AUGUST PI I SUNYER BIOMEDICAL RESEARCH INSTITUTE

REGULATIONS ON INTELLECTUAL PROPERTY RIGHTS



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PREAMBLE¹

IDIBAPS is a consortium under public law comprised of the Generalitat de Catalunya, the Hospital Clínic de Barcelona, the University of Barcelona and the Higher Council for Scientific Research (CSIC), whose main objective is the development of research in the field of biomedical sciences, particularly that oriented to basic and clinical research activity.

In this sense, the activity of IDIBAPS is to integrate quality clinical research with high-level basic research, in order to more efficiently transfer scientific advances to the prevention and treatment of the most prevalent health problems.

The recent reform of the regulation governing research inaugurated by approval of the new Law 14/2011 (June 1) on Science, Technology and Innovation, has had a significant impact on Intellectual Property rights, substantially modifying the legal framework applicable to such work at research centers, as well as to staff providing services to those centers that are part of the National Healthcare System.

Likewise, Law 7/2011 (27 July) on fiscal and financial measures, which provides the legal framework for the Research Centers of Catalonia (CERCA), and which seeks to promote research, development and innovation as key elements of 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, has established a model for the autonomous self-management of these centers in order to achieve these objectives. This model is applicable to IDIBAPS' activities.

Within these guidelines, which apply to the research staff at these Research Centers, are enumerated the rights and responsibilities provided for under said Law on Science, Technology and Innovation, by which the achievement of dual objectives are hereby set forth: on the one hand, in promoting research activity, it seeks to define the legally binding requirements for the parties involved in the development of said research activities; and on the other hand, to involve IDIBAPS staff in these activities, not only recognizing their involvement in the development of new knowledge and technologies, but also allowing them to share the benefits that can be derived from the commercial exploitation of the results of their research activity.

Consequently, and with the intention of continuing to advance and promote IDIBAPS' research, development and / or innovation activities within its field, and in order to comply with the new applicable legal framework, it is deemed appropriate to approve this Regulation on Intellectual Property Rights, which incorporates regulations governing the results of research and innovation developed by IDIBAPS, and the rules regarding their exploitation and the distribution of the benefits derived from them.

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¹ 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 the management and administration policy on intellectual and industrial property rights.

TITLE I. OBJECTIVES AND DEFINITIONS

Article 1. Objective and scope

The purpose of this regulation is to establish a legal framework that regulates the following aspects:

- a) The ownership of the results derived from IDIBAPS' research and the innovation activity carried out by the IDIBAPS Staff.
- b) The procedures to be followed for the protection and exploitation of these results produced by IDIBAPS.
- c) The economic rights resulting from the exploitation of the aforementioned results.

Article 2. Definitions

For the purposes of these regulations, the following definitions will be taken into account:

- a) Investigators: IDIBAPS research staff who, being in possession of the degree required in each case, carry out a research activity, understood as the creative work carried out systematically to increase the body of knowledge, including that relating to human beings, culture and society, the use of this knowledge to create new applications, their transfer and dissemination.
- b) **Research Results:** all technology, knowledge, innovations or processes that have been generated within the framework of the research activities conducted at IDIBAPS.
- c) **Copyright works:** Research results susceptible to protection by copyright, including, but not limited to, books, publications, multimedia works, databases and computer programs (software), excluding conferences, works derived from the teaching activity.
- d) **Inventions:** Research results susceptible to protection by Intellectual Property rights, including, but not limited to, patents, utility models, semiconductor topographies and industrial designs.

TITLE II. OWNERSHIP OF RESEARCH RESULTS, OF INTELLECTUAL PROPERTY RIGHTS DERIVED FROM THE SAME AND EXPLOITATION RIGHTS

CHAPTER I, IDIBAPS' OWN RESEARCH AND INNOVATION

Article 3. Ownership of IDIBAPS' Research Results

IDIBAPS retains ownership of, as well as the exploitation rights over, any Research Results produced by the Research Staff as a result of their research activities at IDIBAPS.

Article 4. Ownership of Intellectual Property rights (industrial application)

IDIBAPS is the owner, and maintains the exploitation rights, of the Intellectual Property rights for Inventions derived from the Research Results described in the previous article.

Article 5. Ownership of Intellectual Property rights

5.1 Ownership of Intellectual Property rights

The Investigators are responsible for the Proprietary Material created as a result of their research activities at IDIBAPS, except in those cases expressly provided for in these regulations.

The exploitation rights for the Propriety Material produced within the framework of the aforementioned functions will correspond to IDIBAPS, under the terms and within the scope provided for by legislation on Intellectual Property. Notwithstanding the foregoing, IDIBAPS will endeavor to reach an agreement with the Research Staff to assign to IDIBAPS the possible exploitation rights of the Proprietary Material generated by IDIBAPS research activities that may eventually remain under the ownership of the Investigators.

5.2 Ownership of Intellectual Property rights in specific cases

a) Collective works

In the case of collective works, those that have been created collectively and under the initiative and coordination of IDIBAPS, the authorship, as well as the ownership of the exploitation rights over the said Proprietary Material, will correspond to IDIBAPS, in the event that this entity edits and publishes it under its name, unless otherwise agreed.

b) Computer program (Software)

In the event that the Proprietary Material developed by any member of the Research Staff in the execution of their research activities at IDIBAPS is software, the ownership of the exploitation rights over it will correspond to IDIBAPS.

In the event that the software is developed collectively and under the initiative and coordination of IDIBAPS, the authorship, as well as the ownership of the exploitation rights over the said Proprietary Material, will correspond to IDIBAPS if the latter modifies it and the software is disseminated under its name, unless otherwise agreed.

c) Database

Ownership of the exploitation rights of the databases that by their design or by the disposition of their contents constitute intellectual creations in accordance with the applicable regulations, and that are developed by Research Staff in the execution of their research activities at IDIBAPS, will be owned by IDIBAPS, unless by its nature the Intellectual Property Law establishes otherwise.

Article 6. Moral rights of authorship of the Investigators

Notwithstanding the provisions of the previous article 4, IDIBAPS will respect in all cases the right of the Investigators to be recognized as the inventor or author of the Inventions or the Proprietary Material that they have developed, in accordance with the provisions of the current regulations in the field of Intellectual Property.

Article 7. Obligation to mention IDIBAPS

In any case, and unless IDIBAPS states otherwise, any Invention or Proprietary Material in which the Investigators participates, made as a direct or indirect consequence of their research activities at IDIBAPS, must acknowledge its link to IDIBAPS.

In this sense, the following statement will be made visible in all the Proprietary Material owned by IDIBAPS: «© Consortium Institute for Biomedical Research August Pi i Sunyer, year (...). All rights reserved".

CHAPTER II. PROJECTS DEVELOPED JOINTLY WITH OTHER ENTITIES

Article 8. Research results derived from projects developed in collaboration with third parties

- 8.1 The carrying out of any commission or project in collaboration with other entities, regardless of the branch of knowledge to which it refers, will require adherence to all stipulations of the corresponding contract.
- 8.2 The system of ownership of the rights of the Research Results obtained under the framework of the execution of an order or a contract, as well as the distribution of the corresponding exploitation rights that are derived, shall be provided for in said contract, without prejudice to the fact that it may postpone the determination of the distribution thereof.
- 8.3 In any case, the rights that may correspond to IDIBAPS must be respected in accordance with these regulations.
- In regards to research activities carried out by the Investigators sponsored by 8.4 private entities, public interest and transparency will prevail. For this reason, necessary agreements will be agreed upon by all relevant parties in order to the protect the intellectual freedom of the Investigators, and commitments or unjustified restrictions on the disproportionate confidentiality publication of the Research Results obtained. Additionally, efforts will be made to may correspond to IDIBAPS. safeguard the rights that
- 8.5 The competent bodies and persons of IDIBAPS will try to ensure that in agreements with third parties, that IDIBAPS will be the party responsible for the protection, management and operation of Research Results as long as IDIBAPS has full or partial ownership of them.

CHAPTER III. MANAGEMENT AND PROTECTION OF RESEARCH RESULTS

Article 9. Communication and management of the protection of the Research Results

9.1 In the event that the Investigators develops a Research Result that warrants protection, they must immediately transfer it to the functional directing or competent body designated for that purpose, providing all relevant information on the creation or invention developed, which will allow IDIBAPS, if it deems it appropriate, to begin the relevant procedures for its legal protection.

Once you have evaluated [...] the information related to the Research Result you have developed, you will transfer it to [...] which will make a decision

- regarding the advisability of protecting and marketing this Research Result, and will notify IDIBAPS [...] of this.
- 9.2 In relation to the Research Results derived from collaborative projects with other public and/or private entities, the protection, management and exploitation will be carried out in accordance with the provisions of the agreements signed between the collaborating entities.

Article 10. Collaboration of the Investigators

- 10.1 The authors or inventors of the Research Results must collaborate with IDIBAPS in all that is deemed necessary to obtain adequate protection of the intellectual property rights and, eventually, their transfer.
- 10.2 The obligation to collaborate shall include, but is not limited to, the requirement to submit any public or private documents that are required by any national and/or foreign office competent in matter of Intellectual Property (nominatively, but not expressly limited to (Patent and Trademark Offices, Intellectual Property Registers, etc.), for IDIBAPS to establish or become, as the case may be, the owner of the Intellectual Property rights of the Research Result, and to exercise its rights according to its status as full owner.

Article 11. Confidentiality and dissemination of Research Results

- 11.1 Investigators working on research project(s) will treat the information regarding any research carried out at IDIBAPS in a confidential manner, and will make every effort to ensure that all involved comply fully with said confidentiality, in order to preserve the rights of IDIBAPS or collaborating third parties.
- 11.2 Once the procedure to be followed for the protection of the Research Results has been defined, the Investigators will respect the deadlines established by IDIBAPS regarding the dissemination of their Research Results, and will undertake not to carry out any act of disclosure until the date to be established so as not to prejudice or jeopardize their legal protection.
- 11.3 In the case of joint development of research projects with other entities, IDIBAPS will endeavor to include in the respective regulatory agreements those policies of IDIBAPS regarding the confidentiality of the Research Results developed.

Article 12. Assignment of Intellectual Property rights

12.1 IDIBAPS may require Investigators who participate in research activities that, prior to the start of said activities, to sign a contract or similar document establishing the assignment of exploitation rights regarding the intellectual

property rights that are developed during the execution of their research activities at IDIBAPS, or that use the means, infrastructures or resources thereof, in favor of IDIBAPS.

- 12.2 In the aforementioned document, efforts will be made to ensure that the assignment of such rights will be realized without temporary, territorial or material restrictions, according to the provisions of Title II.
- 12.3 Even if no prior document is signed, this will not mean, in any case, that IDIBAPS waives its corresponding rights provided for in these regulations; thus, the regulations regarding the attribution of ownership of the shares derived from the Research Results will be fully applicable.

Article 13. Relinquishing of rights in favor of the Investigators

- 13.1 In the event that IDIBAPS is not interested in ownership of any international title or extension of an Intellectual Property right or decides to waive the application or maintenance thereof, it will notify the relevant inventors. In the event that they are interested, IDIBAPS may transfer the aforementioned rights, provided that the applicable regulations allow it.
- 13.2 Notwithstanding the foregoing, in the event that IDIBAPS has signed a contract with a third party that grants the latter a preferential right to assume the ownership of the aforementioned Research Results in the case of relinquishment or abandonment by IDIBAPS, the provisions set forth in the contract will be followed.
- 13.3 In the case of relinquishment or abandonment of any title of Intellectual Property, the express approval and resolution of the statutory competent body will be required.
- 13.4 In the event that IDIBAPS has abandoned or renounced its rights in favor of the inventor, it may commercially exploit the Research Results provided that the commercial activity is not contrary to the guiding principles of IDIBAPS.
- 13.5 IDIBAPS reserves the right to participate economically in the exploitation of the Research Results transferred to the inventors, both in the case of their own exploitation and in the case of their transfer to third parties. In addition, IDIBAPS reserves in all cases the right to use the Research Results for non-commercial purposes, through a non-exclusive, non-transferable and license-free use for research and / or clinical activities by IDIBAPS and its related entities.
- 13.6 In the event of the relinquishment of rights in favor of the Investigators, IDIBAPS may establish mechanisms it deems appropriate to recover any

expenses incurred for the management, drafting, processing, or maintenance of the corresponding Intellectual Property rights.

TITLE III. EXPLOITATION OF THE RESEARCH RESULTS

CHAPTER I. EXPLOITATION FORMULAS OF THE RESEARCH RESULTS

Article 14. Formulas for Exploitation of the Research Results

IDIBAPS may commercially exploit the Research Results in the way it deems most appropriate for the fulfillment of its purposes, seeking in any case the greatest possible dissemination to society of new knowledge and technologies.

In any case, for the transfer of rights, the applicable rules and procedures for the disposition, disposal and encumbrance of IDIBAPS' assets will be followed.

CHAPTER II. DISTRIBUTION OF THE PROFITS FROM THE EXPLOITATION OF THE THE RESEARCH RESULTS

Article 15. Distribution of Profits Derived from Commercial Exploitation

- 15.1 Profits from IDIBAPS arising from the commercial exploitation of Research Results will be distributed using the following proportion arrangements:
 - a) One-third part for those Investigators who are who are deemed to be an author or inventor;
 - One-third part for the IDIBAPS research group to which the author or inventor belongs, for the promotion and promotion of their R&D activities; and
 - c) One-third part for IDIBAPS.

If the author or inventor does not belong to a research group, or the work or invention was carried out in activities outside of any group or structure, the corresponding part, per section b) above, will be credited in favor of IDIBAPS.

15.2 Notwithstanding the foregoing provisions, the following exception to the general rule will apply:

In the case of publications and articles, the profits obtained from their commercial exploitation will be fully attributable and accredited to the authors, as long as they do not exceed the amount of twenty thousand euros $(20,000 \in)$.

Using the apportion scheme outlined in this paragraph, the distribution of profits established in point 15.1 will apply.

- 15.3 In the event that the Investigators has direct or indirect participation in the shared capital or economic rights of the company that commercially exploits the Research Results at the time of the accrual of profits, the percentage of participation that will correspond to him/her in accordance with the benefits obtained by IDIBAPS will be determined by a Commission established for this purpose, and designated by the competent body.
- 15.4 In the event that there is more than one member of the Investigators who has the status of author or inventor, IDIBAPS will pay the amount corresponding to the benefits to each of them, in accordance with a document drafted by all interested parties that establishes the percentages of contribution of each author or inventor, or via judicial or arbitral resolution where the participation of each of them is determined.

Notwithstanding the foregoing, in the case of profits obtained from the exploitation of patents, such distribution shall be made, pro-rated, among the inventors according to their share of participation in the patent and, failing that, in equal parts.

- 15.5 For the purposes of this article, "benefits" shall mean the difference between the following concepts:
 - a) IDIBAPS' gross income from the exploitation of the Research Results, including those payments received from the company that exploits them, and the income derived from a possible relinquishment by the owners of the Research Results;
 - b) Less the costs directly attributable to the protection, valuation and development of Research Results and the management costs (including, but not limited to, the cost of intermediary services, lawyers, patent agents, etc.).
- 15.6 The distribution of the profits obtained from the commercial exploitation of the Research Results developed in projects carried out jointly with other public and / or private entities or with external researchers in a personal capacity will be determined contractually between the entities involved in the project, and failing this, the parties will come to an agreement by consensus, respecting in any case the contribution of each of them in obtaining and protecting the Research Results.
- 15.7 In any case, the distribution of the benefits provided for in this article must respect the possible limitations established in the general regulations applicable to IDIBAPS and its staff.

TITLE IV. FINAL DISPOSITIONS

First. Entry into Force

These regulations will enter into force on the day following their approval by the competent designated body of IDIBAPS.

Second. Transient provisions

The rights and duties contained in these regulations will be applicable from the entry into force of the regulations to all research activities carried out by IDIBAPS, both before and after their entry into force, without prejudice to the fact that the regulation of the distribution of the profits derived from the exploitation of the Research Results will only apply to income obtained after the entry into force of this regulation.

IDIBAPS will endeavor, within the shortest possible timeframe, to adapt all existing contracts entered into within the framework of its activities, such as contracts with its staff and current agreements with other public and / or private entities, to the provisions established in these regulations.