Agreements: A Review of Essential Tools of IP Management

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ABSTRACT

Public-sector research institutions can use a variety of agreements to protect and manage intellectual property. These agreements are powerful tools to foster competition in the private sector and reduce prices for consumers in developing countries. This chapter provides an overview of the following types of major agreements—confidentiality, material transfer, development (in which the licensee is responsible for further development), co-development (in which two parties collaborate on continued development), and distribution—explains the functions of those agreements, and suggests strategies for their effective use. The chapter also discusses the meaning and usefulness of the standard elements and formulas found in such agreements. It explains the meaning and significance of the terms and language used and discusses such key issues as product liability, fees and royalties, and arbitration. The chapter emphasizes the importance of establishing and maintaining trust when negotiating and implementing agreements.

1. INTRODUCTION

One important goal of public sector licensing should be to promote competition between private companies. Monopolies and high prices are not caused by patents themselves but by how patents are managed, so the goals of the public sector can be served by using licensing strategies that foster competition and reduce prices.

Many kinds of agreements are used to protect and manage intellectual property (IP). These include agreements for confidentiality, material transfer, development (in which the licensee is responsible for further development), co-development (in which two parties collaborate on continued development), and distribution.

Most agreements are between two parties, but some may involve three or more parties. The public sector agency or the negotiating party may provide the first draft of an agreement for negotiation. Whoever writes the first draft often has the advantage, so public sector agencies should, whenever possible, take the initiative to prepare the agreement. Regardless of who provides the first draft, the proposal should adhere to the principle of good negotiations: offer an agreement that you would be willing to sign, if you were the other party. A good agreement benefits both parties. For an agreement to work, the two parties must trust each other and maintain this trust throughout the implementation of the agreement. With a high level of trust, moreover, a request to renegotiate by either party may be better received should circumstances change. Finally, since enforcing international agreements through legal remedies may be difficult, such agreements should be considered solemn commitments that must be observed.

2. THE USE AND LIMITATIONS OF TEMPLATE AGREEMENTS

The chapter provides a number of template or sample agreements for each major type of contact.

Mahoney RT and A Krattiger. Agreements: A Review of Essential Tools of IP Management. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

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The online version of this *Handbook* also provides many agreements from different institutions from countries around the world. Each of these agreements can be downloaded in Microsoft Word or Adobe PDF formats.

Evidently, no template agreement can be nor should be considered as the "correct" or "best" agreement. Any agreement must embody, specifically, the deal that has been struck between the parties, and a good deal for all parties will depend on the purpose of the deal and the context in which the deal takes place. The template agreements are merely intended as illustrations and possibly become a starting point for discussions and negotiations. In the discussion of the agreements in the Section 3, special reference is made to humanitarian-use clauses where appropriate and relevant.

It should be noted that template agreements are useful when used judiciously and as a starting point in the total process that ends in a final agreement between or among the parties. A template agreement may be more or less complete, but clauses will always have to be changed, deleted, or added. It is useful, however, for any organization to develop its own template agreements that include the major elements that are regularly used. The final draft agreement should be reviewed by the institution's counsel before signature (and in some cases even before sending it to the other party for review).

The online version of this *Handbook*[1] will include a section with several hundred actual downloadable agreements from many different institutions.

3. MAJOR TYPES OF AGREEMENTS

Two parties establishing a long-term working relationship could sign a series of agreements, or they could sign one or two agreements that combine several agreements within them. The following list appears roughly in the order that agreements would be signed when two parties are engaged in the development and distribution of a new or improved product.

3.1 *Confidentiality agreements*

Confidential information will probably be part of discussions to establish business relationships involving proprietary health products. Such confidential information could concern laboratory data and other research data, sources of materials, methods of production, the nature of licensing agreements, detailed design of specialized equipment, staff-training requirements, countries in which the developer would like to sell the product, and so on. It is wise to conclude a confidentiality agreement before entering into serious discussions about a relationship with another party. Aside from the obvious aim of protecting confidential information, such an agreement ensures that both parties are treating the discussions seriously. An agreement to convey and protect confidential information is a measure of the willingness of both parties to proceed. This is especially important for the party receiving confidential information. They should be able to ask any reasonable question and expect a fairly detailed response. Without a confidentiality agreement, the other party can refuse to provide information that they consider sensitive. It is more difficult to negotiate a confidentiality agreement after negotiations have begun, especially if trust has been damaged.[2]

3.2 *Materials transfer agreement*

Before agreeing to sign a license for further product development, a potential licensee may wish to evaluate the new material(s) or products to see if it works well in his or her hands. Although licensors should be willing to provide samples, they have an interest in assuring that the prospective licensee does not misuse the samples. Misuse might involve passing on a portion of the sample to a third party or using the sample to generate additional material for future use without concluding a license. It is generally recommended that public-sector research organizations use either a Simple Letter Agreement[3] or the Uniform Biological Materials Transfer Agreement and the Implementing Letter format developed by the National Institutes of Health.[4] In cases where large numbers of materials need to be transferred on a regular basis, such as by plant breeders, a simple material transfer agreement, such as that developed by with the International Network for Genetic Evaluation of Rice (INGER),[5] various national agricultural research and extension

systems in Asia and the International Rice Research Institute (IRRI) might be most appropriate (Box 1: see also Appendix of this *Handbook* at the end of Volume 2, page 1853).

3.3 *Invitations to collaborate*

To achieve its product-development goals, a research institute will often need to collaborate with another organization. This need may arise at any point, from laboratory studies through licensure and distribution. For example, when a public-sector research program requires prototype products for clinical trials, it will probably need to find a partner because most public-sector research centers lack high-quality production facilities. Likewise, for many neglected diseases in developing countries, highly specific, highly sensitive, affordable diagnostics are unavailable, and so collaboration might be needed when diagnostics are required for surveillance or clinical trials. Collaborators are such an important part of successful development that public-sector research institutions should have a thorough process for identifying them. Collaborators may be sought through Invitations to Collaboration, which should be widely distributed in international journals or other media, including the Internet and an organization's Internet home page. Summaries of the goals of the collaboration might also be included in the invitation. Responses to an invitation should be reviewed according to well-defined criteria, and all applicants should receive a report on the outcome of the process. An open and transparent process (with appropriate protection of confidential information) will establish a reputation for fairness. Sometimes, sole sourcing for one of the collaborating entities may be appropriate because of the undisputed capability of one organization to undertake the work rapidly, effectively, and inexpensively. Cases of sole sourcing, however, should be clearly documented, and management should be able to explain clearly why the sole-source route was chosen (see Box 2). Once a collaborator has been identified, it will be timely to negotiate a co-development agreement.[6]

3.4 *Co-development agreements*

If research and development have reached a stage at which further extending the work requires additional capabilities that a public-sector research institution either lacks or does not wish to allocate, then the institution will want to enter into a co-development agreement with a partner identified through the Invitation to Collaboration process.

Co-development agreements vary widely with regard to the extent to which the original owner or product developer retains control over the product. A lone inventor with no development capability may have very little control over what happens to the product once a co-developer is brought into the picture. On the other hand, a large firm that has completed virtually all of a product's development, and only needs, for example, to clinically test the product at a new dosage, may retain almost complete control (in such cases, the firm may simply execute a subcontract with the clinical-testing organization). A co-development agreement will define the nature of the final product or other output sought, the role of each party in the development process, the resources (financial, personnel, and institutional) each party will invest, the process by which the project will be managed, the interim goals (milestones) and timetable, and provisions for sharing in the success or failure of the effort. Of particular importance is the project-management system. It is common to establish a project-management committee comprising staff from each party. The number of members from each party, the authority of the committee, the frequency of meetings, and the requirements for written reports will be specified in the agreement (see the Appendix of this *Handbook* for a sample co-development agreement).[7]

3.5 *Technology licensing agreement*

These are the most common types of agreements negotiated by universities. It allows one party to use, make, or sell products involving the intellectual property of the other party. The agreement has terms defining the length of time the license is valid; the markets (territory) in which the licensee can make, use, or sell the product; whether or not sublicenses are permitted; the nature and amount of up-front fees and royalties; and whether or not the licensor has rights to any improvements developed by the licensee. Many other terms can appear in a licensing agreement. See Appendix for a

sample technology-license agreement, and Sections 11 and 12 in this Handbook contain many chapters dealing with specific elements of licenses.

3.6 *Distributorship agreement*

Distributorship agreements permit the licensee to receive a product from a licensor or to purchase a product from a third party for distribution in a defined market under a number of conditions involving price, quantities, quality, labeling, royalties, and so on. The agreement often allows the distributor to arrange for clinical trials, submit required documentation to the national licensing authority, and prepare and carry-out product promotion. A public-sector research institute, for example, may arrange for a diagnostic to be manufactured by a commercial company that may not be interested in marketing the diagnostic in any or all territories.

Because they place a valued product in the hands of a second party, distributorship agreements are treated very carefully, especially the negotiation and implementation phases of such agreements. In cases of drugs, vaccines, and diagnostics, a license grants the licensee the right to obtain a regulatory permit to sell the product in a given market. If the license should be terminated because the licensee does not perform or loses interest in the product, the licensor and a new licensee may find it difficult to get a new permit from the regulatory authority. They may have to repeat many expensive activities with the attendant delays. One way to address this potential problem, if local law permits, is to require the regulatory license to be transferable to a third party selected by the licensor. A distributorship agreement can also be the first step in building a long-term relationship that can lead to technology-licensing agreements and additional co-development agreements. The Appendix of this *Handbook* contains a sample distributorship agreement.

4. STANDARD ELEMENTS OF AGREEMENTS

4.1 *Recitals, preamble, and whereas clauses*

Laying out the broad motivations and goals of the parties, this opening section is important, particularly in agreements between public and private sector agencies. It documents that the parties believe their motivations and goals are complementary, and because the objective of an agreement is to have a win-win outcome, this section should set the right tone and clearly state the parties' reasons for entering into the agreement. If a dispute ever arises between the parties, the information in this introductory section could be invaluable should the dispute end up in arbitration or litigation.

4.2 *The parties*

The parties are those persons, companies, or institutions that willingly enter into an agreement. Most often, there are two parties, but the number may be more than two. The agreement may be between two institutions or two individuals, or an institution and an individual. It is important to note that if one of the parties is an institution, then the entire institution is bound by the agreement.

Note that the incorporated names of the institutions involved, as well as their headquarters, are included in the parties' names and addresses list. Some organizations have regional offices or subsidiaries with authority to enter into agreements. The addresses here may be different from the addresses to which notifications or data must be sent.

4.3 *Definitions*

Any agreement is built around the meaning of the written words. Many words or phrases are legal "terms of art" that do not require definitions if the usage is standard within the corresponding field. Including a definition section enables a lawyer, in drawing up an agreement, to use the language of the agreement precisely, clearly, and consistently without deviation in either the forms of terms or their meanings. For example, as a legal term of art, the term *infant* refers to any child up to the age of adulthood—not just a baby—and a "foreign corporation" is one incorporated in any jurisdiction, not necessarily another country. If there is any doubt whether a term will be understood, it is advisable to define it, in order to avoid any confusion later.

4.4 *Confidentiality*

Confidential information disclosed in tangible form is managed very carefully. The information is placed in a secure, locked filing cabinet or in a password-protected computer and marked "CONFIDENTIAL." Only those staff covered by the confidentiality agreement have access to the material. Either they should complete a check-out form when they remove the material, or, with digital materials, a record should be made of the materials being accessed. Orally transmitted information should be put in writing soon after it is provided and the written form checked in and out as appropriate. Scientists commonly discuss research findings freely and seek to publish them early. However, if the generation of intellectual property is an important goal, scientists will have to consider how they can disseminate their findings while helping to produce the intellectual property. One way to overcome this difficulty is for IP management offices to swiftly evaluate whether to patent a new discovery. Some technology transfer offices can complete such an assessment in 30 days, which does not unreasonably delay the presentation or publication of the work. It should always be remembered that confidential information has commercial value and its improper release can cause substantial damage. The original owner of the confidential information could seek financial damages for the unauthorized release of confidential information. Divulging confidential information might also be grounds for terminating the agreement.

4.5 *Territory and exclusivity*

In a licensing agreement, the territory is the geographic region in which the licensee is permitted to make, use, or sell the product. Applying mainly to distribution agreements, a territory can be a part of a country, a whole country, several countries, or the whole world. Exclusivity determines whether the licensee will have to share the territory with one or more other licensees of the same products. Licensors grant nonexclusive licenses to stimulate competition among licensees and to provide alternate distributors in case one licensee fails. For health products, a licensor rarely grants anything but an exclusive license when the license is for the limited territory of a single country. One reason for this is the cost and time required to obtain the approval of the national licensing authority. Few licensees would be willing to take on this burden if others could freely take advantage of their costs for obtaining regulatory approval.

In general, licensees want the most territory and the highest level of exclusivity. This gives them the greatest opportunity to exploit markets, seek profits, and keep competitors away. Moreover, it generally lowers the licensee's risk. With an unproven licensee, it is prudent to limit both territory and exclusivity to the minimum necessary for the project to succeed (at least initially). It is a licensor's nightmare to spend several years working with a licensee only to have that licensee fail to develop the product's market. A compromise middle ground is for the licensor to grant increasing levels of territory and exclusivity as the licensee achieves various performance milestones. For example, the licensee could receive a license to a new territory after successfully completing a marketing plan for that territory and investing some base levels of funds to implement the plan. Or a licensee could be required to pay a separate license fee for each additional territory granted. The amount should be large enough to ensure that the licensee will want to protect the amount paid by actually developing the market in the new territory. A good rule of thumb is that a license should be granted only when it is probable that the licensee will be able to develop that market. A key consideration for the licensor is to calculate the minimum market size necessary to reach its financial goals with the product. One issue with exclusive licenses is that they de facto form monopolies, which can make it difficult for the public sector to obtain the product at an affordable price.

4.6 *Product liability*

Product liability is increasingly important. Once an issue primarily of concern in the United States, product liability is becoming a problem in Europe as well as the rest of the world. It affects many aspects of the health product business, from the conduct of clinical trials to product

prices, which are increased to cover the cost of liability self-insurance.

All health-product manufacturers and distributors should be concerned about the safety of their products. There is a chance that a product will harm an individual. Preventive products (for example, vaccines) are the cause of greater concern than therapeutics, since the former are given to healthy individuals. When a health product harms an individual, it is reasonable for that person to be compensated for the injury. The form of compensation, however, will vary depending on the country. Unfortunately, in developed countries, "product liability" has, to some extent, become a kind of lottery: individuals seek huge awards based more on the ability of the company to pay than on the actual losses. Sometimes the awards are so large that the very survival of the company is threatened. This situation has made companies quite defensive regarding liability, affecting their willingness to enter new markets and to develop new health products.

When negotiating a license, the key question with respect to liability is: who should accept product liability and for what? For some matters the answer is clear. A manufacturer, for example, should be responsible for adhering to good manufacturing practices and should be responsible for any injury caused by errors in the production process. A public sector licensor will usually expect the licensee to assume most of the liability because the licensee sells the product. A licensor may, as a condition for granting the license, make acceptance of liability by the potential licensee, which places a special burden on the licensee to assess carefully the product's potential liability implications. It is extremely rare for a licensor to be brought into a liability suit. If accused, it is even rarer for a licensor to be found liable.

Even if a licensee holds the licensor harmless, doing so would not prevent the licensor from being named in a suit. The costs of defending a suit, especially in the United States and Europe, can be very large—sometimes almost as damaging as a liability judgment itself. The licensor should therefore request, and have this specified in the agreement, that the licensee meet all costs incurred, within reasonable limits, by the licensor in defending a liability case. Insurance is available to cover just the legal costs of defense. The licensor should ask for proof that the licensee has obtained liability insurance and that the insurance is kept in force. Liability is an extraordinarily important issue, and public sector research groups are well advised to obtain high-quality professional advice.

4.7 *Up-front fees and royalties*

A license transfers value. The up-front fees and royalties, therefore, are the agreed price representing that value. Since licenses are not traded in open markets, where the price can be set through supply and demand, each negotiation is unique and reflects the evaluations of each party. A licensor will have several considerations. First, the licensor will want, at a minimum, to recover the expense, or some reasonable portion of the costs, already invested in the product. Second, the licensor will want to generate a steady flow of income.

Up-front fees have to balance two issues. First, they should be high enough, if possible, to meet the licensor's need for short-term income and to assure that the licensee is seriously seeking to develop the product. Second, they should not be so high that they limit the ability of the licensee to invest in the product and make it a success. Other factors to consider are the expected life of the product and the lifetime of the IP rights being granted. The shorter the life of a product (because other, better products are expected to emerge quickly), the less the licensor can ask for up-front fees and, to a lesser extent, royalties. If the license is based on a patent, at the end of the patent's life the level of royalties may decrease or the license may even expire. The term of the license is more complicated when the license is for know-how. A reasonable but complicated approach for such licenses is to have the royalty diminish with time and eventually reach zero when both parties agree that the know-how is no longer valuable. Such an event might occur when the licensor stops using the know-how. But if the know-how is essential for successfully manufacturing and selling the product throughout its lifetime, there is no reason for the royalty

to change. Also, a licensor may make continual changes in the know-how and pass those on to the licensee. In this situation, royalties may be collected for a very long time.[8]

Having said all this, it is important to remember that the goal of the licensing strategies discussed here is to maximize benefits for the public sector. Possible up-front fees and royalties should be seen simply as two ways to extract value for the public sector—and perhaps not the most desirable ways.

4.8 *Arbitration*

Successful agreements are based on trusting relationships, and both parties in an agreement should work to maintain trust in implementing the agreement. Some agreements, usually those negotiated between two parties in the same country, can allow for disputes to be settled in court. The more common practice, however, is to use arbitration. The issues for consideration here are the number of arbitrators, how they are chosen, their operating rules, the location where the arbitration shall take place, which party shall bear the costs of the arbitration process (or what share each party will bear), and whether the arbitration should or should not be administered by an arbitration institution.

In one formulation, three arbitrators are used. Each party chooses one, and the two arbitrators, so chosen, choose the third. The third arbitrator serves as the chairperson of the panel. The arbitrators may operate according to various rules. An international set of rules is a common reference, and many arbitration institutions have their own arbitration rules. In addition, most countries have laws that govern arbitral proceedings conducted within their territory. These laws should be carefully considered when choosing the arbitral locale. Location is also important because of costs. If arbitration occurs at the offices of one party, the other party will have to incur costs to be present for the proceedings. Cost allocation can be specified in the agreement, or the arbitrators can allocate the costs. Arbitration can be very costly, which further emphasizes the need to ensure that the initial negotiations are as thorough and specific as possible.[9]

4.9 *Term and termination*

Term and termination clauses specify the term over which an agreement is to last. The beginning date can be either a specified calendar date or, more usually, the date on which the last signature is applied. A specified date might apply when certain calendar-specific tax matters are important or when it is essential to ensure that one party does not delay initiation of the agreement.

Termination is a much more complex issue. A standard termination provision should include cases in which one party breaches a part of the agreement. The party that feels there has been a breach by the other party will be required to send a notice of breach. Usually, a period of time is provided during which the supposedly breaching party can correct the breach or prove that a breach has not occurred. Also, since circumstances can change, it may be desirable to allow one or both parties to terminate the agreement following the expiration of a defined notice period (for example, 60 days). It may be desirable to define the circumstances under which such termination is allowed.

4.10 *Jurisdiction, warranties, notices*

The agreement will specify that, in the case of a dispute, laws will apply in a particular country, state, or province. The jurisdiction will usually be that of the licensor, although there may be reasons to have a neutral third location.

Each party to the agreement should warrant that it has the authority to do what is contained in the agreement. For example, if the agreement is a patent license, the licensor will warrant that it owns the patent and that it is not aware of any infringement of the patent. Conversely, this warrant may include that the licensee cannot hold the licensor liable for any unknowing infringement that may be discovered. Warrants are often symmetrical (that is, each party warrants the same things).

An agreement will specify the name, address, and other contact information of the individuals or positions within each party to which official communications should be directed. The notice clause may also specify whether fax and electronic documents are acceptable.

4.11 *Other potentially important clauses*

In certain types of agreements or jurisdictions, the following clauses may be of particular importance:

4.11.1 *Illegal/unenforceable provisions*

In some jurisdictions, it might be advisable to include certain limitations:

Should any court of competent jurisdiction later consider any provisions of this Agreement to be invalid, illegal, or unenforceable, such provisions shall be considered severed from this Agreement. All other provisions, rights, and obligations shall continue without regard to the severed provision, provided that the remaining provisions of this Agreement are in accordance with the intentions of the Parties.

4.11.2 *Statement of completeness*

Many organizations have more than one agreement with a specific third party in place. If that is the case, then the formerly existing agreements should be cited whenever possible and reviewed for consistency with any new agreement. Alternatively, the agreement may be limited to the purpose that has previously been defined. Typical language could read:

The above constitutes the full and complete Agreement on this Purpose by and between the Parties.

4.11.3 *Subject law*

In the subject-law section, the Parties clarify where they wish to have an agreement interpreted and adjudicated. Such a determination is not always necessary but can make future interpretation less difficult, particularly if the Parties are located in different countries. Typical language is:

This Agreement shall be interpreted, construed and adjudicated under the laws of _____ province [or state, canton, etc.] _____ within the nation of _____.

4.12 *Signatories*

Representatives with authority to bind their respective institutions are the persons who should sign agreements. It is advisable to include the person's title to make clear that the person is representing the Party and not signing the agreement as an independent entity.

In some cases, more than one representative from each party should sign an agreement. For example, when materials are transferred to a laboratory of a specific scientist, it is important to ensure that the scientist is fully aware of the obligations so the scientist may be included as a signatory.

Further, in a university setting, different departments or even legal entities may have certain responsibilities over in-licensing and out-licensing. For example, an office of sponsored programs may be responsible for incoming materials, whereas a foundation that commercializes university inventions may also have a stake in the agreement. In such cases, there may be signatories representing at least three entities, one of which may include the chief scientist.

5. CONCLUSIONS

No agreement will ever be perfect. Evidently, there are good and not-so-good agreements (and even poorly written ones or highly ineffectual agreements). The better ones may take longer to negotiate, but the good news is that each time an agreement has been successfully developed by two parties, the process gets easier. Taking time to think through and discuss the terms of an agreement helps foster communication between the partners. Such an activity, especially if carried out early on, sets the project on a path for success. In any case, the critical aspect of any agreement is what the parties do after the agreement has been signed; an agreement should always be seen as just the beginning of a long and mutually beneficial relationship. ■

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1 www.ipHandbook.org. Included there are many actual agreements including confidentiality, material transfer (for germplasm, biological resources, materials for testing, research tools, and experimental animals), IP licenses for copyright, software, trademarks, trade secrets, and various forms of exclusive, coexclusive and nonexclusive licenses, as well as the Model Provisions for an Equitable Access and Neglected Disease License developed by the working group, based at Yale University, convened by Universities Allied for Essential Medicines. Other chapters in this *Handbook* also contain sample agreements including nonasserts, invention disclosure, licensing checklist, and more. Please refer to the index for a list of agreements.

2 See, also in this *Handbook*, chapter 7.2 by SP Kowalski and A Krattiger.

3 See, also in this *Handbook*, Box 3 in chapter 5.7 by AB Bennett.

4 See http://ott.od.nih.gov/policy/rt_guide_final.html and http://ott.od.nih.gov/NewPages/UBMTA.pdf.

5 The swift program at Cornell University and IRRI collaborated at the time for the INGER Training-Workshop on IPR, 17-18 July, 2001, Maruay Garden Hotel, Bangkok, Thailand.

6 See, also in this *Handbook*, chapter 17.10 by KR Schubert.

7 Ibid. and chapter 7.4 by MB Steinbock.

8 See, also in this *Handbook*, chapter 5.4 by BJ Weidemier.

9 See also, in this *Handbook*, chapter 15.3 by E-J Min.

10 Mahoney RT (ed.). 2004. Handbook of Best Practices for Management of Intellectual Property in Health Research and Development. MIHR: Oxford, U.K.

Box 1: Material Transfer Agreement for the Genetic Evaluation of Rice to and from INGER Collaborators

The International Rice Research Institute, MCPO Box 3127, Makati City 1271, Philippines ("IRRI"), provides the "Material" _____

_____

under the following terms and conditions:

1. The Material provided is not intended for the exclusive use of any single organization.
2. IRRI requires written notification if the recipient distributes the Material to a third party.
3. Recipients may not seek any form of intellectual property rights protection on the Material without prior written consultation with IRRI. IRRI reserves the right to refuse to grant such permission.
4. Use of the Material will be publicly recognized when and where appropriate, and recipient will provide IRRI with reports on its use of the Material on a reasonably frequent basis.
5. IRRI does not warrant or guarantee the title, quality or correctness of the Material being supplied and will not be held liable for the Material or its use.
6. IRRI provides the Material on acceptance of the terms and conditions of this MTA. Recipient's retention of the Material shall be deemed to constitute acceptance.

Name of Recipient _____

Title _____

Institution _____

Address _____

E-mail _____

Date _____

Box 2: Invitation to Collaboration

Development of a Health Product A

Objective
The Public Sector Research Centre (PSRC) is seeking collaborative relationships with one or more organizations capable of completing the following tasks for prototype health products: industrial development, manufacturing, clinical testing, and licensure by national regulatory authorities.

Health Product A can be produced in a number of different ways. The PSRC believes that one or more of these production methods could be viable for commercial scale-up.

The Public Sector Research Centre
[insert a description of the PSRC including governance, funding, research programs, goals, history, capabilities, etc.]

_____

_____

_____

Participating Scientists
The following scientists have played a leading role in the development of methods for synthesizing Health Product A as described in the attached documents. [attach copies of relevant publications]

_____

_____

_____

and their collaborators.

Mode of Operation
The PSRC has the ability to mobilize assistance for the health-product development process by a variety of means including financial, technical, and in-kind support.

Companies should contact the PSRC to initiate an agreement on a development project.

The following issues are open for discussion with respect to a collaboration agreement:

- Product development including consultation on details of manufacture, adjuvanting, packaging, heat stability, etc.
- Cost sharing of the manufacture of sufficient health product for Phase I through Phase III trials.
- Assessment and planning for the introduction of the health product into private-sector markets.
- Assessment and planning for the introduction of the health product into public-sector markets.

(Continued on Next Page)

Box 2 (continued)

- Development of regulatory standards through interactions with national regulatory authorities and the World Health Organization.
- Conduct of Phase I through Phase III trials in developed and developing countries in a variety of populations.
- Obtaining regulatory approval in developed and developing countries.

Intellectual Property Rights
Details on patent applications will be discussed with interested parties following execution of a suitable confidentiality agreement. The PSRC possesses extensive know-how, which will be essential for the cost-effective implementation of a health-product development program.

Desired Product
The envisaged health product is expected to consist of _____. Further information on specific methods for health product manufacture is provided in the attached documents.

In the developing world, the principal use of the product is expected to be _____ _____. In the developed world, the health product may find use in _____. See the following dossier for further discussion of potential market.

Submission of Expression of Interest
At this time, a letter containing the following information is requested:
- the nature of your interest in this project
- if you wish, a summary of the capabilities and experience of the organization
- names of other collaborators or partners
- an indication of the types of assistance/collaboration desired from the Institute

Interested parties are requested to write to the PSRC _____ _____. Submissions are requested prior to _____.

For further information, contact either [name 1] _____or [name 2] _____ _____ of the PSRC at telephone _____ or fax _____ _____ or write to them at [e-mail address] _____or the above address.

Review and Contracting Procedure
Interested parties will be contacted to arrange for meetings and development of collaborative agreements.

Background on Health Product A and Collaborating Scientists
Health Product A is involved in acute, chronic, and _____. Health Product A is widespread in both developing and developed countries and infects _____. Infection persists throughout life. Health Product A transmission is primarily by _____ _____.

(Continued on Next Page)

Box 2 (continued)

Health-Product-A–associated diseases are significant causes of morbidity and mortality.
For example, in developing countries _____.
In developed countries, it leads to significant morbidity_____.

Short biographies of collaborating scientists [include as an attachment]

Market Potential for Health Product A

Scientific and other References

Source: Mahoney[10]