

## ***WIPO Re:Search***

***Sharing Innovation in the Fight Against Neglected Tropical Diseases***

## **Guiding Principles**

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# Guiding Principles

## Overview

*WIPO Re:Search* is a Consortium sponsored by the World Intellectual Property Organization (WIPO) in collaboration with BIO Ventures for Global Health (BVGH). The Consortium aims to accelerate the discovery and product development of medicines, vaccines, and diagnostics to create new solutions for people affected by neglected tropical diseases (NTDs<sup>1</sup>), malaria, and tuberculosis by making intellectual property and know-how available to the global health research community. These diseases affect more than one billion people across the globe.

The Consortium will comprise institutions from all relevant sectors, including public, private, academic, and civil society.

The Consortium is a voluntary endeavor open to all *bona fide* private and public entities, including intergovernmental institutions, that endorse these Guiding Principles for the purpose of developing new medicines, diagnostics or vaccines (hereinafter “Products”) in the field of NTDs.

The objective of the Consortium is to encourage and support research and development of Products for NTDs. In particular, *WIPO Re:Search* will benefit patients in the Least Developed Countries (LDCs as defined in Annex 1) by creating an open innovation platform through which public and private sector entities can share, for this purpose, Intellectual Property<sup>2</sup>. The Consortium has three major components:

1. A **Database**, hosted by WIPO, providing details of Intellectual Property available for licensing from a Provider (as defined below), as well as services and other technology or materials not necessarily protected by intellectual property rights which can be accessed by Users (as defined below).
2. A **Partnership Hub**, managed by a Partnership Hub Administrator, which shall be BVGH or any subsequent competent entity, in cooperation with WIPO, where Members (defined below) and other interested parties that support or are considering supporting these Guiding Principles can learn about the Consortium, available licensing and research collaboration opportunities, networking possibilities, and funding options.
3. A range of specific **Supporting Activities**, led by WIPO in cooperation with BVGH, to facilitate negotiation of licensing agreements and to address technical matters such as identifying research needs and opportunities, among others, with technical advice from the World Health Organization (WHO).

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<sup>1</sup> The term “NTD” herein means the NTDs listed in Annex 2 which include malaria and tuberculosis.

<sup>2</sup> The term “Intellectual Property” as used herein includes, patent and related registered rights, know-how, manufacturing processes, and regulatory data and the corresponding physical materials such as proprietary compounds and technologies.

WIPO's sponsorship of this Consortium supports WIPO's mandate from its Member States as expressed in the "Development Agenda"<sup>3</sup> recommendations. These aim to ensure, *inter alia*, that development considerations form an integral part of WIPO's work, specifically:

- facilitating access to knowledge and technology for developing countries including LDCs,
- promoting the transfer and dissemination of technology to the benefit of developing countries, including LDCs,
- encouraging Member States, especially developed countries, to urge their research and scientific institutions to enhance cooperation and exchange with research and development institutions in developing countries, especially LDCs, and
- cooperating with other intergovernmental organizations to provide developing countries, including LDCs, upon request, advice on how to gain access to and make use of intellectual property-related information on technology.

WHO draws its rationale for collaboration with WIPO and for providing technical advice on research needs and opportunities from elements of the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (GSPA-PHI), which is being implemented by WHO and its Member States in collaboration with other stakeholders, including WIPO. Moreover, a World Health Assembly Resolution<sup>4</sup> specifically requests WHO to implement the GSPA-PHI in collaboration with other IGOs, including WIPO. Specific provisions of the GSPA-PHI that are relevant to the objectives of the Consortium include:

- prioritizing research and development needs,
- promoting research and development,
- building and improving innovative capacity,
- improving transfer of technology, and
- improving delivery and access.

WHO is committed to provide technical advice on research needs and opportunities to WIPO as appropriate.

*WIPO Re:Search* is a cooperative, voluntary arrangement among groups and institutions collaborating towards a common set of principles and objectives but each acting on its own. No legal structure is hereby created.

### **Principles and Objectives**

The Members believe that public health challenges in developing countries are complex and require multiple approaches, and that:

- there are opportunities to use Intellectual Property innovatively and to encourage both public and private sector research and development of health solutions that are particularly needed by the world's poorest populations, and
- an open innovation framework for the sharing of Intellectual Property, and technology and research materials not protected by intellectual property rights, can facilitate such research and development into new Products for NTDs.

The primary objective of *WIPO Re:Search* is to catalyze new research and development for NTDs, with a particular focus on the needs of patients in LDCs, by making Intellectual Property available on concessionary terms to researchers everywhere. The commitment to sharing Intellectual Property, however, goes beyond research. Members also commit to the licensing of Intellectual Property contributed to the Consortium under the following terms, subject to individually negotiated licensing agreements:

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<sup>3</sup> WIPO, 2007. The 45 Adopted Recommendations under the WIPO Development Agenda. <http://www.wipo.int/ip-development/en/agenda/>

<sup>4</sup> WHA 61.21, May 24, 2008.

1. Providers agree to grant Users royalty-free licenses to this Intellectual Property for research and development, anywhere in the world, of products, technologies or services, for the sole purpose of addressing public health needs for any or all NTDs in LDCs.
2. Providers agree to grant Users royalty-free licenses to this Intellectual Property anywhere in the world to make or have made such products, technologies or services, and to import and export, for the sole purpose, to sell or have sold, these products in LDCs.
3. Users shall be allowed to retain ownership of and apply for registration of intellectual property rights generated as they deem fit, but shall be encouraged to license to third parties through *WIPO Re:Search* new intellectual property rights generated under an agreement made pursuant to membership in the Consortium under terms consistent with these Guiding Principles.
4. For the avoidance of doubt, Providers will not make any claims to rights in new intellectual property, materials or derivatives of materials generated by a User under a license agreement made pursuant to membership in this Consortium, but may require such User not to assert such new intellectual property rights against the Provider.
5. The provision of physical supplies of active pharmaceutical ingredients (API) is encouraged subject to resource availability, but such provision is not required.
6. In the event of the need for arbitration and/or dispute resolution, Users and Providers are encouraged, but not required, to use the services of WIPO's Arbitration and Mediation Center which shall develop mediation procedures specific to the needs of WIPO Re:Search.

For products resulting from licenses through the Consortium, all Providers of Intellectual Property agree to:

- Provide licenses for these products on a royalty-free basis for use and sale in all LDCs.
- Consider in good faith the issue of access to these products for all developing countries, including those which do not qualify as LDCs. This includes considering in good faith the granting of a license under any relevant Intellectual Property on a case-by-case basis, taking into account the economic development of the countries and the need to facilitate access to disadvantaged populations.

## Structure and Governance

Membership in the Consortium is open to those that agree in writing to these Guiding Principles. The Consortium shall comprise a Membership, a Secretariat, and a Governance Committee.

**Membership** shall include Providers, Users and Supporters, and each may define themselves as Members by indicating their commitment to these Guiding Principles via the relevant facility on the *WIPO Re:Search* website or in writing to the Secretariat (Global Challenges Division, WIPO, 34 chemin des Colombettes, 1211 Geneva 20, Switzerland; [re\\_search@wipo.int](mailto:re_search@wipo.int)) providing suitable personal or corporate identification and contact details. Specifically:

- “Providers” are Members that contribute Intellectual Property, materials or services to *WIPO Re:Search* for license or use. Certain further understandings in relation to Providers are set out in Annex 3.
- “Users” are Members that have entered into license agreements with Providers to use Intellectual Property and/or materials and/or services made available through *WIPO Re:Search* in accordance with, and in furtherance of, the Principles and Objectives.
- “Supporters” are Members that encourage the facilitation of research and development of Products for NTDs. Supporters may voluntarily offer to provide support, services or assistance of any kind to the Consortium or its members in order to facilitate achievement of the Principles and Objectives. WIPO and the Partnership Hub Administrator shall, if requested by a Supporter, consider publishing on the website of the Consortium details of the availability of such support, services and assistance.

Any Member may withdraw from the Consortium by giving notice via the relevant facility on the Consortium's website or in writing to the Secretariat. Any withdrawals shall not lead to the termination of licensing agreements executed as a result of participation in the Consortium unless so provided in such agreement.

**The Secretariat** will be financed and administered by WIPO and shall provide the following services, among others, in coordination with the Partnership Hub Administrator:

- Promote the sharing of information on available Intellectual Property, materials or services for licensing through the creation, development and operations of a database and website.
- Liaise with WHO, which provides technical advice to WIPO on NTD research challenges and opportunities.
- Organize an Annual or Biennial Meeting of Members.
- Develop, with Members and others, a range of specific supporting activities to facilitate licensing, including offering model licensing clauses, and support capacity building activities, in particular by building on and expanding WIPO's existing and numerous activities in these areas.
- Encourage policy dialogue among Members and other interested parties, with a particular focus on supporting the Partnership Hub.
- Facilitate the establishment of a Partnership Hub for the Consortium, administered by the Partnership Hub Administrator, to provide the following services, among others, as mutually agreed by those Providers participating in the Partnership Hub, in coordination with WIPO:
  - i. create opportunities for Members and other interested parties, such as potential Users, to learn about available licensing and research collaboration opportunities, networking possibilities, and funding options,
  - ii. recruit Users to the Consortium by identifying potential research and product development organizations and introducing them to the assets of WIPO Re:Search, and
  - iii. facilitate the discussions between Providers and potential licensees leading to research projects.

**The Governance Committee** is comprised of the Members. In addition to the Annual or Biennial Meeting, the Secretariat shall, as required organize meetings of the Governance Committee by teleconference. Over time, should a consensus of the Providers and Users deem it necessary, a Steering Committee may be established to ensure the efficient oversight of the Consortium's activities. WIPO, WHO and/or the Partnership Hub Administrator may participate as observers in the meetings of the Governance Committee and the Steering Committee and provide technical advice within their respective areas of expertise.

The principal duties and responsibilities of the Governance Committee shall include inputs on and guidance of the general activities and operations of WIPO Re:Search, including its effectiveness at realizing its stated aims.

The Governance Committee has no powers in regard to financing of WIPO Re:Search.

Changes to the Guiding Principles and Annexes 1, 2 and 3 shall only be possible by unanimous vote of those Members who cast a vote.

Where proposed changes to the Principles and Objectives significantly affect WIPO's or the Partnership Hub Administrator's interests, the respective Organization's approval will be required prior to their adoption.

All decisions on individual collaborative and supporting activities will be made solely by the parties involved in the transactional activity and any resulting agreements are the sole responsibility of the licensing partners. Any changes to the Consortium's Guiding Principles will not affect already executed licensing agreements unless so provided in such agreements.

**Financing Consortium Activities:** In addition to WIPO's financing of the Secretariat function as set out above, it is recognized that the activities of the Consortium may require direct disbursement of funds to support the Partnership Hub Administrator or for other matters.

[Annex 1 follows]

## ANNEX 1

**Least Developed Countries (LDCs)**

LDCs, as defined by the United Nations Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and the Small Island Developing States (UN-OHRLS), as of November 29, 2010:

**Africa (33)**

Angola	Madagascar
Benin	Malawi
Burkina Faso	Mali
Burundi	Mauritania
Central African Republic	Mozambique
Chad	Niger
Comoros	Rwanda
Democratic Republic of the Congo	São Tomé and Príncipe
Djibouti	Senegal
Equatorial Guinea	Sierra Leone
Eritrea	Somalia
Ethiopia	Sudan
Gambia	Togo
Guinea	Uganda
Guinea-Bissau	United Republic of Tanzania
Lesotho	Zambia
Liberia	

**Asia (15)**

Afghanistan	Nepal
Bangladesh	Samoa
Bhutan	Solomon Islands
Cambodia	Timor-Leste
Kiribati	Tuvalu
Lao People's Democratic Republic	Vanuatu
Maldives	Yemen
Myanmar	

**Latin America and the Caribbean (1)**

Haiti

[Annex 2 follows]

## ANNEX 2

The neglected tropical diseases and conditions covered by *WIPO Re:Search* are:

1. Buruli Ulcer
2. Chagas disease (American trypanosomiasis)
3. Cysticercosis,
4. Dengue/dengue hemorrhagic fever
5. Dracunculiasis (guinea-worm disease)
6. Echinococcosis,
7. Endemic treponematoses (Yaws)
8. Foodborne trematode infections
  - Clonorchiasis
  - Opisthorchiasis
  - Fascioliasis
  - Paragonimiasis
9. Human African trypanosomiasis
10. Leishmaniasis
11. Leprosy
12. Lymphatic filariasis
13. Onchocerciasis
14. Rabies
15. Schistosomiasis
16. Soil transmitted helminthiasis
17. Trachoma
18. Podoconiosis
19. Snakebite

As previously defined, the scope of the Consortium and the term NTD as used herein also includes the following:

20. Malaria
21. Tuberculosis

[Annex 3 follows]

## ANNEX 3

Providers of Intellectual Property or services agree to the following common understandings relating to their participation in WIPO Re:Search, whether in relation to research and development, manufacture and/or sale of products:

1. Providers' contributions to the Consortium are made entirely at their own discretion. Access by Users to Providers' contributions will occur under individually negotiated agreements, in accordance with the Consortium Principles and Objectives, and be consistent with any obligations any Provider may have under existing agreements, as well as international agreements related to trade, intellectual property, and proprietary regulatory data.
2. Providers will clearly identify a contact point for potential Users seeking information about the contributions to the Consortium made by the Provider and about such matters as terms of license to Intellectual Property, materials and/or services.
3. The following information regarding Intellectual Property may be made publicly available on the Consortium website/database:
  - (a) Patents and, published patent applications.
  - (b) Chemical structures.
  - (c) Additional information, if the provider chooses to make such information available, in the form of a plain language summary, of the compound's known characteristics/mode of action for which utility against one or more NTDs is suspected.
  - (d) Whether or not physical materials, regulatory data or know-how, including information relevant to manufacturing, is available for licensing. The provision of physical supplies of active pharmaceutical ingredient (API) or supplies is encouraged, subject to availability, but not required.
  - (e) Scientific or other literature relating to contributed Intellectual Property
  - (f) Any caveats or exclusions required by existing Provider's activities, obligations or licenses.
4. Subject to considerations of business confidentiality, Providers and Users agree to inform WIPO and BVGH of concluded agreements and to provide regular and simple reports of the progress of collaborations made pursuant to the licenses, and will consider making public disclosure of general aspects of any collaboration(s) for the purposes of tracking the use and impact of the Consortium.

[End of annexes and of document]