

*This English version of the Policy only represents a translation of the original Italian version.*

*If there is any conflict or inconsistency between the Italian version and the English version, the Italian shall be the governing and prevailing version.*



**Foundation for the Institute for Research in Biomedicine, Bellinzona**

# **Policy on technology and knowledge transfer**

The IRB Foundation Council, represented by the President and Vice-President, registered in the Canton Ticino Commercial Register of the Foundation for the Institute for Research in Biomedicine (IRB Foundation), Bellinzona, and in compliance with the articles of the Statute of the Foundation for the Institute for Research in Biomedicine, the Rules of the Foundation for the Institute for Research in Biomedicine, and the Staff Regulations of the Foundation for the Institute for Research in Biomedicine, hereby promulgates the following articles:

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## Preamble

The Università della Svizzera italiana and the Affiliated Institutes hold the intellectual property rights to all technical intellectual creations and research results obtained by their employees in the course of their work. In order to regulate the details of application, this Policy is drawn up. The specific versions for each Affiliated Institute of this Policy are based on the same principles but take into account their respective organizational and legal structures.

## Art. 1. Field of application

- 1.1. This policy (hereinafter referred to as 'Policy') applies to each organisational structure of the Institute for Research in Biomedicine (laboratories, management, administration), and deals with technology and knowledge transfer ('KTT') issues.
- 1.2. For the signature of acts of academic and administrative relevance referred to in this Policy, the respective internal regulations and their decision-making procedures prevail.
- 1.3. The Foundation Council, upon notice from the Technology Transfer Manager, may, in justified cases, establish specific exceptions to this Policy.

## Art. 2. Subject

- 2.1. The Policy deals with the following issues:
  - intellectual property and in particular patent applications and patents, copyright with regard to computer programs and the exploitation of research results;
  - the drafting of KTT contracts, their management, types and main contents;
  - creation of entrepreneurial initiatives – spin-off - from academic circles or research institutions on the initiative of a group of doctoral students, post-doctoral students, professors and possibly former students to start an independent entrepreneurial activity aimed at exploiting the skills acquired and research activities performed within the organization.
- 2.2. IRB intends to actively encourage, promote and support the exploitation of research results and collaborations with third parties provided that it safeguards the institution itself, the principle of academic freedom, without having a negative impact on research. In this regard, a consultancy and support service has been specifically set up through the TTM active at the Research and Knowledge Transfer Service ("SRIT") of the Università della Svizzera italiana.
- 2.3. All references in this Policy to the singular shall include the plural where applicable, and all references to gender shall include both genders and the neuter.

## Art. 3. Purpose

Purpose of this Policy is to:

- 3.1. inform Collaborators about the different options to protect and enhance research results;
- 3.2. define the steps to be followed to obtain the protection of intangible assets and set the rules for their marketing;
- 3.3. enhance intellectual property in its various forms, including the role played by the Inventor himself;
- 3.4. optimise the exploitation of intellectual property arising from research activities and possibly obtain benefits from it;

- 3.5. provide researchers with general information on the terms of the contracts, their different types and the content of these contracts under the KTT;
- 3.6. encourage the entrepreneurial spirit of employees by creating attractive framework conditions to encourage the creation and exploitation of new innovative ideas and the attraction and support of research talent.

## Art. 4. Definitions

**Patents:** patent applications as well as granted patents, both individually and as groups sharing the same inventive step and/or the same priority date (so-called "patent families").

**Collaborators:** academic and administrative staff with an employment contract with IRB.

**FNI:** The form for the notification of an invention is a confidential internal form with the most important information on the potentially patentable invention.

**Inventor:** the Collaborator who had the patentable idea and who is responsible for the Invention.

**Invention:** in legal terms, it means a solution to a technical problem that is new, inventive and industrially applicable. The legal basis is defined by the Federal Act for Patents on Invention (PatA) and the Ordinance on Patents of Invention (OBI).

**Affiliated Institutes:** institutes that are governed and financed by third parties affiliated to the Università della Svizzera italiana according to Art. 12 of the Law on the Università della Svizzera italiana, the University of Applied Sciences and Arts of Southern Switzerland and research institutes.

**Know-How:** information of a confidential nature that can give a competitive advantage such as unpatentable or unpatented inventions, trade secrets, formulas, patterns, designs, methods, processes, materials, skills and experience.

**Knowledge and Technology Transfer (KTT):** knowledge and technology transfer.

**Partners:** third parties that establish a collaboration with IRB, mainly within projects, in order to achieve common interests.

**Priority Date:** The date (day/month/year) of the first submission of a patent application.

**Net profit:** revenues deriving from the exploitation of an invention less direct and indirect costs for patents, as well as any research costs contractually due to the financiers of the research from which the invention originated.

**Projects:** agreements with industrial or academic partners with the aim of transferring technology and knowledge, respectively to enhance and advance research results.

**Computer programs:** computer programs ("software") protected by copyright under CO and CopA.

**Intellectual Property (IP):** this means the set of legal principles that aim to protect the fruits of human inventiveness and ingenuity, in particular: patentable inventions, computer programs protected by copyright, semiconductor topographies, design, trademarks and know-how.

**Inventors' share:** the part of the Net Profit derived from the exploitation of an Invention that belongs to the Inventors.

**Project Manager:** means the person who has responsibility for a Project.

**Foundation Council:** The Foundation Council is the supreme body of the IRB.

**Spin-off:** entrepreneurial initiatives born by gemmation from the IRB to start an independent entrepreneurial activity aimed at the exploitation of skills and research activities developed within IRB.

**SRIT:** Research and Knowledge Transfer Service at the Università della Svizzera italiana.

**Third parties:** means natural or legal persons outside IRB and who are not part of the Collaborators.

**TTM:** the Technology Transfer Manager is the person in charge of providing support for technology and knowledge transfer activities.

**IRB:** Foundation for the Institute for Research in Biomedicine and its institute.

## **Art. 5. Legal bases and implementing regulations**

This Policy is based on the following laws and regulations.

- 5.1. Federal Patent Law (LBI);
- 5.2. Ordinance on patents of invention (OBI);
- 5.3. Federal Supplementary Law to the Swiss Civil Code (Book 5: Bond Law, CO);
- 5.4. Federal Law on Copyright and Neighbouring Rights (CopA);
- 5.5. Law on the Università della Svizzera italiana, the University of Applied Sciences and Arts of Southern Switzerland and Research Institutes (LUni);
- 5.6. Statute of the Foundation for the Institute for Research in Biomedicine;
- 5.7. Rules of the Foundation of the Institute for Research in Biomedicine;
- 5.8. Regulations for the staff of the Foundation of the Institute for Research in Biomedicine.

## **Art. 6. Inventions and Computer Programs**

### **Art. 6.1. Properties of Inventions and Computer Programs**

- 6.1.1. IRB is the owner of the Intellectual Property rights generated by the Collaborators in the exercise of their activity.
- 6.1.2. IRB Computer Programs holds the exclusive right of exploitation.
- 6.1.3. Ownership includes, in particular, the faculty to patent the Inventions, and to exploit the Patent. IRB decides on the use of the Patents, arranging them in the ways it deems appropriate. Technical inventions that are new and inventive compared to the state of the art and industrially applicable are patentable.
- 6.1.4. The safeguarding of a potential Invention is a duty of every Collaborator who is required to actively collaborate and support the TTM and SRIT.

- 6.1.5. IRB must be able to transfer, when contractually provided for, all or part of the rights of ownership of research and development activities to third parties. This applies in particular in the case of mandates and/or research contracts with Third Parties, in this case the Collaborator is required to collaborate in the fulfilment of any obligations relating to the transfer of ownership of the rights and do not apply to Art. 6.3.1; Art. 6.3.2 and Art. 6.4.1.
- 6.1.6. Upon conclusion of the employment contract, the Collaborator is required to inform IRB of the status of the IP developed during the employment relationship. Even after the end of the employment relationship, the former employee is required to safeguard the interests of IRB, in particular with regard to the willingness to sign documents relating to the protection and enhancement of the Inventions after the end of the employment contract.

#### **Art. 6.2. Protection of Inventions**

- 6.2.1. Each Collaborator is responsible for informing his or her superior, respectively the TTM, of the discoveries made. The TTM will transmit a questionnaire on the state of the Invention called "form for the notification of an invention" (FNI) which the Collaborator must fill in as truthfully and diligently as possible. The procedure is confidential and the Invention must in no way be disclosed to the public before the submission of the patent application. Upon receipt of the FNI duly completed and signed, the TTM will propose to the competent decision-making bodies how to proceed with the Invention.
- 6.2.2. After the Invention has been patented, or IRB has waived patenting it, the Collaborator is authorized to disclose it.

#### **Art. 6.3. Marketing of Inventions**

- 6.3.1. The commercial exploitation of an Invention can basically follow two paths:
- the establishment of its own company (Spin-off) by one or more Collaborators;
  - an independent company that studies the market, develops the product and markets it.
- 6.3.2. In both cases, the rights for the commercial exploitation of the technology must be transferred from the IRB to the company in question. This is usually done in the form of a license, which allows the company to use the results in a specific way.
- 6.3.3. In some cases, third party companies reserve certain rights for the exploitation of the results in the form of an option already at the beginning of the research collaboration with IRB. In most cases, the cooperation agreement determines who will be able to exploit the results and to what extent.
- 6.3.4. In the KTT field, the Patent is the most common tool to protect an Invention. It must always be kept in mind that the purpose of a Patent is the commercial exploitation of the Invention which must normally take place before entering the regional/national phase so as to limit the costs borne by IRB. Except in special cases, the patent process for an IRB-approved Invention consists of three phases:

1. First submission of the patent application and obtaining a Priority Date;
2. within 12 months of the Priority Date, entering into the PCT ("Patent Cooperation Treaty") phase;
3. After the PCT phase, the next regional/national phase can be considered, this represents the nationalisation of patent application in the individual countries.

Access to each subsequent step, which involves significant additional costs, is subject to approval by the relevant decision-making bodies upon prior notice from the TTM. It is necessary to carry out the appropriate evaluations from time to time, in particular according to the status of the Patent (its patentability with respect to the "search report" and "office actions" of the respective patent offices) and its valorisation process (contacts with possible Partners interested in a license). In particular, regional/national entry, the costs of which can be extremely high, should always be borne by a licensee. In the absence of a concrete interest on

the part of third parties, the decision-making bodies evaluate the abandonment of the patent in order to contain the costs.

- 6.3.5. The Inventor, with the support of TTM, is required to take first-hand action with regard to the marketing of the Invention, in particular by presenting it at congresses and conferences in the industrial sector and making contact with potential Partners.
- 6.3.6. IRB negotiates with third parties contracts for the commercial exploitation of the Invention, usually license agreements.
- 6.3.7. The administration verifies and distributes the revenues.

#### **Art. 6.3.1. Revenues from Inventions**

- 6.3.1.1 Any Net Profit derived from the exploitation of an Invention is distributed according to the "third party rule":
  - 1/3 paid to the Inventors privately, to be divided in case of several Inventors;
  - 1/3 centrally to the IRB;
  - 1/3 to the unit (laboratory, research group) that generated the Invention in the form of research funds.
- 6.3.1.2 In case of multiple Inventors, the Inventors' Quota shall be divided among the various Inventors according to their respective contributions. Unless otherwise specified, the percentage indicated in the FNI shall be used. If the Inventors disagree on their respective inventive contributions, the irrevocable decision will be taken by IRB upon notice from an ad hoc committee of experts, any costs will be borne by the Inventors.
- 6.3.1.3 In case of renunciation by IRB, the Inventors will be free to proceed with the protection and enhancement of the Invention, assuming the related costs. IRB is in any case entitled to use the Invention for academic purposes and to a share of the revenues, net of protection expenses, generated by the Invention according to a specific agreement between the parties. In this case the Inventors are not entitled to compensation from IRB under the "third party rule". The revenues paid to the IRB, will be divided equally between the research unit that generated the Invention and centrally.

#### **Art. 6.3.2. Revenues from Computer Programs**

The rules according to Section 6.3.1 section 6.3.1.1 of this Guideline shall apply to revenues from commercial licenses of Computer Programs.

#### **Art. 6.4. Know-How Enhancement**

- 6.4.1. It is also possible to grant licences on Know-How without a patent or copyright component. In the case of a Know-How license it is important to consider how it does not impede research activities.

#### **Art. 6.4.1. Revenues from Know-How**

- 6.4.1.1 After cost recovery, the Net Profit is divided:
  - 1/3 to the research unit that developed the Know-How;
  - 2/3 centrally to the IRB.

#### **Art. 6.5. Intellectual property of universities or third party research institutes**

- 6.5.1. In the event that a Patent involves professors or researchers affiliated to third party universities or research institutes, it is necessary to agree on the management of intellectual property between the parties.

### **Art. 6.6. Intellectual property of students**

- 6.6.1. Inventions and results made by students without an employment contract with IRB as part of their study training are the property of the students (private inventions). Therefore, in the case of a Patent and its exploitation, it is necessary to find an agreement between the parties.
- 6.6.2. In the case of third-party company-projects on internal company issues, the student is required to sign an agreement in which he or she commits to confidentiality obligations and the transfer of any IP rights to the third-party company in accordance with the relevant agreements.

## **Art. 7. Drafting of contracts in the field of knowledge and technology transfer**

- 7.1. For each Project, the Project Manager will contact the TTM who will provide advice and support in the negotiation and drafting of contracts.
- 7.2. The TTM may, after previous agreement on the charge of costs, request external advice.
- 7.3. For other contractual aspects which are not specifically mentioned in this Policy, the general conditions and regulations in force shall apply.
- 7.4. It is the task of the Project Manager to establish and internally agree on the use of resources such as: infrastructures, researchers, spaces, tools as well as cost calculation.

### **Art. 7.2. Confidentiality contract**

- 7.2.1. A non-disclosure agreement (NDA: "non-disclosure agreement" or CDA: "confidential disclosure agreement") defines the obligations of the party to whom confidential information concerning intangible assets (IP, sensitive information) is disclosed. The agreement lays down the duration of the confidentiality clause and the penalties in case of violation. A confidentiality agreement may also be included in other types of contract.

### **Art. 7.3. Letter of intent / Memorandum of Understanding**

- 7.3.1. A letter of intent ("letter of intent" / LOI) or a memorandum ("memorandum of understanding" / MOU) is a statement of intent between the parties regarding negotiations on a possible contract or collaboration.
- 7.3.2. A LOI/MOU is usually non-binding and does not deal with legal aspects, however it is possible to include specific binding clauses (e.g. confidentiality, IP, financial terms).

### **Art. 7.4. Service contract**

- 7.4.1. Services and technical advice can be provided by the IRB when a Partner lacks specific expertise or infrastructure. This type of service must be provided in return for the payment of full costs (so-called "full costs" which include personnel, administration and internal services, investments, special infrastructure costs, consumables, value added tax) also to avoid potential situations of unfair competition with the private economy. Specific rates are available from the administration upon request. The services are governed by a service agreement ("service agreement"), where IRB is normally not bound to any result obligation. The terms and remuneration are defined in the contract. In this way a Partner can make use of the IRB expertise, usually for a limited period and in a specific field.
- 7.4.2. Services provided by staff as private consulting are not considered in this Policy and no support is given.
- 7.4.3. Services and consulting outside the KTT as well as the sale of goods are not part of this Policy, these will be handled by the competent offices.

- 7.4.4. In the case of services, as a rule, the IP as well as the exploitation rights of Computer Programs is the exclusive use of the purchasing client in exchange for payment of the full costs. IRB should in any case maintain at least one free, non-exclusive license for educational use and academic research.

#### **Art. 7.5. Collaboration contract**

- 7.5.1. Research collaborations with Partners are mainly focused on the development of new results. In contrast to services where IRB's interests are purely financial, in collaborations the scientific interest of IRB plays a central role, which is why a reduction in standard rates in the form of an "in-kind" contribution by IRB can be envisaged. It remains a priority that academic and publishing freedoms are not compromised. Industry partners get the option for a commercial license to use the results against payment.
- 7.5.2. The type, extent and duration of the contract as well as the amount of remuneration are set out in the contract. Unless otherwise agreed in the contract, the IP will be owned by the party that generates it.
- 7.5.3. In the case of collaborations, both existing IP rights (so-called "background") as well as access to search results ("foreground") should be regulated. The rights of commercial use of the search results are granted to the Partner generally in the form of a non-exclusive license limited to the commercial scope. In specific cases, it is possible to grant exclusive licences for a fee, limited in a specific area and/or geographically, over time and linked to the achievement of results ("milestones"). Full assignment of the IP should be avoided. Free and non-exclusive use for academic and educational research purposes for IRB should always be considered. Parallel processes and methods resulting from research ("sideground") remain the property of the IRB. In the case of results obtained with the support of third parties, in the case of exploitation, the interests of the entities that contributed to the results must also be taken into account.
- 7.5.4. This type of contract also includes projects with industrial partners financed by Innosuisse or the European Union.

#### **Art. 7.6. License Agreement**

- 7.6.1. The license agreement is an agreement by which the owner of Patents, Computer Programs, Know-How or IP generally regulates the (usually non-exclusive) rights of use of the IP against payment while retaining ownership. The object of the contract is the marketing of intangible assets. The agreement mainly defines the rights of use, for example: the area in which the patent can be marketed, the concession in use of copyrights, the geographical area of sale, the duration. It also determines the extent of the license, resolves liability issues and sets the amount of royalties. The licence is adapted to the needs on a case-by-case basis. In specific cases, exclusive licences may be granted provided that they are limited in a specific field of use, linked to defined milestones, limited in time and geographically. Assignment of rights ("assignment") is normally to be avoided.
- 7.6.2. Given the complexity of the agreement, the terms of the contract should first be agreed in the form of a list of conditions ('term sheet') and then move on to the actual contract in a second stage.

#### **Art. 7.7. Material transfer contract**

- 7.7.1. The Material Transfer Agreement ("Material Transfer Agreement" / MTA) refers to a Partner interested in evaluating, testing and using material (e.g. biological material such as samples, cells, antibodies, DNA or RNA, etc...), equipment, instruments developed by the IRB, owned by the IRB, respectively. The terms for the transfer of material and property rights must be defined in the contract as well as the limits of use.

### Art. 7.8. Conclusion of the contract and contents

- 7.8.1. The mentioned contracts and agreements must be concluded in accordance with Art. 1.2 of this Policy.
- 7.8.2. The Project Manager and the TTM jointly develop a valorisation strategy, addressing IP issues, contractual provisions or the calculation of the amount due to the IRB in agreement with the administrative management.
- 7.8.3. The valorisation strategy must take into account the image and good name of IRB.
- 7.8.4. The contract must be signed in at least two copies, or in the same number as the partners involved in the contract. Except in special cases, an original copy shall be archived by the IRB administration.
- 7.8.5. The final decision whether or not to accept the risks associated with a contract is always up to the authorised signatories as per Art. 1.2 of this Policy.
- 7.8.6. Depending on the type of contract there are certain minimum contents to be considered:

CONTENTS	TYPE	Confidentiality	LOI/MOU	Collaboration	Service	License	MTA
Preamble / Project description		X	X	X	X	X	X
Project manager, communication			(X)	(X)	(X)	(X)	(X)
Milestones and obligations				X	X	X	(X)
Confidentiality		X	(X)	X	X	(X)	X
Publications			(X)	X	(X)	(X)	(X)
Intellectual Property (IP)			(X)	X	X	X	X
Partner performance			(X)	X	X	X	X
Finance (amounts, payment rates, ratios)			(X)	X	X	X	(X)
Beginning and end		X	X	X	X	X	X
Cancellation and consequences		(X)	(X)	X	X	X	(X)
Liability and guarantees		X	(X)	X	X	X	X
Place of jurisdiction and applicable law		X	(X)	X	X	X	X

### Art. 8. Spin-off

The term Spin-off of the IRB is understood:

- As a company (Limited Company, Limited Warranty Company or Simple Company) based on IP generated at IRB;
  - As a rule, it is founded by natural persons with a link to IRB, including Employees, who act as entrepreneurs;
  - is based on sound and well-designed business principles ("business model")
- 8.1. The creation of a spin-off is aimed at developing discoveries obtained at IRB in a commercial product or service that may have an impact on society.
- 8.2. IRB may participate in the spin-off, for example in the form of shares or options.

### **Art. 8.2. Information for founders**

- 8.2.1. Spin-offs recognized by IRB will be supported in the following activities during the establishment phase, as well as in the initial phase:
- Consultancy and advice on the first steps to found a company. From the evaluation of the product to the decision of the company form, the idea will be discussed and a solution will be sought;
  - Infrastructures: during the first two/three years the IRB can rent space or make material available for common use under special conditions, if financial and logistical capacities permit and always giving priority to research activities.
  - Licensing Spin-offs: In general, the IRB is willing to license the use and development of its IP. However, it is not possible for a spin-off to obtain exclusive rights for all the results of a research group or laboratory.

### **Art. 8.3. Conflict of interest**

- 8.3.1. Transparency and fairness is required towards the IRB, its employees and the research unit (laboratory, group, department). The establishment of a spin-off must be communicated in a transparent manner.
- 8.3.2. IRB and Spin-off interests must be separated, e.g. in the context of mandates, use of IRB materials and equipment by the Spin-off or in the case of a Spin-off Collaborator.
- 8.3.3. In the event that a Collaborator plays an active role in the Spin-off, in particular decision-making roles, the role of the Collaborator must also be clarified and, as far as possible, the duration over time, which should not exceed two/three years. Transparency must be guaranteed to avoid any possible conflict of interest.
- 8.3.4. The internal provisions on general working conditions always apply.

### **Art. 8.4. Transfer of personnel**

- 8.4.1. With the transfer of a Collaborator from the IRB to an external entity, as in the case of a spin-off, the specific knowledge of this person will also be transmitted. For this reason, specific agreements between the parties are to be considered. IP developed during and as part of use at the IRB, remain the property of the IRB.

### **Art. 8.5. Main agreements between Spin-off and IRB**

- 8.5.1. License Agreement (in case of IP): This agreement covers the assignment or use of the Inventions and Know-How, from IRB to Spin-off, as well as the respective fee;
- 8.5.2. Lease agreement (for the use of premises/laboratories): In case of temporary necessity, this agreement covers the use of IRB offices and laboratories and their remuneration. The content of the contract will be based on the individual needs of each Spin-off and the availability of IRB, internal research activities always have priority;
- 8.5.3. Infrastructure Use Agreement (for the use of equipment): This agreement covers the use of the IRB's equipment and infrastructure, as well as its remuneration;
- 8.5.4. Agreement on conflict of interest management;
- 8.5.5. Agreement for the use of the IRB name by Spin-off.

## **Art. 9. Amendments and approval procedure**

Amendments to this Policy shall be made consistently on all versions for the Università della Svizzera italiana and each Affiliated Institute in order to comply with common strategies and general rules (Art. 12 para. 2 LUni) with the following process:

- a) proposals for amendments shall be forwarded to the TTM or on the TTM's own initiative;
- b) the TTM will instruct the practice in coordination between the Università della Svizzera italiana and the Affiliated Institutes, agreeing on the changes;
- c) the changes are subject to the approval of the Rectorate of the Università della Svizzera italiana and the respective Foundation Council of Affiliated Institutes;
- d) The approved and ratified amendments are implemented in all versions of this Policy.

## **Art. 10. Contacts**

### **Institute for Research in Biomedicine**

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Approved by the IRB Foundation Council at its meeting of 14 June 2019.

.....  
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.....  
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Vice-President IRB Foundation

**Annex: index of abbreviations:**

**FNI:** form for the notification of an invention

**IP:** intellectual property

**KTT:** knowledge and technology transfer

**SRIT:** research and knowledge transfer service

**TTM:** technology transfer manager