How to Draft a Collaborative Research Agreement

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ABSTRACT

A collaborative research agreement has five major parts: (1) statement of objectives, (2) statement of work, (3) general provisions, (4) budget, and (5) list of materials. This chapter provides a step-by-step discussion of the issues that need to be addressed in each part of the agreement, emphasizing the importance of crafting an agreement that is mutually beneficial and, above all, clearly written. Whereas all parts of any agreement are important, for collaborative research agreements, extra care should be taken in describing the objectives and work of the collaboration, the research plan, and the mechanisms for agreeing on changes in the research plan. Partnerships grow and change; this invariably leads to the need for amendments. Arguably, many of the best collaborative research agreements need numerous amendments in order to reflect the evolving needs of the parties involved.

1. INTRODUCTION

The objective of writing a collaborative research agreement is to clarify for both parties what they are trying to accomplish together and to clearly set forth the rules that will govern the collaborative effort. A good partnership must be mutually beneficial, and an effective collaborative research agreement will help both parties understand and accept mutual benefit as a goal. Of course, simply writing that an agreement is mutually beneficial does not make it so. An effective agreement must be based on an actual win-win relationship, one that is truly mutually beneficial. So to start with, the concept of the collaborative research project must involve a research project through which both parties benefit from the work that will be done.

A poorly written agreement can tear apart an otherwise harmonious relationship. On the other hand, a well-written agreement, in which all parties understand their responsibilities, will build and strengthen a productive scientific relationship. An effective agreement will be clear both to the researchers doing the research work and to the managers of both parties. And a well-written collaborative research agreement can lay the groundwork for moving the results of research toward commercialization.

For the sake of simplicity and to facilitate discussion of the issues involved, the chapter focuses on one scenario: developing a research agreement between a National Agricultural Research System (NARS) government laboratory and a private company. Many of the points made are equally valid for collaborative research agreements between other types of entities.

2. PARTS OF AN AGREEMENT

Most collaborative research agreements have five general parts. The agreements can be somewhat flexible in the terminology they use. The names

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assigned to the subparts are not terribly important. What is important is that the agreement covers each the following points:

1. statement of objectives
2. statement of work
3. general provisions
4. budget
5. list of materials

The first part of the collaborative research agreement is commonly called the statement of objectives. This explains the overall setting of the agreement. It describes what the parties want to accomplish together and why the collaboration is important.

The second part of a well-drafted collaborative research agreement is called the statement of work. This may sometimes be called the research plan. It describes the research that the parties propose to conduct and includes which approaches will be undertaken and which methodologies will be used. Most importantly, this part of the agreement specifies who is responsible for what and specifies the due dates for completing each part of the research project.

The third part of an effectively written collaborative research agreement is called the general provisions. These are sometimes known as the legal provisions. They cover a series of important details, the mechanisms of collaboration, and the rules by which the collaboration will be conducted.

The fourth part of a agreement is the budget. This part sets forth the resources that each party needs and contributes to the collaborative research project.

For collaborative research agreements in which biological or other materials (germplasm, plant parts, biotech components, and so forth) are passed from one party to the other for use in the project, the agreement typically includes an additional section called the list of materials. This section is often attached as an appendix to the agreement. In some cases there may be more than one appendix, since the materials being used and transferred may change over the course of the project.

In its simplest form, the list of materials should provide a unique name for each item that is sent to the project, as well as the quantity of each item and the dates those materials were transferred from one party to the other. By updating the list of materials each time new materials are sent from one of the collaborating researchers to the other, all parties are assured of having a current and complete list.

2.1 *Statement of objectives*

The statement of objectives should be concise and clear. Use terms that nonscientists will readily understand and avoid the excessive use of scientific jargon. The statement of objectives should explain the real-world issues that the collaborative research agreement will address. It should articulate both the what and the why of the collaboration. When someone outside of the science community reads the agreement, they should be able to tell why the parties believe it is important to undertake the collaboration. In addition, the statement of objectives should clearly specify the scientific goals of the collaboration. Care should be taken to differentiate long-term goals, which may happen years after the agreement is completed, and short-term goals, which will be accomplished by the end of the agreement.

Consider the following examples from two statements of objectives from actual agreements:

- *Good:* to develop, test, and evaluate transgenic tomatoes expressing the "N" gene, which encodes for resistance to tobacco mosaic virus.
- *Not as good:* to determine basic breeding biology, including ploidy levels of a resistance biotype of *Lolium*.

The first one is quite well written. It clearly and specifically explains the objective. From this clear statement, most readers will get a feel for what the agreement hopes to accomplish.

The less well-written statement vaguely states the goal. Phrases like *basic breeding biology* do not really mean much unless they are further defined, and terms like *ploidy level* may not be well understood by the nonscientific community. Remember, the goal of the statement of objectives is to set the stage for the agreement by clearly stating what the parties hope to accomplish.

2.2 *Statement of work*

The next part of a well-written collaborative research agreement is what is often referred to as the statement of work. This is by far the most important part of the agreement. Sometimes, the statement of work is attached to the agreement as an appendix. This is not to diminish its importance in any way. It is merely a convenience to have this research plan slightly separated from the general body of the agreement. The advantage of having it self-contained is that it will be easier for the scientists to relate to it, and in the event of modifications to the work plan, it can be more easily amended.

The statement of work contains the scientific objectives, methodologies, and approaches. It should be broken down into subsections, with each section explaining what "partner A" will do and what "partner B" will do, with the time frames and benchmarks specifically laid out.

In drafting this section of a collaborative research agreement, the parties must work together closely. The other parts of a collaborative research agreement can be initially drafted by a technology transfer officer and/or intellectual property management officer and then can be exchanged between the partners for review, comment, and negotiation. But the collaborating researchers themselves should prepare a first draft of the statement of work, which can then be edited by the technology transfer officer. This is because the collaborating scientists are the ones who really understand the complexity of what is to be undertaken, and it is the scientists who must fully embrace the plan that is developed.

Within the statement of work, there should be a section stating the project's scientific objectives. With complicated or longer projects, there may be many objectives and subobjectives. In such cases, the use of a numbering or outlining system makes the objectives clear and readable.

Each objective in the statement of work should be followed by a description of the methodologies and approaches to be used to address the scientific questions involved. Further, each objective must include very clearly what each partner (the institute scientists and the company scientists) will be doing, separately and collaboratively. This statement of responsibilities is perhaps the most critical element of a research agreement because without a clear understanding of responsibilities, the partners may have unrealistic expectations and become frustrated. If it is unclear who will be doing each piece of experimentation, both parties may be sitting back, waiting in vain for the other to produce something. *It cannot be stressed enough that it is very important to break down each of the scientific objectives of the statement of work into tasks and clearly state who is responsible for each.*

Another point to consider is to quantify the work that is to be done. It may not be necessary to use exact numbers (for example, the types and replications of an experiment or the number of test tubes you will be using), but do insert general guidance about the size and scope of the collaborative research. For example, if you are going to do a feeding study and will be using 30 mice per replication, state that in the agreement. That way both parties will be clear as to the order of magnitude of the data types that are to be generated and the level of resources needed for their part of the work. Researchers often believe they understand what the other has in mind, but without written descriptions, such assumptions often lead to misunderstandings. For example, if an institute researcher says he or she will "field test" a new variety, he or she may have in mind a half-hectare plot necessary to generate enough plants for a publication, while the company scientist has in mind 100 hectares. So, be as clear as you can about the sizes or numbers of replications and other quantifiable aspects in the statement of work.

Another aspect that is very important is to build-in time frames and benchmarks. Generally, you want to have built into the statement of work at least an indication of when each party should have completed their responsibilities under each objective or subobjective. Often researchers will object that time-frame specifics make them feel pressured, but such a plan will help the collaborating scientists make progress in an orderly fashion. It also helps prevent one party from having to wait for the other and causing lost time. Time frames are important to make the experimentation run

smoothly and they help the partners garner the resources that will be needed to move the project along.

Benchmarks are important to help measure work progress. They specify that at a certain point both parties expect certain pieces of data to have been generated, certain parts of the experiments to have been completed, or certain questions to have been answered. You will want to write these goals as benchmarks. In a larger agreement, with multiple objectives and multiple people involved, sometimes there may be activities that will flow sequentially (one has to be completed before another can begin). Other research may be occurring simultaneously in parallel experiments. In these complicated situations, project-management software can be helpful when preparing the statement of work.

A collaborative research agreement can grow to be a lengthy document. However, you should not think that it is like a grant application that can be 20, 30, 40 or more pages. A collaborative research agreement is not designed to convince an outside party that the work is worthwhile, nor does it aim to show that either of the collaborating scientists are high-quality researchers. Rather, it should clearly spell out the respective research that the partners will be doing. So, a statement of work should only be as long as it needs to be to ensure that both parties know what is expected of them. A typical agreement will be 10–15 pages, and the statement of work is often no more than two or three pages.

3. GENERAL PROVISIONS

The next part of a collaborative research agreement is the general provisions. This is the body of the agreement that covers the how of working together and provides mechanistic guidance to the scientists at the institute and at the company, as well as to managers. Normally, an institute or an entity has a standardized set of general provisions that has been reviewed by their legal counsel and that can serve as a starting point for negotiating agreements. Each person studying this chapter should consider developing such template agreements. In the process of such development of template agreements, a person can often begin to fully understand which points are negotiable and which legal provisions are required by organization policy or law. At the same time, collaborative research agreements should be as user-friendly as possible and avoid unnecessary stipulations.

There are a wide range of typical general provisions. These include a public disclosure/publication policy, which addresses how the parties will communicate with each other and the outside world; reports; confidentiality issues; the important issues of intellectual property management and technology transfer from the institute to the company; regulatory approvals; indemnity and liability statements; dispute resolution plans; and provisions for termination. This part of the agreement should also spell out an amendment procedure and name the persons responsible for the agreement, both managerially and scientifically, at the institute and the company.

3.1 *Publications*

Public disclosure is a crucial part of any research agreement. Science is driven by the need to publish, and scientific careers depend on such publications. Public disclosure, including publication in patent literature, keeps innovation going. The phrase *public disclosure* is a broad term that includes many types of disclosure of research results. Public disclosure can include any form of public dissemination of research results: articles, abstracts, poster sessions, both informal and formal seminars, talks, information posted on the Internet, and grant applications. Most organizations that enter into collaborative research agreements will want to put some limitations on the right to public disclosure. Such a delay in public disclosure may be necessary to ensure that patent applications can be filed for discoveries made under the agreement.

A publication clause should protect the interests of both parties. Generally, there is a statement that both parties reserve a right to review and comment on all public disclosure by the other party. Typically, a specific time frame (usually 60 or 90 days) is set up for such a review. Often there is also a provision written into the collaborative research agreement stating that one party requires

the other party to delay public disclosure of project-derived information for a specific length of time to allow for patent preparation or exclusive use by the other party. The bottom line is that a well-written agreement should clearly state all such limitations of public disclosures.

3.2 *Confidentiality*

Another aspect of the general provisions involves confidential information, sometimes called confidential business information, or CBI. It is important for the collaborative research agreement to differentiate between two types: (1) confidential information that a party brings into the project and that predates the agreement, and (2) confidential information that is generated under the agreement and that the parties generated while working together and conducting project experiments. A collaborative research agreement should specify how both types of information are to be handled by the parties.

For information that is created by one of the parties prior to or outside the scope of the agreement, you may find it helpful to use the terms commonly found in a confidentiality or nondisclosure agreement. Like any confidentiality agreement, these clauses should specify a time limit during which the information is to be kept confidential. Typically, such time limits are between two and five years after the end of the collaboration or from the point the information is generated. If the parties have an earlier signed nondisclosure or confidentiality agreement, that document may simply be referenced in the collaborative research agreement or the collaborative research agreement can state that it replaces the confidentiality agreement.

The confidential treatment of information generated under the project will be closely tied to the treatment of intellectual property (IP) and tangible property.

3.3 *Intellectual property*

Perhaps the most important section of the general provisions deals with the intellectual property and tangible property (TP) provisions. This section is important because what motivates most collaborative research is the potential for gaining access to such IP/TP as may be created under the collaborative research agreement. For an institute, working with a company is an effective way to transfer technology. Many believe that it is the most effective and efficient way for research results to move from the laboratory, through a development process by the company partner, and finally into the marketplace. Without such provisions, the benefits of collaboration may be lost.

The first step in drafting this section is to clearly define IP and TP rights.

IP rights are rights under various types of statutory protection. These IP rights include the intangible property rights obtained from:

- issued patents and patent applications
- plant variety protection (or a breeder's rights) applications and granted certificates
- copyrights (including software)
- trade secrets
- trademarks and service marks

TP rights are the second broad class of property rights. These include ownership rights in various classes of biological materials, germplasm, databases, business plans, research plans and protocols, laboratory notebooks, and the like. They involve the ownership of things that one can touch, see, taste, smell, and hear.

The second step in dealing with IP/TP issues is to establish who owns what. The collaborative research agreement should clearly state that all IP/TP contributed to the collaborative research, but predating the project, should be owned by the party who contributed its use to the project. This is why there should be a clear inventory of all IP/TP that either party contributes to the project.

For example, if the company has a genetic construct or a genomics database that the collaborators will use, then whether or not these contributions are covered by a filed or issued patent or some other sort of statutory protection, these contributions need to be clearly identified in the agreement. Similarly, if the institute brings germplasm lines, a site-specific promoter, or a transformation vector into the project, these too should be identified and documented in the agreement.

In this way, collaboration can be promoted because each party recognizes and acknowledges the other party's ownership of the contributed materials.

After establishing an inventory (in the list of materials) of the IP/TP that is brought into the project, the next step is to clearly establish how the ownership of new property discovered under the project (new IP/TP) will be determined. In a typical collaborative research project there is the potential for three classes of new IP/TP:

1. New IP/TP that is solely discovered by the institute researcher
2. New IP/TP that is solely discovered by the company researcher
3. New IP/TP that is jointly discovered by the institute researcher and the company researcher

In collaborative research, many of the discoveries fall into class three. A well-written collaborative research agreement will address how and by whom the ownership determinations are to be made in cases in which the IP/TP is discovered by one party or the other.

Globally, patent laws differ. Under the patent laws of nearly all countries outside the United States, inventorship is determined by whomever files the patent first (and has been involved in the discovery process). In the United States, inventorship is determined by first-to-invent and ownership follows inventorship, that is, ownership goes to whoever files first. This is the so-called first-to-file approach. It is therefore necessary for a collaborative research agreement to address the matter of ownership determination, or refer to the national laws of the partners.

Normally, inventorship is determined when the patent attorney talks with the researchers. If a patent is being sought in the United States, great care must be taken to include on the patent application only the actual inventors (those researchers who make the creative, intellectual contributions to the discovery). If someone who is not an inventor is named as an inventor on the patent application, this will prevent the issuing of a legitimate U.S. patent.

In a first-to-file country, the rules for the determination of actual inventorship are different. As in a first-to-invent country, ownership follows inventorship. So, whoever files first will be listed as the inventor and as the owner. Clearly, it is important to understand the rules of the country in which the patent filing is taking place. Yet it must be remembered that if the new IP/TP is to be protected in the United States (and other first-to-invent countries), regardless of where the research takes place, the rules of first-to-invent apply to all patent filings.

In general, if only employees of the institute are listed as inventors, then the institute owns the invention. If only employees of the company are listed as inventors, then the company owns the invention. However, if at least one employee of the institute and one employee of the company are listed as inventors, then the invention is jointly owned by both the institute and the company. Regardless of whether the patent filing is in a first-to-invent country or a first-to-file country, it is important to address the matter of patent ownership in a well-written collaborative research agreement. However, equally important than patent ownership are the rights that are granted under the patent.

A key part of the IP provision is what the agreement is actually promising in terms of the granting of licensing rights, or the "grant." Normally, the parties enter into a collaborative research agreement in order to obtain access to the discoveries that flow from the collaborative project.

The scope of the grant must be considered very carefully. For example, if the scientists are conducting mer research and are seeking a technology for disease resistance, it is possible that the technology may apply to other plants as well. Thus, the collaborative research agreement should be clear that the grant is for a license for mer only (or for some other agreed-upon subset of plants). This will be a key point in the negotiation of the agreement. Normally, one party will want a very broad grant of rights and the other party will keep trying to narrow the grant.

The next thing to consider is whether the grants will be for *an option* to a license or an *actual*

license. There are pros and cons to both approaches. Granting an option, with a preset fee structure, is sometimes all that will be requested, because such an option allows both parties adequate time to thoroughly evaluate the invention before signing an actual license. On the other hand, one party may strongly prefer a direct grant of a license, with the business licensing terms clearly spelled out, because this reduces the amount of uncertainty.

Granting an option normally makes a great deal of sense because it is very difficult to predict what IP/TP will be generated. Further, it is difficult to predict the value of such new IP/TP. Therefore, agreements that give a direct grant of a license and fully spell out the license terms can lead to a gross miscalculation of the new IP/TPs worth, either undervaluing it or overvaluing it. If the IP/TP is overvalued, this would likely act as a disincentive for future development of such IP/TP. If the new IP/TP is significantly undervalued, this may act as a block on the future relationship of the parties because one party has been treated unfairly.

With either approach, the collaborative research agreement should include time frames during which the party who receives the option to a license must decide whether it wishes to execute its option and take a license. The option grant should not be open ended. This will allow another licensee to be sought if the collaborating party does not wish to develop and market the new IP/TP.

Likewise, it is important to specify the license grant's level of exclusivity. Is the license (or the option to a license) for an exclusive license or a nonexclusive license? Is the license exclusive by country or region? Is the license limited by crop? By product? By time? Or, is the license more general? Most companies (and many other collaborators as well) will want some sort of exclusivity in their license (or option to a license). It may be adequate for such a collaborating partner to have an exclusive right for some specified time period, or for a certain well-defined field of use, or for a certain licensed territory, or for a combination of these. Most organizations are reluctant to put their resources into an agreement if the organization is not assured of an exclusive license because their competitors may also seek a license.

The negotiation of the grant of intellectual property is a key part of the collaborative research agreement. Take time to think it through clearly and come up with a solution that meets the needs of both parties.

3.4 *Amendments*

The last part of the general provision section is the amendment process. Strong partnerships grow and change; therefore, agreements need to be amended. In fact, many of the best collaborative research agreements need constant amendments. It is not unusual for a collaborative research agreement to be amended as often as every six months or every year. This is because the researchers often identify dynamic, new opportunities that the partners want to explore together. Thus, a well-written agreement can be amended so that the statement of objectives, the statement of work, and the budget reflect the new needs.

All amendments should in writing and signed by the proper authorities as an appendix to the agreement. Guard against informal amendments that may sneak in as the project gains momentum and the researchers become excited. If they are not written down, such amendments can lead to disputes and litigation. So make it clear to everyone that all significant changes in the research must be written and appended to the agreement.

3.5 *Termination*

All agreements should have a specific date upon which the cooporation ends. Termination clauses may be added that stipulate when and under what conditions each party may elect to terminate the agreement before the end date. The end date may be extended through the amendment process, if both parties agree. This is common in successful collaborations.

4. BUDGET

The fourth section of a well-written collaborative research agreement is the budget. There is a tendency to view this as the most important section because it documents the funding that the parties

contribute. This, however, is an improper emphasis. While it is true that public sector agricultural research is grossly underfunded, and therefore funds obtained from collaborating partners have an extremely important place in the overall research budget, collaborative research should never be viewed principally as a way to raise revenues. Collaboration is much more than that. Concentrating only on research funding overlooks both the use of the agreement as a means of technology transfer and as a way to build an intellectual synergism that can result when researchers collaborate.

Developing the budget must begin with a clear statement of work. This will help determine for the collaborators the amount and the timing of the resources required for the collaborative project. This is the starting point. There must be enough funding to undertake the project without detracting from other projects that are already underway.

Staff time should be considered, as well as tangible resources (such as space and equipment that will be required to support the project). For example, if one partner will need to recruit graduate students, technicians, or other personnel, then salary and benefit costs for the new staff must be included. Also, do not overlook in-kind contributions that a collaborating partner may be able to provide. A company, for example, may have very specialized equipment, expertise, formulation technology, or access to facilities that would be extremely costly for an institute to procure on its own. The value of such in-kind contributions should be noted in the budget.

The budget for a collaborative research agreement should be absolutely clear *as a research budget* and be totally separate from any sort of licensing revenue that might be projected. The budget should also specify when the payments will be made and clearly indicate when the contributed in-kind resources will be provided.

5. LIST OF MATERIALS

The final section of a collaborative research agreement is the list of materials. As with the budget, this section provides a clear listing of the TP that each party provides to the project. This is critical because all such materials were developed outside of the project and are owned by one partner or the other. They are *not* new TP that will be divided according to the granting clauses. Rather, materials that are included in the list of materials are fully owned by one of the collaborators. Sometimes items listed in the list of materials have IP rights associated with them; sometimes they do not.

In truly collaborative research, the list of materials may have to be amended on a regular basis. This will require the agreement to be amended easily (as noted above). A well-written collaborative research agreement, the list of materials will dynamically respond to the emerging needs of the researchers.

6. CONCLUSION

Collaborative research agreements can be extremely beneficial to both partners. No single entity ever has adequate money, resources, and intellectual capacity to do all the research it might want to do. Forming partnerships can be an effective and economical way of accessing resources. Collaborative research agreements, moreover, are often the first step in establishing longer-term partnerships. They can be effective technology transfer tools, as well. The benefits are much more than monetary. Taking the time to think through and discuss the terms of the collaborative research agreement helps foster communication between partners and sets the project on a path for success. Indeed, good partnerships spur creativity and help innovation to serve the public welfare.

Lastly, it should be said that writing and negotiating a collaborative research agreement might seem like a very difficult process. In fact, a first attempt to write such an agreement usually is difficult. The good news is that each time one does it, the process gets easier. ■

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