



Creating Partnerships under the Guiding Principles of WIPO Re:Search



WIPO | Re:Search

Sharing Innovation
In the Fight Against
Neglected Tropical Diseases

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This document is intended as an **optional** resource for WIPO Re:Search members in developing legal agreements in alignment with the WIPO Re:Search Guiding Principles. Members are not required to incorporate this guidance and language into their WIPO Re:Search legal agreements. The guidance and example contractual language provided herein capture the spirit of the Guiding Principles and the purpose of WIPO Re:Search. If you have any questions regarding the purpose or content of this document, please contact Charles.Randolph@wipo.int.

Introduction

WIPO Re:Search is a consortium created to advance early-stage scientific collaboration in support of the development of new medicines, diagnostics or vaccines for the treatment of neglected tropical diseases (NTDs), malaria, and tuberculosis. Membership is open to Providers and potential Users of relevant items, such as intellectual property, expert knowledge or physical materials, which may assist in achieving this purpose. The items shared with a User by a Provider are referred to as “assets”. All members of WIPO Re:Search have endorsed its Guiding Principles.

Although WIPO Re:Search is a voluntary consortium, the creation of partnerships between individual Providers and Users will normally involve the parties’ entering into a legal agreement to govern their relationship. The Guiding Principles set out in general terms the core obligations that will be included in any such agreement, such as the licensing of relevant intellectual property on a royalty-free basis for the use and sale of medicinal products in all Least Developed Countries (LDCs). The purpose of this document is to offer assistance to members in settling the detailed terms of any such legal agreement in accordance with the Guiding Principles.

Identifying the parties

It is important to be clear as to the parties who are undertaking responsibilities under the partnership. A Provider may be referred to in ordinary speech by reference to a corporate

brand, but for there to be an effective agreement, the contracting entity must be identified by its precise, formal name. In the case of a corporation, this will be the name registered at the companies' registry. Similar considerations apply to the User, which may need to contract through a University, via a research or development corporation ("X Enterprise Ltd") or as an unincorporated charity ("Mr. A.B and Ms. C.D., as trustees for the X. Medical Research Center").

The agreement should also identify the parties' addresses. This is of particular importance for the User, since the Provider may require the assets to be kept and used at a particular location; and at the end of the project, if the agreement does not provide for their destruction, unused tangible assets may need to be returned to the Provider at its premises.

Nature of the agreement

The key element of any partnership under WIPO Re:Search is the assets that are to be made available by the Provider to the User. The nature of the agreement will depend on the nature of the rights enjoyed by the Provider in the assets. The assets can be tangible or intangible in nature. Where the partnership consists merely of the sharing of expert advice, it may not be necessary to consider various issues mentioned below.

Type of Assets	Tangible or Intangible	Provider's Rights
Compounds	Tangible	Possessory/IP
Reagents	Tangible	Possessory/IP
Samples	Tangible	Possessory
Equipment	Tangible	Possessory/IP
Assays	Intangible	Possessory/IP
Datasets	Intangible	Possessory /IP
Expert knowhow	Intangible	IP/No IP
Patented technology	Intangible	IP

Where the partnership is concerned with physical material of some sort, the agreement has to provide for the transfer of possession of those materials to the User and the conditions that will apply to their use.

Where the Provider is enabling the User to make use of private information, this may be protected by the law as a trade secret or by the simple fact that the Provider controls access to the information – or both. In such case, the agreement will govern the method of disclosure of the information to the User and the User's obligations to protect the Provider's continuing interest in it.

Where the assets comprise a patented product or process, the essence of the agreement is a license of the patent to the User. Of course, tangible and intangible elements may both be involved, as, for example, where a Provider makes available to a User a patented compound or device. In such case, the agreement has to provide for both the transfer of possession of such compound/device and the license of the patent.

Identifying the asset

The agreement should identify the assets that are being provided to the User. This can conveniently be done by defining “the Assets” as the items specified in an annex to the agreement, in which they are fully described. Where the assets include patented technology, the patents in question should be identified by application/registration number.

It may be that the parties’ collaboration will entail the provision of advice and information over time. In such a case, the assets can be defined by reference to the persons who will be providing the advice or information and the subject matter of the advice or information.

Alternatively, the substance of the agreement may simply be the cooperation of two sets of researchers in the pursuit of a particular study. In such a case, where no assets other than the expertise of the parties is being made available, the agreement will not require much elaboration. Simply the objective, term, allocation of expenses and termination of the partnership will have to be provided for.

Grant of license

Under the Guiding Principles, Providers of IP agree to grant royalty-free licenses for use of the IP to produce products that will assist in the fight against NTDs, malaria and tuberculosis and for the use and sale of those products in all LDCs. Since more than one IP right may be implicated in a particular asset and the nature of the protection may differ from jurisdiction to jurisdiction, it may be desirable to adopt fairly broad language as to the scope of the license. It is unnecessary to determine with precision whether a particular asset, say a database, is protected by copyright, *sui generis* database right, the law of confidential information or some other form of protection or none. The objective is to enable the User to use the asset without infringing any applicable rights belonging to the Provider.

A contractual term to govern the grant of a license to use intangible assets could be as follows:

The Provider grants to the User a royalty-free license of any intellectual property rights in the Assets to which the Provider may be entitled under the conditions described below.

It will be noted that this wording offers no guarantee on the part of the Provider that it is in fact entitled to license the asset to the User. In a commercial license, it would be commonplace for the licensor to warrant that it owned the rights licensed. It is of course open to a User to request such a warranty or seek an indemnity in case there is any risk that the proposed project will infringe the rights of some third party.

Conditions of permissions/licenses

Providers share valuable assets with Users, and Users apply their expertise, skills and effort to those assets in order to create products to assist in the treatment of NTDs, malaria and tuberculosis in LDCs. Given the focused, humanitarian objective of the consortium, any permission to use IP or physical assets granted by a Provider may be limited to use directed to that specific purpose.

The Guiding Principles state that Providers also agree to “Consider in good faith the issue of access to these products for all developing countries including those which do not qualify as LDCs”. This commitment may result in the definition under the agreement of a wider field of permitted use of any IP-protected technology or material. Alternatively, the Provider may wait to see the progress of the partnership before deciding whether to extend the permitted supply of products to all developing countries (or all countries).

In addition, the Provider may require the project on the User’s side to be undertaken by specific individuals or in a specific location. If so, this should be reflected in the agreement.

An example of such provisions would be the following:

The User shall use the Assets solely with a view to the production of products to assist in the treatment or prevention of NTDs, malaria and tuberculosis and to the use and sale of such products in LDCs [or: all developing countries].

Where a specific researcher has been designated by the Provider, the User shall use the Assets only under the direction of that researcher or others working under that researcher’s direct supervision. Breach of this term shall be deemed to be a material breach for the purposes of this Agreement.

The User shall keep and use the Assets only at its address as indicated above [or a specified address or addresses].

Where the asset consists of confidential information, such as trade secrets, the Provider may wish to include a provision addressing the protection of the asset against unauthorized disclosure.

If it is clear that the Asset – say, a confidential dataset – requires protection from public disclosure, the parties can set out in the agreement the specific asset that requires that protection and specify the measures that must be taken to ensure the security of the asset from unintentional disclosure. Where confidentiality of the asset is not a major concern, a term such as the following might be included in the agreement:

The User will use the Assets in accordance with any reasonable directions as to the preservation of confidentiality communicated in writing by the Provider to the User.

Where the assets are principally physical items, such as devices, compounds, reagents or samples, different concerns may arise. For example, for reasons of safety or security, the asset may need to be stored in certain conditions. A Provider may want the User to agree to maintain the integrity of the assets in accordance with guidance provided by the Provider or certain public standards, such as those of the United States Occupational Safety and Health Administration. Further, the agreement may need to address the ownership of physical assets which turn out to be surplus to requirements or which remain in existence at the end of the project. A clause might be included along the following lines:

The User shall use, store and maintain the Assets in accordance with any reasonable directions as to safety and security communicated in writing by the Provider and on the termination of the Agreement, if so requested, shall return to the Provider to the extent possible any Assets in its possession or control. The Provider shall retain ownership in the Assets, unless inextricably incorporated in material not of its ownership.

Improvements

In any research based on existing IP, the question of the ownership of improvements is of great importance. A User may develop a new product based on the licensed IP that has commercial potential in all markets. The agreement should regulate the allocation of potential benefits in accordance with the spirit of the Guiding Principles.

The Guiding Principles provide as follows:

“Users shall be allowed to retain ownership of and apply for registration of intellectual property rights generated as they deem fit... 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.”

It is up to the parties to decide how to implement this commitment. Given the separate commitment referred to above on the part of Providers to consider the licensing of products for all developing countries, it is evident that the Guiding Principles envisage that the license granted to the User will be limited to use in or for LDCs. Where the User develops a valuable product which may be of value in countries other than LDCs, it will, in the absence of prior agreement to the contrary, have to negotiate the terms of broader license from the Provider in order to distribute the products in those countries or enter into licensing arrangements with third parties to that end.

As indicated above, the Guiding Principles envisage a balance between User and Provider, such that the User retains the benefit of its follow-on innovation, but will not assert its rights against the Provider. Given that the User’s royalty-free license is limited to use in LDCs, it would seem logical that the User’s obligation not to assert its rights against the Provider should be similarly limited. Where a new product can be exploited in developed markets, it may be thought to be a fair balance for the User to have to negotiate an extended license of the Provider’s technology, and the Provider to have to negotiate a license of the follow-on innovation. A term expressing this compromise might be the following:

The User shall be entitled to any improvement or new product or service developed by it using the Assets. Unless otherwise agreed, the User shall grant to the Provider a royalty-free license in any IP right attaching to such improvement, product or service for activities of the Provider directed to the production of products to assist in the treatment or prevention of NTDs, malaria and tuberculosis and to the use and sale of such products in LDCs.

As mentioned in the Guiding Principles, Users are entitled to seek IP protection for their innovations and are encouraged to use WIPO Re:Search to license their IP to the wider community.

Duration and termination

The agreement will normally provide for its duration and the events that might result in its premature termination. In the context of WIPO Re:Search, the anticipated duration of the research project will typically determine the period during which the parties will actively cooperate. Where the assets are physical pieces of equipment or samples, which will need at the end of the project to be returned to the Provider for re-use, it may be useful to specify that the User's access to the assets will terminate on a certain date unless otherwise agreed. In many cases, however, it may not be necessary to specify a fixed date at which the agreement will terminate. More probably, the parties will agree upon a procedure for bringing the cooperation to a close by the giving of a period of notice. The period of notice will be based on an estimate of the time required for the winding up of the project and the return or disposal of any remaining assets.

Commonly a cooperation agreement of any sort will specify events in which one party or the other can bring it to an immediate end. Given the voluntary and cooperative nature of WIPO Re:Search, such circumstances are unlikely to arise, but it may be prudent to provide for them in case the unlikely does happen.

Typical conditions justifying summary termination are:

- a material (i.e., significant) breach of one of the terms of the agreement;
- insolvency;
- a change of ownership or control.

Given that the Provider may be entrusting commercially valuable assets to the User, it has an interest in ensuring that they are looked after properly (for example, that confidentiality is preserved or that volatile compounds are properly conserved) or that the particular individuals remain in charge of the project. Thus, a failure to store the assets in a particular location or under certain conditions or the removal of a particular person from management of the project could amount to such material breach. On the other hand, a delay in the delivery of a report would typically be a minor breach that would not justify the immediate termination of the agreement. Contractual language for these purposes might be as follows:

Subject to clauses [a and b], the Provider shall make the Assets available to the User for a period of [n months] from the date of this Agreement. At the end of that period or on the termination of the Agreement, the User will make such part of the Assets as have not been consumed available for collection by the Provider from the address indicated as its address in this Agreement.

a. Either party may give [3] months' written notice to the other to terminate this Agreement.

b. Either party may give written notice to the other to terminate this Agreement with immediate effect in any of the following circumstances:

- the other party commits a material breach of the Agreement;

- the other party applies for the administration of its affairs in insolvency or is adjudged insolvent.

If, as suggested above, the agreement includes a specific obligation relating to the leadership of the project on behalf of the User, it will be unnecessary to provide separately for termination of the agreement on a change of control. Such a change would be a "material breach" within draft clause b.

Resolving disputes

A common characteristic of partnerships in WIPO Re:Search is their international nature. Where disputes have to be adjudicated across borders, legal complications can arise. Even if it is highly unlikely that partners will have recourse to formal dispute resolution procedures, it would be good practice to seek to reduce any uncertainties as to the proper course for any party seeking a remedy.

The two principal questions that need to be considered are, first, which tribunal should decide the dispute; and, second, which law should the tribunal apply.

The choice of tribunals lies between the courts in any specific country and private adjudication through arbitration. The WIPO Arbitration and Mediation Center offers independent services in relation to arbitration that may be of assistance to parties. Providers may, however, require the reassurance that, if they wish, the dispute can be settled in the courts of their own country. The parties will have to consider their own preferences, as there

are many possible variations of a dispute resolution clause. One possible approach would be the following:

In the event of any dispute relating to the cooperation of the Provider and the User through WIPO Re:Search, the courts of the state in which the Provider is principally established shall have non-exclusive jurisdiction. The law of that state shall apply in any proceedings arising from such a dispute, wherever initiated.

In case of such a dispute, the parties will seek to agree to refer the same to arbitration or mediation in accordance with the rules of the WIPO Arbitration and Mediation Center.

Such an agreement does not constitute a binding arbitration agreement. It is hoped, however, that in the unlikely event of a dispute, the parties would rely on WIPO's good offices to resolve it.

A skeleton for the drafting of a partnership agreement is set out in the Annex to this document.

[Annex follows]

Annex

Agreement Skeleton

Parties	This Agreement is made on the [date] Between A Limited, of [address] (the Provider) And B.C.D., of [address] (the User)
1. Definitions	“Assets” shall mean [patent CH400800/the Provider’s Bioactive Compound Library Catalog No. B1234].
2. Grant of license	The Provider grants to the User a royalty-free license of any intellectual property rights in the Assets to which the Provider may be entitled under the conditions described below.
3. Conditions of the permission/license	<p>The User shall use the Assets solely with a view to the production of products to assist in the treatment or prevention of NTDs, malaria and tuberculosis and to the use and sale of such products in LDCs [or: all developing countries].</p> <p>The User will use the Assets in accordance with any reasonable directions as to the preservation of confidentiality communicated in writing by the Provider to the User.</p> <p>Where a specific researcher has been designated by the Provider, the User shall use the Assets only under the direction of that researcher or others working under that researcher’s direct supervision. Breach of this term shall be deemed to be a material breach for the purposes of this Agreement.</p> <p>The User shall keep and use the Assets only at [its address as indicated above or a specified address or addresses].</p> <p>The User shall use, store and maintain the Assets in accordance with any reasonable directions as to safety and security communicated in writing by the</p>

	<p>Provider and on the termination of the Agreement, if so requested, shall return to the Provider to the extent possible any Assets in its possession or control. The Provider shall retain ownership in the Assets, unless inextricably incorporated in material not of its ownership.</p>
4. Improvements	<p>The User shall be entitled to any improvement or new product or service developed by it using the Assets. Unless otherwise agreed, the User shall grant to the Provider a royalty-free license in any IP right attaching to such improvement, product or service for activities of the Provider directed to the production of products to assist in the treatment or prevention of NTDs, malaria and tuberculosis and to the use and sale of such products in LDCs.</p>
5. Duration and termination	<p>Subject to clauses [a and b], the Provider shall make the Assets available to the User for a period of [n months] from the date of this Agreement. At the end of that period or on the termination of the Agreement, the User will make such part of the Assets as have not been consumed available for collection by the Provider from the address indicated as its address in this Agreement.</p> <p>a. Either party may give [3] months' written notice to the other to terminate this Agreement.</p> <p>b. Either party may give written notice to the other to terminate this Agreement with immediate effect in any of the following circumstances:</p> <ul style="list-style-type: none"> - the other party commits a material breach of the Agreement; - the other party applies for the administration of its affairs in insolvency or is adjudged insolvent.
6. Dispute resolution	<p>In the event of any dispute relating to the cooperation of the Provider and the User through WIPO Re:Search, the courts of the state in which the Provider is principally established shall have non-exclusive jurisdiction. The law of that</p>

	<p>state shall apply in any proceedings arising from such a dispute, wherever initiated.</p> <p>In case of such a dispute, the parties will seek to agree to refer the same to arbitration or mediation in accordance with the rules of the WIPO Arbitration and Mediation Center.</p>
Signatures and dates of execution	

[End of annex and document]

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