



EDCTP policy on intellectual property rights

Introduction

EDCTP is a not-for-profit public-funded organisation whose mission is to accelerate the development of new intervention tools (diagnostics, drugs, vaccines and microbicides) against HIV/AIDS, tuberculosis and malaria. This is done by funding clinical trials and strengthening capacity including that for enabling the environment to conduct clinical trials using best practices.

In order to accelerate the development of new intervention tools it is important that the results of the clinical trials funded by EDCTP must be published as soon as possible. However, in doing so, it is equally important that the rightful owners of the developed tools and knowledge get the protection needed to enable them to secure their implementation in developing countries, especially in sub-Saharan Africa.

To realise both objectives EDCTP has a clear policy on intellectual property rights (IPR) that recognises and distinguishes between copyrights and patent rights.

EDCTP is funded under the sixth framework programme (FP6) of the European Commission (EC). The guidelines for newly generated knowledge (results) provided for by this programme therefore form the basis for this EDCTP policy on IPR. However, within the FP6 structures, EDCTP is exceptional in that it supports a European-African partnership and conduct of clinical trials, so that other international guidelines and standards, in particular the ICH-Guidelines for Good Clinical Practice (ICH-GCP) apply to EDCTP and its funded projects. Accordingly, all clinical trials need to be conducted under the responsibility of a clinical trials sponsor as defined in the ICH-GCP guidelines. However, as a compensation for the financial risks, such a responsibility involving sponsorship is normally taken on the condition that the sponsor becomes the owner of the trial data. At times, the sponsor may need to or have already concluded agreements with other parties, on further development or exploitation of the investigational product or other results of funded projects. EDCTP does not act as a clinical trial sponsor or carry the associated risks and responsibilities nor does it make any direct contractual arrangements with the clinical trial sponsor. Also, since EDCTP does not develop products on its own, most of its funded clinical trials utilise products or methods that have been or will be further developed by other public or private organisations.

The instrument for implementing EDCTP IPR policy is the Grant Agreement that EDCTP signs with the host institution of the Project Coordinator (PC) and the PC. This implies that EDCTP lays the responsibility for the process of dissemination of the results via the same Grant Agreement with the host institution and the PC irrespective of whether the host institution will take the role of sponsor or will become the owner of the results.

Awareness of the importance of the IPR in general and of the EDCTP IPR-policy in particular by all participants, especially those from developing countries, is crucial for the short and long-term success of the EDCTP mission.

The EDCTP IPR policy provides for strengthening the situation and position of sub-Saharan African collaborators in its funded projects. This is pertinent in cases where EDCTP funded clinical trials are conducted in developing countries where intellectual property management capacity and practices either at individual, institutional or country level may not be well established. In view of this, EDCTP takes into account the point of view of the African Regional Intellectual Property Organization and the Bamako resolution on research for health.

In view of the situation described above, EDCTP sees a paramount need to properly protect, disseminate and realise a fair share of intellectual results by all stakeholders involved in its funded projects and ensure that maximum benefit is passed on to the public at an affordable price.



Definitions and Abbreviations

Access Rights	The right to get access to the generated results with the possibility to use these results
Background Intellectual Property	IPR relating to the subject matters of the project, which are held prior to the signing of the EDCTP grant agreement.
Foreground Intellectual Property	IPR generated in or arising out of the project, including data, know-how and information, independent of whether the project results are within or outside the project objectives.
ICH-GCP	The principles as laid down in the “ICH Topic E6, Guideline for Good Clinical Practice, step 5, Consolidated Guideline 1.5.96” (CPMP/ICH/135/95, status: September 1997, version July 2002).
IP(R)	The Intellectual Property (Rights) vested on the project results.
Participants	Any person or legal entity that is directly involved, in the broad sense, in an EDCTP funded project, either as Contractor, PC, Collaborator or research participant.
Project Coordinator (PC)	The main conductor of an EDCTP project – under the responsibility of the Project Contractor – and in particular responsible for the coordination of the project activities, the disbursement of EDCTP funds to the Collaborators in conformity with the budget (unless otherwise agreed with EDCTP), the spending of the EDCTP contribution and the (scientific/) technical and financial reporting, according to the provisions of the Grant Agreement.
(Project) Collaborators	The legal entities and individuals participating directly in an EDCTP funded project including the Contractor, according to the provisions of the Grant Agreement.
(Project) Contractor	The party/parties – normally the Project Coordinator and his/her employer – with whom the EDCTP enters into a Grant Agreement for a specific project, and including any subcontractors who are hired by the contractor or the PC to carry out specific parts of the grant.
Sponsor	Sponsor as defined in the applicable version of the ICH Guidelines for Good Clinical Practice
Subcontractors	All sub investigators of the research team of the Project supervised by the Project Coordinator and, if any, their employees (in case of institutions).



Policy Objectives

The main objective of EDCTP intellectual property rights policy (IPR Policy) is to promote the creation, proper ownership, access rights, dissemination, exploitation and fair allocation of the knowledge and other innovative outcomes from EDCTP funded projects. The main elements of these objectives are described in the section on policy statements below.

Policy Statements

A. Creation

1. The Collaborators are encouraged to create innovative results and to ensure the protection of these results adequately.
2. All costs related to IPR activities shall be regarded as eligible project costs for the entire duration of the project.

B. Ownership

Background IP

1. All background IP shall remain by the owner of such property.
2. Each Collaborator shall identify its background IP which may be relevant to the funded project including any legal restrictions which exist relating to its background IP.
3. Information on background IP relevant to the successful execution of an EDCTP funded project should be disclosed and made available for use within that project by Collaborators owning such property - via a confidentiality disclosure and (non-transferable) royalty-free licence agreement – to the other Collaborators and, where applicable and needed, to Subcontractors.
4. Each Collaborator shall remain free to license, assign or otherwise dispose its background IP provided that all rights and obligations stated in the EDCTP grant agreement are respected.
5. Before signing the Grant Agreement a Collaborator may identify specific elements of the background IP and provide a reasoned request to EDCTP that such elements should be wholly or partially excluded from the obligations referred to in this policy or in the Grant Agreement.

Foreground IP

6. In principle, the ownership of the foreground IP for EDCTP funded projects should not belong to individuals. The Contractor must guarantee that the Collaborators comply with this rule.
7. The Collaborators may agree to allocate the ownership of foreground IP among themselves as long as the Contractor can ensure the compliance with the provisions of the Grant Agreement on IPR (currently articles 5 and 6) and, where applicable other regulations.
8. In case of joint ownership, unless otherwise agreed, each joint owner shall have the right to use such jointly owned foreground IP.
9. The Contractor has to ensure that whoever becomes the first owner of the IP, this owner or any of its successors cannot transfer the IPR to a third party without approval of EDCTP and that the IPR can only be transferred if the owner shall pass on the IP together with all its restrictions on the Collaborators to the new (assigned) owner. Moreover, the Collaborators must be given at least sixty days notice in advance of the envisaged transfer and the name and address of the assignee.
10. The Contractor must guarantee that any owner of the IP shall exert diligent effort to ensure that the investigational product shall be accessible and affordable in developing countries, in particular sub-Saharan Africa.



C. Access Rights

1. EDCTP has a transferable, licence-free, nonexclusive, irrevocable access right to the patented results from all its funded projects to reach its mission and objectives. This right can be invoked in case the Contractor does not comply with its obligations concerning IPR as stated in the Grant Agreement.
2. All Collaborators in EDCTP-funded projects will be granted non-transferable, nonexclusive, royalty-free access rights to all foreground IP where such foreground IP is reasonably required to undertake any activity under the project. In case the owner of the foreground IP is prevented or restricted to effect this rule by commitments or obligations to third parties which existed before the date of signing the Grant Agreement, it is up to EDCTP to decide whether funding of the project is still worthwhile in view of these commitments/obligations.
3. Access rights must not jeopardise the protection of the project results.
4. If a Collaborator stops participating in a project, its obligation to grant access rights to the remaining Collaborators remains valid.
5. Collaborators shall not disclose or use any confidential information concerning the project except for the sole purpose of the project under the condition that no local, national or international standards are violated.

D. Dissemination

1. All data, know-how and results (on sufficiently detailed level, including, where needed, raw trial data as approved by the Sponsor and other results) from and EDCTP funded project must be widely disseminated to all Collaborators, other African researchers and institutions and the public at large (in a for the public suitable format), as soon as possible, however without jeopardising the protection of any patentable project results.
2. The Contractor must take care that all Collaborators will disseminate all relevant information they acquire related to the project through journals, lectures, or otherwise, provided that prior knowledge of the other Collaborators is ensured. The details of such prior knowledge shall be arranged in writing prior to the start of the project activities between the Collaborators.
3. EDCTP has the right to disseminate any data, know-how resulting from its funded projects via its website in case these results have not been disseminated within two years of their production by the Collaborators and/or the sponsor in absence of a good reason to do so, provided that EDCTP has given the Contractor at least 30 days written notice of its intention to do so.
4. The EDCTP capacity building policy aims to improve the capacity of African researchers to manage and own their data in order to appropriately inform policy and decision making.

E. Exploitation

1. The owner of the IP has the right to exploit all foreground intellectual rights as far as this right is not restricted by the obligations of the Contractor as laid down in the Grant Agreement.
2. All exploited results (products or services) must be made accessible and affordable, in developing countries, particularly in sub-Saharan Africa.



Useful Resources and links

1. African Regional Intellectual Property Organization: www.aripo.org
2. Bamako Resolution on Research for Health: www.wipo.org
3. European Commission:
 - a. [Management of intellectual property in publicly-funded research organisations: Towards European Guidelines](#)
 - b. [Commission Recommendation on the management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research organisations](#)
 - c. FP6 innovation guidelines: (ftp://ftp.cordis.lu/pub/fp6/docs/innovation_guidelines_fp6.pdf)
4. IPR Helpdesk: <http://www.ipr-helpdesk.org>
5. European Patent Office: <http://www.european-patent-office.org>)
6. European National Patent Offices (<http://www.european-patent-office.org/onlinelinks/a/aa>)
7. World Intellectual Property Organization (WIPO):
8. [Creating and Embedding an IPR Policy in an Educational or publicly funded research and development institution](#)
9. [Guidelines on Developing Intellectual Property Policy for Universities and R&D Organizations](#)
10. EDCTP resources: www.edctp.org