

FUNDACIÓN INSTITUTO DE INVESTIGACIÓN ONCOLÓGICA DE VALL D'HEBRON



INTERNAL REGULATIONS ON THE INDUSTRIAL AND INTELLECTUAL PROPERTY
OF RESEARCH FINDINGS

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CONTENTS

I. Purpose and Definitions	4
1. Purpose and scope of application	4
2. Definitions	4
 II. Ownership of Research Results	5
II.1 VHIO Own Research.....	5
3. Ownership of VHIO Research Results.....	5
4. Ownership of industrial property rights	5
5. Ownership of intellectual property rights	5
II.2 Research Projects Undertaken Jointly with Other Entities.....	6
6. Ownership of Research Results in collaboration projects with other entities	6
 III. Management and Exploitation of Research Results	7
7. Communication and management of the protection of Research Results.....	7
8. Collaboration from VHIO Staff.....	8
9. Waiver in favour of the Researcher.....	9
10. Confidentiality and dissemination of Research Results.....	10
 IV. Exploitation of Research Results	11
11. Formulas for exploiting the Research Results	11
12. Profit distribution in commercial exploitation.....	11
13. Final Provisions	14

Internal Regulations on the Industrial and Intellectual Property of Research Results

La Fundación Privada de Investigación Oncológica de Vall d'Hebron (VHIO) was set up to promote and develop pre-clinical and clinical research of excellence with an entirely translational focus for improving the prevention, early detection and treatment of cancer.

These INTERNAL REGULATIONS have two aims: (i) to promote research activity, aiming to improve the clarity required from the parties involved in carrying out this activity and (ii) to involve VHIO staff in this activity by recognising their participation in the development of new knowledge and technologies and giving them the opportunity to share in any profits earned though commercially exploiting the results of their research activity.

Thus, VHIO sees it necessary to approve these INTERNAL REGULATIONS to establish a detailed and coherent framework, especially with regard to the research results, that supports research undertaken at VHIO.

I. Purpose and Definitions

1. Purpose and scope of application

- 1.1 These INTERNAL REGULATIONS establish a framework that regulates the determination and assignment of the ownership of RESEARCH RESULTS arising out of research undertaken at VHIO, the procedures for appropriately protecting and exploiting them, and the economic rights resulting from the exploitation of these Research Results.
- 1.2 These INTERNAL REGULATIONS are applicable to all research undertaken at VHIO by RESEARCHERS, either independently or in collaboration with other entities.

2. Definitions

In these INTERNAL REGULATIONS, the following terms used have the following meanings.

- a) "VHIO" means the *Vall d'Hebron Institut d'Oncologia* Private Foundation.
- b) "RESEARCHER" means a person employed by VHIO that, in having the required qualifications, carries out research understood as the creative work undertaken systematically to increase knowledge, including knowledge related to the individuals, culture and society; the use of this knowledge to create new applications; the transfer and dissemination of this knowledge by means of tangible and intangible resources or funding provided by VHIO, either directly or through grants, subsidies or any other financial support.
- c) "RESEARCH RESULTS" means all technology, knowledge, know-how, processes or results developed as a result of research undertaken by the Researcher as part of the Researcher's work at VHIO.

- d) "AUTHOR" means a VHIO Researcher that, as part of their duties and activities at VHIO, creates Research Results considered a Work under applicable legislation and these Internal Regulations.
- e) "INVENTOR" means a VHIO Researcher that, as part of their duties and activities at VHIO, creates Research Results considered an Invention under applicable legislation and these Internal Regulations.
- f) "WORKS" means Research Results subject to protection under Intellectual Property rights, including but not only books, publications, academic treatises, lectures, multimedia works, databases and software.
- g) "INVENTIONS" means Research Results subject to protection under Intellectual Property rights, including but not only patents, utility models, mask works and industrial designs.

II. Ownership of Research Results

II.1 VHIO Own Research

3. Ownership of VHIO Research Results

VHIO owns the RESEARCH RESULTS resulting from research done by the RESEARCHER and the rights to exploit these results.

4. Ownership of industrial property rights

VHIO owns the exploitation and industrial property rights to the INVENTIONS derived from the RESEARCH RESULTS defined in Article 2.

5. Ownership of intellectual property rights

5.1. Ownership of intellectual property rights

- 5.1.1. RESEARCHERS own the authorship of the WORKS created as a result of their research carried out at VHIO, except where otherwise set out in these INTERNAL REGULATIONS.
- 5.1.2. The rights of exploitation on the WORKS created as part of the aforementioned functions belong to VHIO under the terms and with the scope set out in the intellectual property legislation. Without prejudice to the above provisions, VHIO tries to come to an agreement with the RESEARCHER for the assignment of any rights of exploitation on WORKS created in VHIO research activities that could remain the property of the RESEARCHER.
- 5.2. Ownership of intellectual property rights in specific cases
 - 5.2.1. Where a WORK is created by more than one person under the initiative and coordination of VHIO, authorship and the rights of exploitation on said Work belong to VHIO where VHIO publishes and disseminates the Work under its name and except where otherwise stated in an agreement.
 - 5.2.2. If the WORK created by a RESEARCHER carrying out research activities is a software program, the rights of exploitation belong exclusively to VHIO.

Where software is developed by more than one person under the initiative and coordination of VHIO, authorship and the rights of exploitation on said WORK belong to VHIO where VHIO publishes and disseminates the WORK under its name and except where otherwise stated in an agreement.

II.2 Research Projects Undertaken Jointly with Other Entities

6. Ownership of Research Results in collaboration projects with other entities

- 6.1. Collaborative research agreements should be signed for all Research projects or jobs carried out by RESEARCHERS, regardless of the field of knowledge.
- 6.2. The ownership of the rights on RESEARCH RESULTS obtained from a collaboration agreement and the distribution of the resulting rights of

exploitation is covered in the collaboration agreement. This agreement may postpone the determination of allocating said ownership and rights.

- 6.3. In all cases, any rights that may belong to VHIO under these INTERNAL REGULATIONS must be observed.

III. Management and Exploitation of Research Results

7. Communication and management of the protection of Research Results

- 7.1 Where RESEARCHERS create RESEARCH RESULTS that may be subject to protection, they must immediately notify VHIO's Research Results Transfer Office (*Oficina de Transferencia de Resultados de Investigación del VHIO*, OTRI), directly or via the head of their research group. All information relevant to the creation or invention in question (which must include a report outlining the Research Results, the staff involved in their creation and the proportion of participation of each Researcher, and their generation and possible applications) must be attached so that VHIO, where it sees fit and subject to any relevant studies or authorisations, can initiate procedures for providing legal protection.
- 7.2 For RESEARCH RESULTS arising out of collaboration projects with other public or private entities, the provisions regarding agreements signed between collaborating entities are applicable. Collaboration projects in which VHIO participates in more than 15 % of the ownership of Research Results must be approved by VHIO's Executive Committee except where said participation is legally required or derives from other agreements previously approved by the Executive Committee or the Board of Trustees.
- 7.3 Based on the information provided by the Researcher, the OTRI has one month to deliver a report with recommendations on the appropriateness and feasibility of protecting the RESEARCH RESULTS and the measures required for said protection. This period may be extended where external reports or studies are required on reasoned request to the Authors and/or Inventors.

- 7.4 The report drafted by the OTRI is sent to the Director of VHIO who, based on the report, submits a proposal for the protection or waiver of the rights to the Research Results to the Executive Committee, which is the body responsible for final approval for the process to follow. Based on this proposal, the Executive Committee decides on what happens to the Research Results.
- 7.5 If an urgent need to provide the Research Results with protection makes it contrary to VHIO's interests to wait for the scheduled meeting of the Executive Committee to determine whether to protect the Research Results, the Director of VHIO may authorise instigating actions for providing said protection, which must in all cases be subsequently approved by the Executive Committee. If the Executive Committee later decides to abandon the actions initiated for protecting these rights, VHIO abandons the procedures started.
- 7.6 The OTRI, or the area of VHIO with the delegated authority, carries out the tasks for protecting RESEARCH RESULTS deriving from VHIO own projects taking into account all relevant circumstances and in particular the scientific, social and business interest given rise to in said protects. The OTRI may seek the assistance of internal and external experts for carrying out these tasks.

8. Collaboration from VHIO Staff

- 8.1 The Authors or Inventors of the RESEARCH RESULTS must collaborate with VHIO or the body or entity carrying out the task of handling all aspects of protecting the industrial and/or intellectual property rights and their transfer.
- 8.2 This obligation to collaborate includes signing any notarially-recorded and non-notarially-recorded documents, in particular, at any national or foreign office with authority in matters of industrial and intellectual property (including but not only patent, brand, trademark and intellectual property offices) for VHIO to prove that it is or for it to become, depending on the situation, the owner of industrial and intellectual property rights on the RESEARCH RESULTS and to exercise its rights as the owner of them.
- 8.3 VHIO may require staff taking part in research activities to sign, prior to the provision of their services, an agreement or similar document that establishes the assignment of rights of exploitation on industrial and intellectual property rights arising out of their participation in services connected to VHIO or that

make use of VHIO means, infrastructure or resources. Such assignments are made without time, geographical or material restrictions in accordance with Chapter II of these INTERNAL REGULATIONS.

- 8.4 Not signing such an agreement does not under any circumstances imply that VHIO waives its rights covered in these INTERNAL REGULATIONS, the provisions of which, therefore, are applicable in their entirety. Even though no such document is signed, staff do not own the rights arising out of their employment or contractual relationship. In all cases, the provisions stated herein are applicable.

9. Waiver in favour of the Researcher

- 9.1 Where VHIO has no interest in owning a right or international extension of an industrial property right, or it decides to waive any industrial property rights, it notifies the INVENTORS of this.
- 9.2 If INVENTORS are interested in having the industrial property rights assigned to them, VHIO may transfer said rights in accordance with the conditions agreed upon by VHIO and the INVENTORS subject to the prior, express authorisation from the Executive Committee and on the proposal of the Director. These INVENTORS may market the RESEARCH RESULTS where the commercial activity is not contrary to the principles of VHIO.
- 9.3 Any agreement signed by VHIO with a third party that assigns rights on RESEARCH RESULTS to the third party where VHIO waives its rights prevails over the preceding provisions.
- 9.4 VHIO reserves the right to share in the profits obtained from the exploitation of RESEARCH RESULTS assigned to INVENTORS, both where these rights are exploited by the inventors themselves under licence or are transferred to third parties. VHIO also reserves the right in all cases to use the RESEARCH RESULTS for non-commercial purposes under a non-exclusive, non-transferable and free license for use in teaching and research. VHIO may establish the mechanisms it sees fit to recover the expenses incurred in the management, drafting, procedures and maintenance of said industrial property ownership, which has preference over any kind of remuneration paid to INVENTORS OR AUTHORS.

10. Confidentiality and dissemination of Research Results

- 10.1 RESEARCHERS and all staff taking part in research at VHIO must treat all information relating to any research carried out at VHIO as confidential. They must use their best endeavours to ensure confidentiality to protect the rights of VHIO and third parties collaborating in the research.
- 10.2 RESEARCHERS may not publicly disclose the development of RESEARCH RESULTS subject to protection or exploitation by any means, partially or totally, without prior written authorisation from VHIO. In particular, RESEARCHERS may not make any publication related to the RESEARCH RESULTS until VHIO has initiated the process for protecting them or has notified the AUTHORS or INVENTORS of its intention to not protect them prior to their dissemination.
- 10.3 RESEARCHERS who want to undertake any kind of action for disseminating research that may be protected or exploited at some time must submit a request beforehand to the OTRI that includes the text of the document or lecture to be disseminated and specifies the means for making the action and its reach.
- 10.4 The OTRI has one month to grant or deny the authorisation for the dissemination action. No reply is understood as an approval of the request. Authorisation for the action might entail conditions requiring the edition of the document or lecture as VHIO sees fit to preserve VHIO or third-party rights.
- 10.5 In all cases, disseminating or publicising research undertaken at VHIO must always expressly cite VHIO's participation in the research.
- 10.6 In research projects carried out with other entities, VHIO attempts to include VHIO policies on the confidentiality of RESEARCH RESULTS in the agreements governing such collaborations.

IV. Exploitation of Research Results

11. Formulas for exploiting the Research Results

- 11.1 VHIO may commercially exploit the Research Results as it best sees fit to achieve its goals, although it does aim for the form chosen to provide society with the greatest access possible to new knowledge and technologies.
- 11.2 Without excluding other scenarios, it is envisaged that VHIO may make use of the Research Results directly in its activities or in the activities of entities at the *Hospital Universitari Vall d'Hebron* or externally, which may take place under a licence granted to third parties or Spin-off companies created or participated in by VHIO. In both cases, VHIO's rights are protected. In the case of the Spin-offs, the internal regulations on setting up and equity participation in VHIO Spin-offs apply.
- 11.3 For transferring rights in all cases, the regulations for disposal, transfer and encumbrance of VHIO assets apply.
- 11.4 VHIO staff, in particular those with decision-making powers on the exploitation of the Research Results, must avoid situations of conflict of interest that may directly or indirectly harm VHIO's interests. If a situation of potential conflict of interest should arise, the staff member involved must inform the OTRI immediately and refrain from taking part in decision making on this matter. When any such circumstances arise, the OTRI duly and immediately informs VHIO management so that it may adopt the necessary measures to protect VHIO's interests.

12. Profit distribution in commercial exploitation

- 12.1 Profits obtained by VHIO from the commercial exploitation of the RESEARCH RESULTS where RESEARCHERS do not participate in this exploitation are distributed in accordance with the following proportions:
 - i. When VHIO exclusively owns the Research Results:
 - a. The Researcher who is the AUTHOR or INVENTOR at VHIO receives 33 %.

- b. 33 % goes to the setting up of a fund exclusively for funding the laboratory or laboratories where the Researcher who is an Author or Inventor works, either for new projects or for supplementing other projects not fully funded by specific funds.
- c. The percentage distribution of profit among the different eligible laboratories is established according to actual participation in the Researcher's creation or invention, which the Authors or Inventors of the Research Results agree on beforehand.

These funds are allocated to the head researcher of each laboratory under the same conditions and restrictions applicable to any other provisional funding assigned to a laboratory.

- d. 34 % is allocated as VHIO self-generated revenue for use as it best sees fit to pursue its mission.
- ii. When there are multiple owners of the Research Results and VHIO is responsible for managing or marketing them, the profits obtained by VHIO are distributed as follows:
 - a. Where a collaboration agreement exists between the entities that sets out profit distribution, VHIO tries to ensure that the same percentages are allocated to the Researcher who is an Author or Inventor as those set out in the above provision.
 - b. Where this is not covered in the collaboration agreement, the percentages set out in the above provision for allocation to the Researcher who is an Author or Inventor apply. In these cases, VHIO may deduct the direct expenses it incurs not paid by third-party owners of the Research Results.
 - iii. When there are multiple owners of the Research Results and VHIO is responsible for managing and marketing them, VHIO tries to ensure that profits are allocated under terms as similar as possible to those set out above. Where the distribution is not agreed upon, the distribution in Paragraph (ii) applies.

Where the Researcher who is an Author or Inventor participates in a Spin-off that commercially exploits the RESEARCH RESULTS, VHIO Internal Regulations to Support the Creation of Companies apply.

12.2 For the purposes of Article 12.1, "profits" are:

- a. Gross revenue earned by VHIO from exploiting the RESEARCH RESULTS, including payments received from the operating company and income deriving from any waiver by co-owners of the rights to the RESEARCH RESULTS.
- b. Less the expenses directly attributable to the protection, valuation and marketing of the RESEARCH RESULTS and management costs (including but only expenses for the services of intermediaries, lawyers, patent agents, etc.)

Furthermore, for the scenarios described in Paragraphs (i) and (ii), VHIO reserves payment equivalent to twenty per cent (20 %) of gross revenue as consideration for management activities.

12.3 Where there is more than one Author or Inventor, VHIO pays the amount corresponding to each Researcher in accordance with the ownership established in the documentation submitted by the Researcher to the OTRI, except where all parties sign an agreement establishing different percentages or where a court or arbitration ruling determines each party's stake.

12.4 For publications and articles, all profits obtained from commercial exploitation go to the authors for amounts up to two thousand euros (€ 2,000). Over this amount, the distribution percentages set out above apply.

12.5 The recognised economic rights of the Authors and Inventors of the RESEARCH RESULTS may not be assigned to third parties that were not participants in the project that gave rise to the RESEARCH RESULTS or legal entities except by express agreement with VHIO or where required by law or a court or administrative ruling.

12.6 The distribution of profits obtained from the commercial exploitation of the RESEARCH RESULTS arising from projects carried out jointly with other public or private entities or external researchers acting independently are determined in agreements between the entities involved in the project and, where no agreement exists, according to whatever the parties agree on while observing

the contribution of each party in obtaining and protecting the RESEARCH RESULTS.

- 12.7 In all cases, the profit distribution set out in this Article must observe any limitations established in the general regulations applicable to VHIO and its staff.
- 12.8 Where the RESEARCHER participates in exploiting the RESEARCH RESULTS, either as an equity holder of the operating company or through any type of agreement with this company for sharing in the profit or loss of said exploitation, the regulations governing how Researchers share in profits obtained by VHIO in commercial exploitations are not applicable. In these cases, the agreements on equity participation or the industrial or intellectual property licenses on the operating company apply.

13.Final Provisions

- 13.1 VHIO must, in the shortest time possible, amend agreements it signed related to its activities (e.g., agreements and contracts with Researchers and other public and private entities) to reflect the provisions established in these INTERNAL REGULATIONS.
- 13.2 These INTERNAL REGULATIONS become effective the day after they are passed by VHIO's Board of Trustees.