIBAPS and then to the Governing Board of IDIBAPS for review.

#### **Article 5. Spin-off authorization procedure**

5.1. The Governing Board<sup>2</sup>, in light of the documentation received, will make a determination regarding the application for creation of said Spin-off, as well as the legal framework that will regulate its creation, and any corresponding benefits.

5.2. The Governing Board will communicate its decision to both the applicants and the KTT Office, in order to develop all formal aspects necessary to implement the agreement adopted for those purposes.

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<sup>2</sup> The By-Laws do not provide for the express attribution of the powers to decide upon the participation of companies, and thus are granted to the Governing Board (as the supreme body) or to the Permanent Commission (when delegated by the Governing Board).

5.3. The Director and / or Manager of IDIBAPS will be responsible for signing the documents legally formalizing the agreement, and in particular the contract governing the transfer of Research Results and, where applicable, the agreement between partners, in accordance with the rules established in Article 8 and Article 9 of these Regulations.

5.4. In the event that the Board of Governors does not approve participation in the shared capital of the Spin-off, this body shall notify the KTT Office, thereby allowing it to proceed, where appropriate, with the eventual signing of the corresponding contract for the transfer of the Research Results between IDIBAPS and the spin-off, subject in any and all cases to applicable regulations regarding the equity.

**Article 6. IDIBAPS participation in the shared capital from the spin-off**

6.1. The authorization order of the Governing Board for the participation of IDIBAPS in the equity of the Spin-off will establish the terms and conditions under which said participation will be conducted.

6.2. The contribution of IDIBAPS as a stakeholder in the equity from the spin-off may consist of:

- a) Direct cash contributions.
- b) Contribution of goods and / or rights, such as the Research Results needed to develop the spin-off activity, and/or its valued based on current market value.

6.3. Companies participating in such agreements with IDIBAPS must submit their accounts information, as well as a management report, and any other legally determined documentation, to the KTT Office on an annual basis.

**Article 7. Participation of IDIBAPS in the governing body**

7.1. The participation of IDIBAPS in the equity of a Spin-off may require the presence of its representatives in the governing body.

7.2. IDIBAPS will be empowered to make appointments and, whenever deemed appropriate, to replace and / or remove its representatives from the spin-off administrative body, in the event that IDIBAPS is represented therein. In accordance with the provisions of current regulations, said designation will refer to authorizations of compatibility.

**Article 8. Contract between Partners**

8.1. All IDIBAPS members participating in the Spin-off must sign, prior to or simultaneously with its creation, a contract between the signatory partners, which will determine, among other issues, the rules of administration and governance of the 'Spin-off' in accordance with the provisions of these Regulations and per the authorization agreement approved by the Governing Board. The membership agreement will establish the obligation of new members to join it, unless expressly stated otherwise by IDIBAPS.

**Article 9. Contract for the Transfer of Research Results**

9.1. The transfer of the rights of use and commercial exploitation of Research Results will be carried out in accordance with all applicable procedures and all current regulations.

9.2. In any case, said transfer will require formalization of a contract for the transfer of Research Results. Said contract will govern the terms by which the transfer will occur in favor of the spin-off, as well as corresponding considerations to which IDIBAPS will be granted rights, in accordance with the conditions established by the Governing Board.

9.3. The contents of the research results transfer contract will follow all applicable regulations and good practices in defense of the public interest common to these types of contracts.

**TITLE III. PARTICIPATION OF IDIBAPS' OWN RESEARCH STAFF IN THE SPIN-OFF**

**Article 10. Application for leave of absence to undertake activities related to the development of the spin-off**

10.1. IDIBAPS' Own Research Personnel having a fixed contract and with a minimum history of five years' service who wish to participate in a Spin-off may request a voluntary leave of absence from IDIBAPS for a maximum period of five years.

10.2. Said leave of absence must be requested for 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 under the terms of the existing employment contract.

- 10.3. The granting of a leave of absence will be subordinated to the needs of the services and the interest that IDIBAPS has in carrying out the activities related to the spin-off.

Therefore, in any and all cases, a favorable report from the research group to which the applicant is attached will be required, in which the aforementioned points and concerns are taken into account.

- 10.4. The maximum duration of the temporary leave shall be five years, with no possibility, once this period has expired, to request a new temporary leave for the same spin-off until at least two years have elapsed since re-entry to employment for IDIBAPS, whether active or having been reintegrated into the workplace from a previous leave.
- 10.5. During the leave period, no remuneration will be received from the place of origin.

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

- 11.1. Own Research Staff may request authorization for the provision of services in a Spin-off created through or involving the participation of IDIBAPS, through a paid part-time employment contract and for a fixed duration, in accordance with the provisions of article 18 of Law 14/2011 on Science, Technology and Innovation.
- 11.2. The request must be accompanied by a report justifying the applicant's participation in an activity related to the scientific and technical priorities set forth in the Spanish Strategy for Science and Technology or in the Spanish Strategy for Innovation.
- 11.3. Approvals of compatibility, when deemed appropriate by the Governing Board of IDIBAPS, will not extend to modifications of the stipulated work schedule, and will be rendered automatically invalid in case of an employee's move to the public sector .

**Article 12. Participation Scheme of Research Staff in the spin-off**

- 12.1. The participation of Research Staff in the sharing of capital, as well as the workings of the governing body of the Spin-off, will be carried out in accordance with the provisions and regulations governing staff incompatibilities in the Public Administration sector.
- 12.2. Own Research Staff who participate in a spin-off set up or in joint venture in accordance with the legal structure provided for in these Regulations may request that articles 12.1.b) and d) of Law 53/1984 not be applied to their

case(s), as established in article 18 of Law 14/2011 on Science, Technology and Innovation.

### **Article 13. Protection of Research Results**

- 13.1. Research Staff participating in a spin-off, including those who take advantage of any of the provisions set forth in this Title, must protect the Research Results of IDIBAPS and its research teams, in accordance with IDIBAPS' Regulations on Intellectual Property, and per any and all agreements signed by this entity.
- 13.2. IDIBAPS will establish the necessary measures to protect its position in the event of situations presenting a conflict of interest.
- 13.3. In relation to IDIBAPS' Own Research Staff electing to take advantage of the provisions set forth in Article 11, it will be presumed that the Research Results produced by them during the compatibility period will be subject to said provisions, including creations and/or inventions developed while employed by IDIBAPS, unless by prior agreement or proof to the contrary is provided. In this regard, the necessary measures for the purposes described in this clause shall be contractually established. Thus, the corresponding License and Shareholders Agreements will be signed to compel Own Research Staff to provide reports on the research activities carried out. Equally, in accordance with the provisions of the Patent Law, Researchers are required to report the development of any invention made in the context of their relationship with IDIBAPS.

## **TITLE IV. ACCOMPANYING AND SUPPORTING MEASURES**

### **Article 14. Business incubator**

- 14.1. IDIBAPS may, on its own initiative or in collaboration with entities in its network, create a business incubator; i.e., a space for hosting companies so that they can establish themselves and carry out their activities during the first years of their existence.
- 14.2. In cases involving the creation of a new enterprise, the spin-off may apply for residence in the business incubator, in accordance with the requirements and procedures that have been established by IDIBAPS or the management company of the business incubator, and for those activities authorized therein. In case of conformity, the formulation of a contract will be required, which

will regulate the conditions and terms of use of the spaces and any corresponding considerations.

**Article 15. Use of IDIBAPS facilities and services**

- 15.1. Spin-offs will have access to IDIBAPS' own facilities, such as laboratories, to carry out their activities, albeit with prior authorization and adherence to the corresponding contract, if applicable, and where possible their use by entities other than IDIBAPS. Said authorization will be conditioned on the fact that the use of any facilities by the Spin-off does not result in harm or otherwise interrupt the performance of activities by IDIBAPS and/or other entities in the Hospital Clínic campus.
- 15.2. Likewise, Spin-offs may contract with IDIBAPS to provide research services that fall within the competencies and activities of this center.
- 15.3. The use of IDIBAPS resources, services and facilities must, in any and all cases, be in accordance with the internal rules of use approved by this institution, and must be paid in accordance with the rates established by IDIBAPS for use by third parties.

The spin-off and its staff must comply with all labor regulations currently in force, to include those regulating occupational risks and safety that IDIBAPS has approved for use in its facilities.

IDIBAPS will not be liable in any case, neither jointly nor severally, for any labor matters that might be claimed by the staff hired by the Spin-off, as a result of their employment contract with the Spin-off.

For these purposes, the Spin-off will guarantee that it complies with the labor and social security regulations provided for under Spanish labor laws and will ensure that they are complied with in full, being solely responsible for all purposes and provisions.

- 15.4. IDIBAPS will not assume any responsibility for activity stemming from the Spin-off, beyond that which may correspond to it under the agreement or any other agreement that has been signed with the Spin-off. The spin-off must keep IDIBAPS free from any contingency and liability that may arise from the performance of its own activities.

## **TITLE V. SPIN-OFF SUPPORT SERVICES**

### **Article 16. Training and assistance programs**

16.1. IDIBAPS, in order to promote the creation of spin-offs, will develop a policy promoting entrepreneurship, which may include both programs to support the implementation of entrepreneurial projects and the promotion of grants to such companies.

16.2. These support services will be coordinated by the KTT Office.

### **Article 17. Collaboration agreements**

17.1. IDIBAPS and Spin-offs may sign collaboration agreements for the development of research activities, in any and all cases respecting the founding principles set forth in the IDIBAPS Statutes.

17.2. In the preparation of these agreements, appropriate mechanisms will be established to prevent potential conflicts of interest, as well as the obligation of spin-offs to establish the necessary procedures for staff involved in their activities so as to prevent the disclosure of information or knowledge belonging to or derived from IDIBAPS or third parties with which IDIBAPS collaborates and/or from those who have had access to said information or knowledge via such collaboration, not only during the duration of their stay, but also after the termination of their contractual relationship with the spin-off.

### **Article 18. IDIBAPS spin-off registry**

18.1. The IDIBAPS KTT Office will be in charge of the IDIBAPS Spin-off Registry, in which the following information will be documented:

- a) Any spin-off creation requests that have been submitted.
- b) The participation of IDIBAPS in its sharing of capital and in the governing body, as the case may be.
- c) The acquisitions and transmissions of shares in these companies by IDIBAPS.
- d) The Results of the IDIBAPS Research to which the company has rights, as the case may be, for their use and commercial exploitation.
- e) The registered office of the spin-offs.

18.2. The Legal Department of IDIBAPS will be responsible for storing the original documents.

18.3. Spin-offs, or in the case of IDIBAPS, must update the Spin-off Registry of any changes that occur in relation to any and all aspects described above for their proper updating.

18.4. The Registry will keep the Spin-off information updated as long as IDIBAPS maintains a shareholding or contractual link, as the case may be, with said company.

#### **Article 19. Corporate image used by IDIBAPS spin-offs**

19.1. IDIBAPS will grant Spin-offs created or recognized in accordance with the provisions set forth in these Regulations, a non-exclusive, non-sublicensable and non-transferable license for the logo and the name, "IDIBAPS spin-off" , for the sole purpose of using said logo and name in order to identify themselves as such in the marketplace.

19.2. Spin-offs must indicate that they are an IDIBAPS spin-off, in conjunction with their own corporate image.

19.3. The use of the corporate image and the denomination indicated will not in any way mean that the companies act on behalf of IDIBAPS, nor that the latter endorses their business activities.

19.4. IDIBAPS may at any time require the cessation of use of the denomination and the corporate image indicated in this article. In this case, the company will have to cease use of said denomination and corporate image immediately.

#### **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 comply with any of the responsibilities or stipulations provided for therein, its position within these Regulations will be assumed by an entity designated by IDIBAPS for the further completion of those responsibilities and/or adherence to said stipulations.

### **TITLE VI. ADDITIONAL PROVISIONS**

#### **First additional provision. Compliance with applicable regulations**

IDIBAPS will endeavor, in the shortest possible time, to comply with the provisions established in these regulations and to any possible modifications of applicable legal

regulations, in particular those regarding incompatibilities and the creation of companies.

**Second additional provision. Application to previously created spin-offs or to spin-offs to which IDIBAPS is a member**

Researchers participating in spin-offs created by and engaged in participation with IDIBAPS prior to these Regulations entering into force shall adjust their participation according to the mechanisms provided for in Title III.

The spin-offs created and or engaged in participation with IDIBAPS prior to these Regulations entering into force will be able to access the accompanying measures and services that are regulated, under the same conditions as newly created spin-offs or engaged in participation under these Regulations. IDIBAPS will adapt any and all relevant agreements with these spin-offs to incorporate the provisions set forth in these Regulations.

**Third additional provision. Entry into force**

These Regulations shall enter into force on the day following their approval by the Governing Board of IDIBAPS.