



## **Policy Guidelines on Technology Transfer and Intellectual Property Rights of the International Centre for Genetic Engineering and Biotechnology**

### **Summary**

The purpose of this document is to define the policy for the management of ICGEB's Intellectual Property Rights, and the exploitation of ICGEB patented or unpatented know-how. It should serve as a guiding document for ICGEB staff, fellows, students and guests.

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### **I. General Considerations**

1. The three Components of the ICGEB carry out research in scientific areas within the biotechnology domain, which are of high interest for the development of methods, techniques and products of industrial value (diagnostic methods, vaccines, biotherapeutics, innovative therapeutic strategies, new crops, innovative biopesticides, biofuel production methodologies, etc.).
2. Over the last few years, there has been a growing demand from ICGEB Member States for the development of a framework for the appropriate transfer of technologies, processes or products to the industrial sector. The ultimate goal is to make such innovations available to society at large, particularly in ICGEB Member States.
3. The mandate of the ICGEB to promote capacity enhancement for international development, also involves the education of scientists from ICGEB Member States in the practical application of their research outputs and discoveries. This involves exploring the industrial applications of their research results, the mastering of intellectual property protection, and pursuing entrepreneurship wherever possible.

4. While the mandate of the ICGEB with respect to performing advanced academic research and training remains the priority of the Organisation, the scientific and technical know-how of the Centre in various areas of biotechnology has significant potential in terms of generating income and contributing towards the United Nations Sustainable Development Goals.

5. Policy guidelines based on these principles of the use of ICGEB-owned intellectual property rights and know-how were established at the Seventh Session (New Delhi, 13-14 November 2000) and at the Nineteenth Session of the Board of Governors (Trieste, 14-15 May 2013). These guidelines on the use of ICGEB intellectual property rights and know-how have already fostered the development of industrial partnerships and the successful commercial exploitation of ICGEB's discoveries around the world. The present document now expands and updates these guidelines to take into account the major changes that have taken place in the biotechnology sector during the last decade.

## II. Definition of IP Rights related to ICGEB

1. The present policy applies only to ICGEB's own Intellectual Property (IP). That is, IP owned by the ICGEB itself. It does not apply to Intellectual Property that is owned by ICGEB Member States.

2. The ICGEB will provide its Member States, whenever requested, with advice and consultation on the development and implementation of appropriate Intellectual Property policies.

### Emblem/Logo

3. An emblem or logo is any sign or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of others. They may facilitate the commercialization of the technologies of the Centre, and enable the public to distinguish the ICGEB from other Centres. The ICGEB recognizes the following emblems/logos:

i) the logo, in its short and extended versions:



International Centre for Genetic  
Engineering and Biotechnology

ii) the name "International Centre for Genetic Engineering and Biotechnology"

iii) the acronym "ICGEB"

### Copyrights

4. Copyright (or author's right) is a legal term used to describe the rights that creators have over their literary and artistic works. Copyright is protected by the Berne Convention for the Protection of Literary and Artistic Works, the Universal Copyright Convention and the WIPO Copyright Convention. Works covered by copyright range from written works – including scientific publications, books and editorials -, music, paintings, sculpture, and films (sound and video), to computer

programs, databases, advertisements, maps, photographs and technical drawings. It subsists in works that are in a material form, that is, tangible (books, posters, films, etc.), as well as works in electronic form or which can only be viewed with the assistance of additional equipment (e.g. computer files). A copyright confers on the owner the exclusive right to reproduce the work, prepare derivative works, distribute by sale or otherwise, and display or perform the work publicly. Copyright subsists in "original works of authorship".

#### Patents

5. A patent is granted by a sovereign authority (usually a patent office) of a given country, conferring on its owner the exclusive right over the exploitation of the invention for a limited period of time in return for disclosing the invention to the public. Thus, in general, the patent owner (patentee) can prevent others from making, using, offering for sale, selling or importing for those purposes the patented invention without the patentee's permission. This exclusive right is given for a limited period of time, generally for 20 years from the filing date, as long as annual maintenance fees are paid, and has no effect beyond the territory of the country in which the patent was granted. In some countries, and in the case of pharmaceutical and agro-chemical inventions, this period can be extended for additional five years, by acquiring a Supplementary Protection Certificate.

#### Plant variety rights

6. Plant variety rights (PVR) also known as "Plant Breeders' Rights (PBR), are certificates granted to a breeder for a newly developed variety which is considered to be new, distinct, uniform, stable and has a suitable denomination. PVR gives the breeder exclusive control over the propagating material (including seeds, cuttings, divisions, tissue culture) and harvested material (cut flowers, fruit, foliage) of such a new variety for a number of years. The basic principles of national laws regulating protection of new varieties of plants follow the lines set forth in the International Convention for the Protection of New Varieties of Plants (UPOV Convention) adopted in 1961 and subsequently revised in 1972, 1978 and 1991. PVR are particularly valuable in relation to new biotic or abiotic stress-resistant crops.

### **III. Intellectual Property Policy Objectives of the ICGEB**

1. The statutory objective of the ICGEB is "to promote international co-operation in developing and applying peaceful uses of genetic engineering and biotechnology in particular for developing countries", "to assist developing countries in strengthening their scientific and technological capabilities in the field of genetic engineering and biotechnology" and "to develop and promote the application of genetic engineering and biotechnology for solving problems of development, particularly in developing countries" (Article 2(a), (c), (d) of the Statutes).

2. Towards the fulfilment of its objectives, the ICGEB shall in particular "carry out research and development including pilot-plant activities in the field of genetic engineering and biotechnology" and "maintain close contacts with industry" (Article 3(a), (j) of the Statutes).

3. Such objectives should be achieved through publication of the results of ICGEB research activities and through their commercialization. Publication and commercialization of ICGEB technologies are complementary objectives of the Centre.

4. The legal basis for an effective utilization of rights to intellectual property is secured by the ownership of the ICGEB in "all rights, including title, copyright and patent rights, relating to any work produced or developed by the Centre" (Article 14(2) of the Statutes). As far as results of genetic engineering and biotechnology developed through projects of the Centre with third parties are concerned, the ICGEB is obliged to follow the policy "to obtain patents or interests in patents" thereon (Article 14(3) of the Statutes).

5. ICGEB's Board of Governors, under Article 6(2)(e) of the Statutes, is in principle, free to adopt in its general intellectual property policy, its own rules on the exploitation of the research results of the Centre, as well as on the access to intellectual property rights therein, provided that those rules are in accordance with Article 14 of the Statutes. Member States and developing countries that are not Members of the Centre shall be granted access to such intellectual property rights "in accordance with applicable international conventions" (Article 14(4) of the Statutes). Moreover, ICGEB rules regulating access to intellectual property shall not establish criteria prejudicial to any Member or group of Members.

6. Thus, under the Statutes, it is intended that the benefits, financial or otherwise, of ICGEB-owned patents and other IP rights should be used to promote the development, production and wide application of biotechnology, in the interest of the ICGEB and its Member States.

7. At the same time, the registration of patents, technology transfer to industry, and participation in start-up biotech companies are expected to provide additional funds for ICGEB's research work, and to support the transfer of the results of research and development to society at large, particularly across ICGEB's Member States.

#### **IV. Committee on Intellectual Property**

1. Towards the fulfilment of the objectives outlined above, the ICGEB shall establish a Committee on Intellectual Property (hereinafter also indicated as "the Committee") to supervise the implementation of this policy on a day-to-day basis. The Committee shall advise the Director-General on the management of issues involving the Intellectual Property of the Centre, as set forth in these policy guidelines.

2. The ICGEB Committee on Intellectual Property will comprise the Director-General or his/her Delegate, the Directors of Components, the Chief Legal and Administration and the Head of Fundraising, Technology Transfer and Innovation Office (FTI). The Committee shall be free to involve additional IP Committee members as appropriate, who may also be external experts. The modalities of operation of the Committee shall be decided by the Committee itself.

3. The Committee will be responsible for interpreting this policy and resolving questions and internal disputes in which it is concerned. From time to time, the Committee may suggest changes to this policy to be approved by the Board of Governors.
4. Any modification or amendment of this policy shall become effective upon adoption by the Board of Governors, in line with Article 6(2)(e) of the Statutes.
5. The FTI Office shall have the responsibility for developing the working procedures and documentation necessary for implementing this policy and these shall be subject to the approval of the Committee on Intellectual Property.

## **V. Ownership of Intellectual Property Rights**

### Staff, Fellows, Visiting Scientists

1. Staff Rules and Regulations of the ICGEB provide that staff members of the Centre as well as persons engaged by the ICGEB under special service agreements (SSA), have to vest in the Centre all rights including title, copyright and patent rights, in any work performed by them as part of their official duties.
2. Visiting fellows and students temporarily integrated in the research work of the Centre shall be subject to the same treatment as staff members concerning any work performed by them in the framework of a research project of the Centre.
3. Visiting scientists seconded from another research institute or organization shall obtain from their formal employer an appropriate assignment document for all Intellectual Property developed during their secondment to the ICGEB.
4. Should the research generating the IP be carried out in collaboration with third parties, such IP will be managed as per the terms and conditions of the Collaboration Agreement. It shall be the responsibility of ICGEB Group Leaders and Senior Scientists to conclude, through competent offices, a Collaboration Agreement at the beginning of any new collaboration activity with third parties. As a general principle, IP should be exclusively owned by the Centre.

### Collaborative Research Programmes

5. Collaborative research activities of the ICGEB with Affiliated Centres and Networks, including activity financed by the ICGEB in its Member States through its CRP-ICGEB Research Grant Programme, should be considered as part of the national Research & Development programmes implemented by the Member States; as such, the results emanating from such research activities should belong to the Institute and/or to the scientists who have actually carried them out, in line with national regulations in place.

### IP Developed Outside Official Duty

6. Copyright in works performed outside official duty and patent rights in any invention made by an ICGEB Staff member or visiting fellow in his or her own time and without using ICGEB resources, belong to the author or inventor.

## **VI. Patenting Procedure**

1. As a general rule, the ICGEB Directors of Component, in coordination with the FTI Office, should actively monitor the research within their respective Components to assess whether there may be any patentable inventions or products, which could potentially generate commercial value. This active process could involve periodic visits by external experts in IP rights and the broad biotechnology market, to scout for possible inventions and advise the ICGEB Committee on Intellectual Property.

### Disclosure Obligations

2. The Group Leaders as part of their employment duties shall notify the Director of Component of any invention, computer software or any other technology of potential commercial value, developed by staff members of the ICGEB and/or visiting fellows or visiting scientists temporarily integrated in research projects of the Centre, as soon as possible after conception<sup>1</sup>.

### Ownership Determination

3. Upon review of the disclosure documents, the ICGEB Committee on Intellectual Property (ref. Section IV above), in co-operation with the Group Leader concerned, shall determine who are the Inventors and, if the research was sponsored by a donor, whether the research results are subject to any specific terms or conditions.

### Filing Decision

4. The Committee shall be solely responsible for determining whether a patent application shall be filed on an invention. Filing determinations, apart from the patentability requirements, shall be made on the basis of the commercial potential of the invention for all or any Member State(s), for any specific developing non-Member country, or for reasons that the Committee may deem appropriate. Inventors shall cooperate in the patenting process as required by the ICGEB.

### Other General Criteria

5. In evaluating the commercial potential or industrial relevance of any potentially patentable invention, the Committee, together with the inventor, shall endeavour to answer the following questions:
- a. Does the technology offer a cheaper and/or a better way of accomplishing something?
  - b. Are there competing technologies available, and if so, how much better is this invention?
  - c. Does the invention provide a technological answer to an existing problem?
  - d. Does it have the potential for creating a new market?
  - e. Will the inventors continue to work on the invention?
  - f. What will be the potential pay-off for a company, or a spin-off, that makes an investment in the development of the invention?
  - g. How much investment, in both time and resources, will be required to bring

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<sup>1</sup> Conception means a creation in the inventor's mind of a new and useful way of solving a problem. The act of visualizing an invention complete in all essential detail occurs when a solution is formulated (not when a problem is recognized). Conception is the unequivocal mental discovery of an invention.

the invention to the marketplace?

#### Filing Place and Mode

6. For inventions whose potential commercial value is affirmed by the Committee, patent applications shall be filed in all countries in which the respective inventions could potentially be successfully exploited and where the ICGEB could potentially find commercial partners (licensees). The ICGEB shall use any opportunity offered by international conventions, such as the Paris Convention for the Protection of Industrial Property, in regard to the 12-month right of priority, the Patent Cooperation Treaty (PCT), for subsequent international filing, and the designation of as many PCT contracting states as might be advisable, or the European Patent Convention (EPC). All cost-saving options will be used. Furthermore, the time between the priority filing and the final decision on the subsequent designations will be used for further evaluation of the commercial potential of the invention at stake and in the search for suitable commercial partners.

7. Whenever possible the ICGEB shall avoid situations of co-ownership of patent applications, as these may become a burden, rather than a benefit, depending on the country and legislation involved. In addition, co-ownership may diminish the Centre's autonomy in the exploitation of patent rights, especially if the ICGEB is a minority owner of jointly- owned patent rights.

8. It is understood that, whenever the ICGEB acquires IP rights, the rules of applicable national or regional law and international conventions, as applicable, will be strictly observed. In particular, the provisions of the Convention on Biological Diversity (CBD) and related Protocols, and national and regional laws implementing that Convention, relating, inter alia, to prior informed consent, benefit sharing, transfer of technology, etc., as well as the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, will be applied in full.

9. Costs of protecting, commercializing and defending patent and other IP rights of affirmed general commercial value in which the Centre has vested rights, shall be borne by the regular budget of the Centre. As a general rule, and on a yearly basis, these should not exceed 1% of the annual budget of the Centre. Additional resources to file and maintain patents can be borne by external funds awarded to the individual PIs who are listed as inventors.

9. The ICGEB will actively search for public and private partners interested in the licensing of its IP with the purpose of its commercial valorisation. This might include licensing the IP to third parties acting as intermediary bodies with the capacity of liaising with biotechnology or pharmaceutical companies.

#### Notification and Access to Patented Technologies by ICGEB Member States

10. The ICGEB shall publish on its website without delay any new priority patent application, thus assuring the broadest possible dissemination of information.

11. ICGEB Member States may express their interest in the patented technology and may request the ICGEB to file a subsequent patent in their own Country. Such notification should be made in writing to the ICGEB Director-General no later than

six (6) months from the date of publication on the website, which should correspond to the priority date. If such notification is received beyond that date, the Committee may still positively consider the request, should no other commitment be in place.

12. The ICGEB shall follow up the requests of the Member States. Access - by means of assignment or license of the patent - to the patented technology in that Member State, as guaranteed under Article 14(4) of the Statutes, will be negotiated between the ICGEB and the respective Member State on a case-by-case basis. Costs of protecting, commercializing and defending patent and other IP rights upon the request of Member States shall be borne by the respective requestor(s).

13. The ICGEB shall also be free to file subsequent patent applications in Member or non-Member States that did not make such requests, if it deems subsequent filings appropriate, either for purposes of successful commercialization, or for wide application of the respective biotechnology in that particular country. In the latter case, the ICGEB shall inform the respective Member State accordingly.

14. If no Member State has expressed an interest in the patented invention during the six (6) months following the priority date, the ICGEB shall be free to license or assign the technology to an industrial partner or to any such entity that may guarantee the marketing of the technology, thus making it available to the general public, and obtaining financial returns for the research activities of the Centre. The ICGEB, in negotiating any such license agreement, shall include, wherever possible, terms for the marketing of the technology in its Member States under fair and equitable conditions.

#### Release of Inventions

15. Where the Committee determines that it will not file a patent application on an invention, abandons a patent application on an invention prior to the issuance of the patent, or abandons a granted patent on an invention, the inventor(s) may request a release of the invention.

16. Upon determining that releasing the invention to the inventor(s) will not violate the terms of an external funding agreement and is in the best interests of the ICGEB and the public, the Committee may agree to a release. In this case the ICGEB will assign or release all interests that it holds, or has the right to hold, in the invention to the inventor(s) in equal shares, or such other shares as the inventors may agree.

17. Release of inventions may be conditional upon, among other things, agreement by the inventor(s) to the following:

- a. To reimburse the ICGEB for all legal expenses, developing costs and fees incurred if and when the inventor(s) receive income from the invention.
- b. To share with the ICGEB 10% of the net income (remaining from gross income after repayment of ICGEB expenses, as above, and the inventor(s)' legal and licensing expenses) received by the inventors from the invention. Income subject to this revenue-sharing provision includes equity received by inventors as consideration for the Invention but does not include financing received for purposes of research and development.
- c. Upon request, to report to the ICGEB regarding efforts to develop the invention for public use and, at ICGEB's request, reassign those inventions



- which the inventor(s), their agents or designees are not developing for the benefit of the public.
- d. To fulfill any existing obligations already in place with external donors having funded the research that led to the invention.
  - e. To ensure the ICGEB irrevocable, perpetual, royalty-free, non-exclusive, worldwide right to use the invention for its research and education purposes and a right to transfer the same rights to other non-profit institutions.
  - f. To agree to such limitations on ICGEB's liability and indemnity provisions as ICGEB may request.

## **VII. Technology Transfer Activities**

According to its Statutes, the ICGEB operates in close contact with industry to fulfil its mandate (Article 3 (j)). Three specific modalities of interaction with third parties are envisaged: licensing of ICGEB IP (i); transferring of unpatented ICGEB technologies, know-how or materials (ii); performing services for third parties (iii).

### Licensing of ICGEB Inventions (i)

1. Besides the opportunity given to Member States to access ICGEB technologies as described in Section VI par. 11 and 12 above, the ICGEB will pursue the licensing of any technology owned by the Centre by researching the market for the technology, identifying third parties to commercialize it, entering into discussions with potential licensees, developing a business plan, negotiating appropriate licenses or other agreements, monitoring progress, and distributing royalties to the inventors/authors in accordance with the distribution scheme set forth in Section VIII of these policy guidelines.
2. In the case of inventions of potential general commercial value, the Committee will negotiate with potential partners non-exclusive or exclusive licensing agreements, depending on the market conditions and, in particular, depending on the investment necessary for the successful exploitation of the technology at stake, and advise the Director-General accordingly.
3. In establishing a fair price (down-payment) for the release of the license, due attention shall be given by the Committee to the costs incurred by the Centre for the research activities that led to the patented invention, the administrative expenditures related to the filing and the maintenance of the patent and, whenever applicable, the costs of the development of the invention.
4. The ICGEB may decide to grant unconditional, royalty-free licenses to companies in Least Developed Countries (LDCs) or countries with GDP p/capita of less than USD 4,000.
5. It shall be the policy of the ICGEB not to commit future inventions to licensees even where improvements to a technology are anticipated.
6. As part of its licensing strategies and in the case that no Member State has expressed an interest in licensing an ICGEB-patented technology within the established period as outlined in Section VI paragraph 11 above, the Centre may also

consider the opportunity to license the invention to the inventor(s), if the latter so require(s), or to a start-up company. Although the ICGEB does not give preferential treatment to its inventors, the Centre recognizes the importance of the inventor(s)'s role in helping the transfer of technology and in evaluating the ability of a company to develop licensed products.

7. As part of its licensing strategies and in the case where ICGEB inventions are not suitable for immediate licensing, but hold interest for further generation of IP or commercial value, or in the case where there is unpatented ICGEB know-how that holds potential commercial value, the ICGEB will evaluate the opportunity to support the creation of a start-up company, without any direct involvement in the start-up, but delegating such direct involvement to a third party under an agreed set of conditions (for example, through the licensing or assignment of the invention).

8. The value contribution of the ICGEB to the start-up company will be exclusively by:

- a. Licensing ICGEB's IP in the patented invention to the start-up company directly or to a third party in turn having ownership in the start-up company;
- b. Providing scientific and technological support to the company for further product development, both in the case of a patented invention or an unpatented technology.

In no case will direct financial support to the start-up company be provided through ICGEB funds.

9. In evaluating the opportunity to license to an inventor or to a start-up company, either directly or indirectly, the Committee will obtain evidence that a well thought-out business plan is in place, that adequate resources are available to enable the ICGEB technology to be developed effectively, and also that potential conflicts of interest are recognized and effectively managed (See Section IX).

10. It is understood that, wherever possible, any such license agreements shall contain favourable terms and conditions for sale in ICGEB Member States, especially those with low biotech manufacturing capacity. For sales in such countries the Centre may review or waive its royalty/payment requirements.

11. The Committee shall be available at all times to provide information and assistance to ICGEB staff and fellows, to make them aware of any conflict of interest issues that may arise as part of a start-up venture.

#### Transfer of Unpatented ICGEB Technologies or Research Materials (ii)

12. The ICGEB shall identify industrial partners for the transfer of unpatented expertise, or technologies for which patents have expired (for example, technologies for the production of a number of biosimilar products), or research materials generated by the ICGEB (for example, plasmids, viral vectors, antibodies or other reagents; see also Section X). Such technology transfers shall be performed on a non-exclusive basis and may involve companies located in ICGEB Member States, or companies located in non-Member States, subject to different terms and conditions. Each such technology transfer shall be negotiated between the Centre and the company, and shall be regulated by a specific Technology Transfer Agreement.

13. In accordance with the Conclusions and Decisions of the Twelfth Session of the ICGEB Board of Governors, held in Trieste on 27-28 October 2005, the Centre shall notify the signing of any Technology Transfer Agreement to the Governor of the Member State in which the company is located.

#### Performance of Services for Third Parties (iii)

15. From time to time, ICGEB Group Leaders may be approached by industry to perform particular research services, of a technical, operational nature, where no IP creation is envisaged, and where the results of the research work belong to the industrial partner.

16. Such services shall be performed exclusively if they fit into the general programme of the individual Group as set by the Director-General in conjunction with the Director of Component and according to the general recommendations of the Council of Scientific Advisors of the ICGEB.

#### Dispute Resolution

17. Any dispute arising from the licensing of intellectual property rights or from the transfer of unpatented know-how of the ICGEB shall be settled amicably by consultation between the parties in good faith and in a timely manner. If not resolved by consultation among the parties, any dispute, controversy or claim shall be submitted to the WIPO Mediation and Arbitration Centre and shall be settled in accordance with WIPO [expedited] arbitration rules.

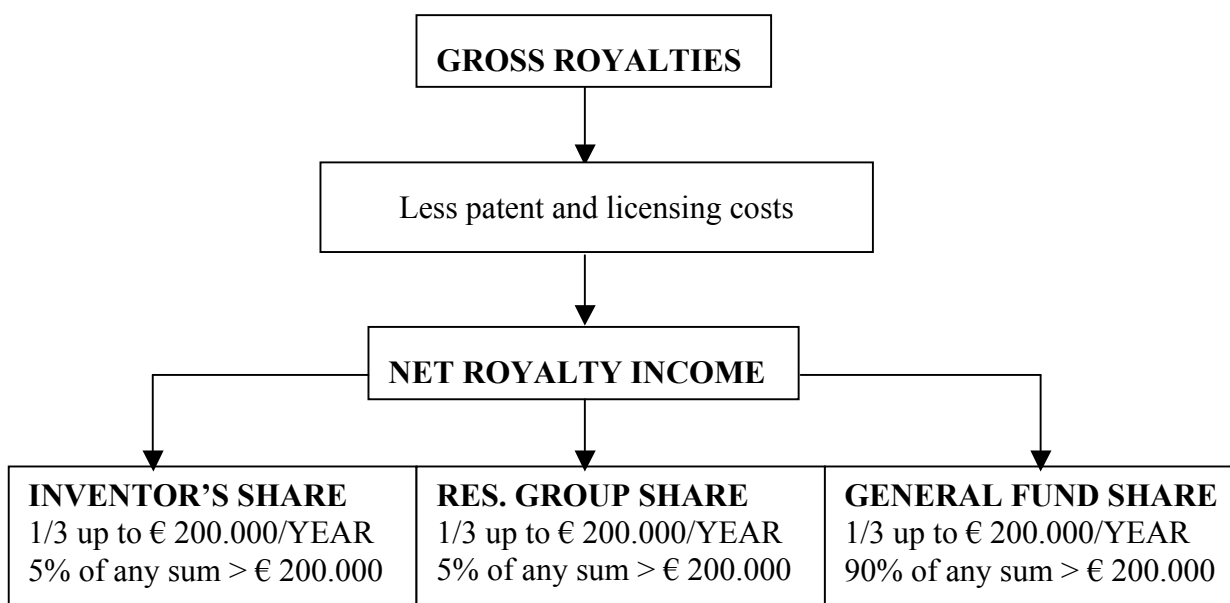
### **VIII. Revenues from Technology Transfer Activities**

This Section regulates the sharing of revenues ensuing from the above detailed three main modalities of interaction of the ICGEB with third parties: licensing of ICGEB IP (i); transferring of unpatented ICGEB technologies, know-how or materials (ii); performing services for third parties (iii).

#### Royalty sharing from IP licencing (i)

1. At the end of the fiscal year, royalties and down payments received in return for the licensing of an ICGEB invention shall be distributed as follows: from the Gross Royalties all patent and licensing and administrative costs will be deducted. The resulting amount will be the Net Royalty Income which shall be divided as follows: 1/3 to the inventor(s), with a ceiling of EUR 200,000 per year and 5% of any sum in excess of that ceiling; 1/3 to the research budget of the Group in which the inventor(s) operate(s), with a ceiling of EUR 200,000 per year and 5% of any sum in excess of that ceiling; 1/3 to the ICGEB General Fund, plus 90% of the sums in excess of the ceilings of EUR 200,000 described above.

2. The funding destined to the General Fund shall be aimed equally at supporting the research activities at the Component generating the IP and the other institutional activities implemented by the Centre (including but not limited to the Programmes for Fellowships, Meetings and Courses, and CRP-ICGEB Research Grants) in order to widen their reach and scope to the benefit of ICGEB Member States. Accordingly, 50% of such funding will be maintained at the Component and 50% will be transferred to the ICGEB Headquarters.



4. Any revenue deriving from down payments and milestone payments related to IP license agreements, in advance of the actual entry into the market, will be treated as described in paragraph 6 below (Transfer of unpatented ICGEB technologies, know-how or materials).

5. Personal royalty shares shall be portable and thus payable to the inventors regardless of their employment status at the ICGEB. Research shares will not follow inventors leaving the ICGEB but will be transferred and payable to the inventor's Research Group or Component as determined by the Director-General. Where an inventor moves from one Research Group to another at the ICGEB, the Research Group share will move with him or her.

#### Transfer of unpatented ICGEB technologies, know-how or materials (ii)

6. Any revenue generated from technology transfer activities as described in Section VII paragraph 12, shall be distributed as follows:

- Up to first 100,000 EUR: 80% shall be transferred to the regular budget of the group performing the technology transfer; 10% shall be transferred to the Component's budget and 10% to the Overhead Fund of the Component that has generated the technology.
- Any sum in excess of 100,000 EUR: 50% shall be transferred to the regular budget of the group performing the technology transfer; 40% shall be transferred to the budget of the Component in which the transfer takes place; the remaining 10% shall be transferred to the Overhead Fund of the Component that has generated the technology.

#### Performance of services for third parties (iii)

7. Funding deriving from technological services to third parties shall be distributed as follows:

- 50% shall be transferred to the regular budget of the group performing the service; 40% shall be transferred to the budget of the Component in which the Group operates; the remaining 10% shall be transferred to the

Overhead Fund of the Component in which the service has been performed.

## **IX. Conflict of Interest**

1. It is the policy of ICGEB that its officers, staff, fellows and guests have the obligation to avoid ethical, legal, financial or other conflicts of interest and to ensure that their activities and interests do not conflict with their obligations to the ICGEB.
2. This section is intended to be a guideline for issues of conflict rather than a policy that covers all possible situations. As a general rule, prior full disclosure to a supervisor is the best policy to follow.
3. Conflicts can arise in connection with performing external professional activities and in connection with licensing and intellectual property.
4. The following situations are considered close financial interests or relationships that may require closer scrutiny, as far as conflicts of interest are concerned:
  - a. Ownership or promise of stock to the value of over Euro 10,000 or 0.5% of the total value, in a publicly traded company.
  - b. Ownership or promise of stock or stock options of any amount in a privately held or start-up company.
  - c. An ICGEB staff member, expert/consultant or fellow serving in a consulting or other fiduciary role for a financially interested company, whether or not remuneration is received.

### Conflict of Interest in Commitment

5. The ICGEB generally believes that its training and research programmes can flourish only when sustained by the continuous, active participation of its staff in research, enriched in many cases by interaction with industry, governments, donors and other actors and institutions. The Director-General has therefore, traditionally authorized ICGEB staff members to devote a portion of their professional effort to outside activities related to their areas of expertise, subject to limits on the amount of time and effort devoted to such activities.
6. For ICGEB staff and fellows the obligation inherent to full-time service is difficult to define, since in the world of research it represents far more than a stated number of hours per week. All ICGEB staff and visiting fellows are expected to devote the majority of their professional time, attention and energy to fulfil the ICGEB's mission. The definition of this obligation remains flexible according to principle rather than formula. As a general guideline, no more than 15% of a staff member's professional effort should be dedicated to outside activities and, in any case, these activities should not be conflict with the ICGEB mission.
7. In deciding whether to grant permission for a specified outside activity the Director-General, with the Committee and the relevant Director of Component, will consider the extent to which the activity:
  - a. Detracts from the staff's own work at the Centre;

- b. Competes with research projects performed at the Centre;
- c. Draws upon special support from the Centre or makes use of its staff and fellows.

This policy is intended to protect against possible misuse of the Centre's name and against misleading representations of the Centre's association with the activity, and is consistent with the mandate of the ICGEB.

8. In accordance with the present policy the following situations are considered as posing a conflict of commitment:
- a. The participation in a research project at another institution that could be conducted appropriately at ICGEB;
  - b. The holding of significant management roles involving supervision of the work of others and/or day-to-day responsibility for operating decisions in a private business or at another public institution.

#### Conflict of Interest in Licensing

9. The highly conceptual or early-stage nature of ICGEB technologies may call for the ongoing involvement of ICGEB inventors in a licensee company's development efforts. The Centre is aware that such involvement may result in a consultancy and in a financial relationship with the licensee, involving potential consulting fees or equity in the company. The Centre supports the commercial development of ICGEB inventions and the involvement of its staff, fellows in this process but it requires that a thorough review of these relationships be performed.

10. Once it appears that a license may be granted to a company in which an inventor, ICGEB staff member or fellow has a close financial interest, each such individual will inform the Committee of this possibility and initiate discussions to resolve any conflict of interest concerns the Committee might have.

11. Before a license is signed with a company in which any such individual has a close financial interest, each such individual will notify the Committee if the license is expected to include rights to future technology (such as rights to separately patentable "improvements" and whether such improvements are limited to technology dominated by the originally licensed technology). In addition, each inventor, ICGEB staff or fellow with a close financial interest is required to provide the Committee with the following:

- a. The details of the inventor's relationship to the prospective licensee company;
- b. The relationship, if any, of such individual's ongoing research to the activities of the licensee company, and
- c. A completed ICGEB Conflict Avoidance Statement. Through this statement, the individual acknowledges the potential for conflict and commits him/herself to certain actions to minimize and manage that potential. In the case of an ICGEB Group Leader, the statement will be signed by the individual and countersigned by the relevant Director of Component, Chief Legal and Administration and the Director-General. If a Director of Component also has a close financial interest in the company, the Director-General and the Chief Legal and Administration will countersign. If the Director-General is in the same position, he/she will disclose the potential conflict of interest to the Board of Governors. It is understood that the Committee may require other forms of disclosure and/or action in addition to this statement.

Sponsored Research

12. It shall be regarded as a conflict to be disclosed for ICGEB staff, expert/consultant or fellow to accept research sponsorship from a company in which they have a significant financial interest. The conflict arises because the outcome of the research could materially affect the personal wealth of the researcher or an immediate family member.

Management of Conflicts

13. Based on conclusions drawn from review of the above information, the Committee shall eliminate, mitigate or manage the conflicts that are deemed to have the potential, or are likely to be perceived as having the potential, to have a direct and significant effect on the research. Strategies for eliminating, mitigating, or managing conflicts can include:

- a. Annual reporting by that individual on the relation, if any, of his/her ICGEB research to the licensee company and how the potential for conflict is being managed;
- b. Monitoring of the research of the individual, also with the help of independent reviewers if required;
- c. Modification of the research plan if needed;
- d. Reduction or elimination of the inventor's, staff or fellow's financial interests, including equity ownership;
- e. Review or severance of relationships that create actual or potential conflicts.

**X. Tangible Research Property (TRP)**

1. Tangible Research Property (TRP) is defined for purposes of this policy as tangible items produced in the course of research projects performed at the ICGEB. TRP includes such items as: biological material and research tools developed at the ICGEB such as plasmids, viral vectors, antibodies or other reagents, as well as drawings, computer databases and prototype devices.

2. TRP is separate and distinct from intangible (or intellectual) property such as inventions, patents, copyrights which are subject to other sections of this policy. Individual items of TRP may be associated with one or more intangible properties such as copyright or patents.

3. TRP owned by the Centre, may usually be distributed for research purposes only, with minimal conditions attached. Any such distribution is subject to an agreement by the recipient that commercial development or commercial use or further transfer of the biological material is not to be undertaken. See the section on Material Transfer Agreements below.

**XI. Standard Agreements**Material Transfer Agreement.

1. The transfer of proprietary tangible property, which is often a biological material, research tool or reagent, is covered by a contract called a Material Transfer

Agreement (MTA). A Material Transfer Agreement (MTA) is a contract governing the transfer of tangible research material (or TRP) between two parties, when the recipient intends to use this for his or her own research purposes. The types of materials typically transferred under MTAs include cell lines, cultures, plasmids, nucleotides, proteins, bacteria, viral vectors, antibodies, chemicals and other proprietary physical materials. Three types of MTAs are most common at academic institutions: transfer between academic or research institutions, transfer from academia to industry and transfer from industry to academia. Each of these calls for different terms and conditions. A template of a standard ICGEB-MTA for transfers between academic research institutions is enclosed as Annex I.

#### Confidentiality Agreement

2. The Confidentiality Agreement (CA) is an agreement through which two or more parties bind themselves not to disclose information covered by the agreement. The CA creates a confidential relationship between the parties to protect any type of confidential and proprietary information they intend to share.

3. A CA is commonly signed when two or more parties consider initiating a common research project and wish to exchange sensitive information in order to understand, evaluate and elaborate future collaboration. Any such CA should be approved and signed by the Director-General or a Director of Component. A template of a standard ICGEB-CA is enclosed as Annex II.

#### Research Collaboration Agreement

4. The Research Collaboration Agreement (RCA) defines a bargain that parties enter into as well as the relationship and the expectations of the parties. Any research collaboration will have an agreement that clearly and objectively indicates the intentions of the parties. RCAs generally include terms and provisions covering grants and payments (if any), dispute resolution, intellectual property emerging from the research collaboration, IP ownership and confidentiality, duration, termination as well as other related legal terms and definitions.

5. The relationship and goals of the parties will define how the agreement is structured. In order to avoid the loss of intellectual property rights of the Centre, any research collaboration should be framed within a RCA, which is the responsibility of the Group Leaders to demand. Any such RCA should be approved and signed by the Director-General or a Director of Component.

#### License Agreement

6. The License Agreement (LA) is an agreement between the inventor or patent holder of a product and another party which grants that party the legal right to market, sell, or otherwise profit from that product. The license agreement may or may not give the other party exclusive right to sell the product and it may be permanent or temporary. In return, the inventor or patent holder receives a royalty or some other compensation. Any such LA should be approved and signed by the Director-General or a Director of Component when specifically delegated.

7. Following an endorsement by the Committee, the LA is negotiated between the third party and the ICGEB.



**Annex I**  
**MATERIAL TRANSFER AGREEMENT**

This MTA is entered into between the International Centre for Genetic Engineering and Biotechnology, an intergovernmental organization established by its Member States on 13 September 1983, having its Headquarters in Area Science Park, Padriciano 99, 34149 Trieste, Italy (hereinafter "ICGEB") and \_\_\_\_\_, and its investigator Dr. \_\_\_\_\_ (hereinafter collectively referred to as "RECIPIENT")

For the purposes of this Agreement MATERIAL shall mean the above-referred biological material plus its progeny, unmodified derivatives and any know-how or data related directly to the MATERIAL.

In response to the RECIPIENT's request for the MATERIAL [*insert description*] for the purposes of [*insert short description of the research project*] the ICGEB asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the MATERIAL

1. The above MATERIAL is the property of the ICGEB and is made available as a service to the research community.
2. THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.
3. THE MATERIAL WILL BE USED FOR TEACHING OR NOT-FOR-PROFIT RESEARCH PURPOSES ONLY.
4. The MATERIAL will not be further distributed to others without the ICGEB's written consent. The RECIPIENT shall refer any request for the MATERIAL to the ICGEB. To the extent supplies are available, the ICGEB or the ICGEB SCIENTIST agree to make the MATERIAL available, under a separate MATERIAL TRANSFER AGREEMENT to other scientists for teaching or not-for-profit research purposes only.
5. The RECIPIENT agrees to acknowledge the ICGEB as the source of the MATERIAL in all publications, presentations and grant applications reporting use of it, consistent with the highest academic standards.
6. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE ICGEB MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, Recipient assumes all liability for claims for damages against it by third parties, which may arise from the use, storage or disposal of the Material except that, to the extent permitted by law, the ICGEB shall be liable to the Recipient when the damage is caused by the gross negligence of the ICGEB.
7. The RECIPIENT agrees to notify the ICGEB of any potential commercial use of the MATERIAL, Modifications of the MATERIAL or any Invention deriving from the MATERIAL. "Modification" shall mean substances created by the RECIPIENT which contain/incorporate any form of the MATERIAL and "Invention" means new uses of the MATERIAL and products containing the MATERIAL. Any commercial use of the MATERIAL, its Modification or Invention, shall be the object of a separate inter-institutional agreement between the RECIPIENT and the ICGEB.

8. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable laws, governmental regulations and guidelines, including any regulations pertaining to research with animals and recombinant DNA that may be applicable to the MATERIAL in the Country where the Research is carried out.

9. The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the ICGEB for its preparation and distribution costs. If a fee is requested, the amount will be indicated here: [insert fee]\_\_\_\_\_.

10. Nothing in or relating to this Agreement shall be deemed a waiver of any of the privileges and immunities of the ICGEB.

The ICGEB, RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the ICGEB. The ICGEB will then send the MATERIAL.

**RECIPIENT Institute**

**Read and Acknowledged:**

Legal Representative _____	Recipient Investigator _____
Title _____	Title _____
Signature _____	Signature _____
Date _____	Date _____
Institutional Stamp _____	

**ICGEB approval:**

Legal Representative _____	ICGEB Investigator _____
Title _____	Title _____
Signature _____	Signature _____
Stamp & Date _____	Date _____

**Annex II**  
**CONFIDENTIALITY AGREEMENT**

This is made and effective from the latest signed date.

This Confidentiality Agreement (hereinafter "Agreement") is entered into between the International Centre for Genetic Engineering and Biotechnology, an intergovernmental organization established by its Member States on 13 September 1983, having its Headquarters in Area Science Park, Padriciano 99, 34149 Trieste, Italy (hereinafter referred to as "ICGEB")

**and**

XX - hereinafter referred to as "**XX**"

WHEREAS the ICGEB and XX intend to exchange information for the purpose of evaluating a possible collaboration in the field of .....hereinafter referred to as "**collaboration**";

and WHEREAS in order to define the content of the **collaboration** the parties wish to exchange technical and/or commercial information of a confidential or proprietary nature presently in their possession and wish to ensure that the same remains confidential;

**Now, therefore, it is hereby agreed as follows:**

1. For the purpose of this Agreement "**confidential information**" shall mean all written and verbal data such as technical and/or commercial information, including but not limited to any documents, drawings, sketches or designs, materials, research results, procedures, samples or prototypes disclosed or supplied either by the ICGEB or by XX to the other party, and which at the time of its disclosure or supply is identified as confidential or proprietary. Oral information which is confidential or proprietary shall be recorded in writing by the disclosing party within (30 days) after disclosure, and the resulting document shall specifically state the date of disclosure and include a brief description of the confidential information disclosed or supplied. The foregoing notwithstanding, the terms of this Agreement also pertain to information not so marked or identified if the party receiving the information otherwise knows or should reasonably be expected to know of their confidential nature.
2. The ICGEB and XX each undertake to treat any and all **confidential information** as confidential, to use it solely for the purpose of the evaluation and definition of a **collaboration** as stated in this Agreement, not to disclose it to any third party, and not to make it publicly available or accessible in any way, except with the prior written consent of the disclosing party.
3. The obligations specified in section 2 above shall not apply with respect to any **confidential information** which:
  - a. the receiving party can demonstrate with written evidence has been known to the receiving party prior to the time of its receipt pursuant to this Agreement; or
  - b. is in the public domain at the time of disclosure or thereafter enters the public domain without breach of the terms of this Agreement on the part of the receiving party; or
  - c. the receiving party can prove becomes known to the receiving party through disclosure by sources other than the disclosing party, having a right to disclose such information; or
  - d. the receiving party can demonstrate with written evidence has been developed independently by an employee of the receiving party who has not had access to any of the **confidential information** of the disclosing party;
  - e. has to be disclosed by the receiving party in response to a valid order of a court or any other

body having jurisdiction over this Agreement or such disclosure is otherwise required by law, provided that the receiving party, to the extent reasonably possible, has first given prior written notice to the disclosing party and made reasonable effort to protect the **confidential information** in connection with such disclosure.

4. Unless it is necessary for the purpose stated in this Agreement and provided that any disclosed **confidential information** or any copy thereof is made accessible only to such employees who have a need to know, the receiving party shall not, without the prior written consent of the disclosing party, copy or reproduce any item or document supplied to the receiving party – being or containing in whole or in part **confidential information**. The receiving party shall return such item or document and any copies thereof at the supplying party's request, and at the latest on termination of this Agreement. This shall not apply to copies of electronically exchanged **confidential information** made as a matter-of-routine information technology backup, and to **confidential information** or copies thereof which must be stored by the receiving party according to mandatory law, provided that such **confidentiality information** or copies thereof shall be subject to an indefinite confidentiality obligation.

5. All **confidential information** shall remain the exclusive property of the disclosing party as well as all patent, copyright, trade secret, trademark and other intellectual property rights therein. No license or conveyance of any such rights to the receiving party is granted or implied under this Agreement. No commercial obligation on the part of either party is intended or undertaken. The parties agree that any **confidential information** is made available "as is" and that no warranties of any kind are granted or implied with respect to the quality of **confidential information**, including but not limited to, its fitness for any purpose, non-infringement of third party rights, accuracy, completeness or correctness.

6. Each party shall ensure that **confidential information** will be disclosed only to its staff, fellows etc. having a need to receive such information for the purposes of the **collaboration**. Each party hereby warrants that its staff, fellows etc. to which **confidential information** is disclosed will be bound and will abide by the terms of this Agreement.

7. The party receiving **confidential information** including materials, samples, prototypes or similar items, shall not analyze it, chemically, by reverse engineering, or otherwise, in order to determine the identity and/or properties of its components.

To the extent that such items have not been destroyed or used during evaluation tests and unless there is no other agreement between ICGEB and XX, they shall be returned to the supplying party or destroyed upon the request of the supplying party, and at the latest on termination of this Agreement.

8. This Agreement shall be effective as of the date of the last signature and shall thereafter continue for ..... months (period of exchange of information for evaluation purposes). The confidentiality obligation hereunder shall terminate in (2/3/5/7/10) years after the date of the last signature of this Agreement.

9. Ancillary agreements, amendments or additions hereto must be made in writing.

10. Any dispute, controversy or claim arising under, out of or relating to this Agreement and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be resolved amicably among the parties, or through negotiation between the Executive Heads.

If, and to the extent that, any such dispute, controversy or claim has not been settled within sixty [60] days from its commencement, it shall, upon the filing of a Request for Arbitration

by either party, be referred to and finally determined by arbitration in accordance with the WIPO [Expedited] Arbitration Rules. Alternatively, if, before the expiration of the said period of sixty [60] days, either party fails to participate or to continue to participate in the negotiations, the dispute, controversy or claim shall, upon the filing of a Request for Arbitration by the other party, be referred to and finally determined by arbitration in accordance with the WIPO [Expedited] Arbitration Rules. The place of arbitration shall be [Trieste] [New Delhi] [Cape Town]. The language to be used in the arbitral proceedings shall be English.

10. If any provisions of this Agreement are invalid or unenforceable, the validity of the remaining provisions shall not be affected. The parties shall replace the invalid or unenforceable provision by a valid and enforceable provision that will meet the purpose of the invalid or unenforceable provision as closely as possible.

11. Nothing in or relating to this Agreement shall be deemed a waiver of any of the privileges and immunities of the ICGEB or its officials.

12. All notices or reports permitted or required under this Agreement shall be in writing and shall be delivered by personal delivery, electronic mail, facsimile transmission or by certified or registered mail, return receipt requested, and shall be deemed given upon personal delivery, five (5) days after deposit in the mail, or upon acknowledgment of receipt of electronic transmission. Notices shall be sent to the addresses set forth at the beginning of this Agreement or such other address as either party may specify in writing.

13. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute the same instrument.

\_\_\_\_\_  
On behalf of ICGEB

Prof.....  
Title.....

Date:.....

\_\_\_\_\_  
On behalf of XX

Prof.....  
Title.....

Date:.....