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# INTRODUCTION

Increasingly, institutions and individuals are thinking about research in a global context. Looking beyond traditional borders and boundaries – transcending disciplines, methodologies, approaches, partners, and sponsors – can open up worlds of opportunity to advance knowledge and transform understanding.

Successfully navigating research administration in a global context means refining your attention to and appreciation for diversities in language, culture, customs, and practices. Often in global partnerships, research administrators and participating faculty must overcome challenges in communication based in cultural, political and practical differences of how to conduct and manage research projects. These challenges can be complicated by unknown regulations and differing practices of sponsors. Furthermore, challenges may increase when collaborating across large geographical distance. While the modern era has resulted in greater international connectivity through multi-media platforms, physical distances can still present issues when performing/managing such cross-national projects. It is important to begin any project with a solid foundation, before partners are selected or funding is obtained, with a clear plan to address mid-project management stages and the more complex regulatory compliance requirements that the project may face. In addition to the financial management requirements discussed, there is a brief discussion of some of the other major regulatory and other considerations for international research projects, that often triggers ethical standards of research, international conventions to which the U.S. is a signatory, U.S. federal laws and regulations and funding agency policies, as well foreign country regulations and policies.

In the end, the purpose of this publication is to present an overview of common issues that arise in global research administration and provide suggestions and resources to senior leadership, research administrators, and faculty at U.S. institutions that support such activity; focusing on pre-award matters such as pre-planning and partnership feasibility, proposal development, and negotiation, as well as post-award issues around award management, regulatory requirements and compliance risks. Put another way, the immediate goal of this publication is to help readers avoid the unfortunate and, often costly, effects of mismanagement, with the loftier intent to continue to erode barriers to the potential positive global impact of such collaborative projects.

## Glossary and Terminology

As many research administrators are already keenly aware, the landscape of sponsored projects management is comprised of a nuanced and specialized vocabulary. Terms like “collaborator,” “sponsor” or “cost sharing” all have unique definitions in that landscape. And, similar to other industries, it is important to ensure that these terms are used consistently when used in an international setting. In order to ensure clarity, this publication shall use the following key terms throughout:

- **Sponsors.** Entities (governmental, non-profit or for-profit) that fund research and other projects typically in the form of grants and contracts. Sponsors can also be called grant-makers, funders or – in the case of gift funding – donors. Sponsors set the terms of the award, through funding calls (or announcements) and through the terms of the award. Dealing with various sponsors requires administrators to learn that particular funder’s terms and conditions, typical organizational structure and compliance requirements.
- **Partners.** Organizations that perform research and other activities often funded by sponsors via grants and contracts jointly with other partners. Partners are often also called collaborators.
- **Partnerships.** Coordination of one or more partners, often through a contractual framework, in order to accomplish the goals and deliverables of a single project. Partners can also be referred to as collaborators or subcontractors, depending on how they are funded and how they interact. Each partner typically has their own group of faculty and researchers who perform the partner’s portion of the project, as well as its own administrative infrastructure to manage the compliance and cost requirements.

## Why Collaborate Globally?

Motivation to initiate and participate in global research endeavors can stem from internal and external sources. Global collaborations provide pathways to maximize institutional strengths by, for example, diversifying the workforce, increasing access to specialized equipment, and opening doors to serve underrepresented target populations. Externally, new opportunities may allow your institution to establish itself in emerging markets, fill a void in a valuable arena left by the sudden departure of an organization, or minimize threats posed by strategic alliances being formed in an already crowded marketplace. And in some instances, the motivation for global engagement may come directly from sponsors themselves: international collaboration may be required as an eligibility criterion for a grant program.

Global partnerships can generate bigger ideas that produce greater responses to scientific challenges. They can lead to a more strategic sharing of human, physical, and financial resources, often ultimately expediting the application research results and lowering distribution costs. There can be, however, a downside to such international collaboration. Poorly matched partners, for example, may suffer from insufficient levels of commitment, unnecessary territorialism, and competing administrative structures that effectively limit research productivity and results. Global collaborations experience added challenges in achieving such successful levels of efficiency and partnership because of factors, such as limited opportunities for face-to-face communications, sensitivities to time differences, valuation of relationships, and contextual understandings. As in any collaboration – domestic or international – it takes time to establish a solid foundation of trust, working rhythm and reliability.

## How to find the Right Partner and Funding Opportunity?

Some institutions and individuals may be actively seeking new global partnerships and funding, while others are interested in global funding opportunities but do not know where to begin identifying global partners. Typical ways to get started with global initiatives include identifying a funding opportunity and then seeking out partners; identifying partners and then seeking a funding opportunity; approaching and attempting to join an established partnership (funded or unfunded); or, waiting until a partnership extends an invitation to join.

Since finding global partners is an integral component to many of these entry methods, it is important to discuss how global partners can be found. Potential international collaborators can be identified in the following common ways:

- Examine lists of known, prior collaborators with whom collaborative work has successfully occurred in the past;
- Examine lists of known, prior competitors who have independently carried out comparable work in the past;
- Talk with potential sponsors - government officials, corporate funders, individual entrepreneurs – who have interest in supporting international endeavors;
- Network through professional associations, learned societies, and groups of like-minded individuals;
- Utilize online resources and social networking sites, particularly exploring alumni connections; and
- Engage community resources such as libraries, nonprofit centers, and chambers of commerce to leverage their existing relationships.

Institutions and individual researchers can enter the global collaboration stage by identifying funding opportunities. Beyond leveraging the more familiar ways to locate such funding opportunities with global components – i.e., using funding databases, online search tools, and professional knowledge and networks to identify sources of extramural support for global partnerships – it is essential to closely review the specific text of the funding opportunity descriptions (commonly called “Requests for Proposals,”<sup>1</sup> or “RFPs”) to determine the degree of collaboration sponsors expect in funded programs. Some RFPs provide linguistic clues as to minimum performance expectations. For instance, an RFP that requires only a “letter of support” might be satisfied with minimal levels of collaboration. A RFP, by contrast, that requests details regarding leadership and communication plans may be seeking significant interactions among collaborators. A RFP that requires cost sharing from each partner could be seeking assurance that collaborators are truly committed to a common cause to such a degree that those partners allocate institutional or additional resources to its success that will not be borne by the grant itself. A RFP that is prescriptive about the types of individuals and organizations that must be included in a partnership may be seeking the formation of a coalition that can sustain programmatic change larger than a pair of collaborators could achieve by themselves. All of these examples help to demonstrate that understanding the sponsor’s expectations can help frame what level of engagement by the global partners is truly being sought.



<sup>1</sup> Some other common names for funding opportunity descriptions are as follows: “calls,” “funding opportunity announcements” (FOAs), and “broad agency announcements” (BAAs).

## How to Communicate Effectively with Partners?

Communicating effectively with global partners often requires additional sensitivities to culture and context, which can affect how communication is both delivered and understood. Objective and subjective cultural elements, such as political and economic systems as well as behavioral norms and social roles, can influence how messages are interpreted. For instance, a conversation about protecting intellectual property may have a different intention in the U.S., which places emphasis on the rights of individuals as opposed to the rights of the collective or society as a whole. A basic understanding of cultural diversity, including awareness of both visible cultural differences and invisible cultural roots, can help you to appreciate partners' differing values, beliefs, and contributions. Understanding such cultural elements and motivations can help partners anticipate each other's concerns as well as provide greater clarity to issues that may have been assumed in previous, domestic-only transactions. Successful international research partners are often those who understand each other's motivations and predict each other's concerns in order to avoid communication break-downs.

While engaging global partners, consider whether the partner is from a high-context or low-context culture. High-context cultures tend to (a) use indirect messages and avoid conflict; (b) have relationships that are built slowly with trust and place authority at the top of the hierarchy; and (c) change at their own pace and value respecting relationships over achieving quick results. Low-context cultures tend to (a) use direct and detailed messages to encourage productive conflict; (b) begin and end relationships quickly in order to accomplish strategic goals; and (c) schedule activities on a timeline to produce immediate change. For instance, an individual in the U.S. and a potential partner in Africa may perceive the meaning of "*right now*" differently. In the U.S., generally considered to be a low-context culture, the phrase conveys "*in the immediate moment*." Conversely, in Africa, generally considered to be a high-context culture, the phrase is thought to be vague, referring to some point in the future, and often used as a gentle way to put something off. In comparison the phrase "*just now*" conveys that an activity will take place relatively soon and the phrase "*now now*" implies it will happen shortly. With practice, your ability to adapt your communication style will increase, thus allowing you to build stronger relationships with global partners. Stronger relationships among partners increase the success of a project as partners are not delayed nor set-back by miscommunications and can spend more time focusing on work performance and results generation.



# PROJECT PRE-PLANNING

Intensive planning, particularly pre-planning, is a key characteristic of most successful major projects, especially those involving international partners. Because an international research project is a complex undertaking with many challenges, intensive and deliberate planning is critical to its ultimate success. And while it is impossible to predict what can go wrong, the following list of common issues can prepare administrators for handling projects of this type and magnitude.

## Partnership/Project Vision

The most fundamental aspect of a proposed international partnership is the *project vision*. The project vision defines what the project's creators are hoping to accomplish through the proposed partnership. A common mistake made by collaborators is the lack of thought about the overall vision of the international partnership. Often researchers are driven by a funding opportunity and have not really thought about the holistic view of what is possible, i.e., they have failed to describe the *ultimate goals of the project and how those goals will be realistically accomplished by taking advantage of the assembled researchers to develop and address the world-class research question*. Although it may be difficult to assemble potential partners in order to compose a holistic vision, it is vital that such a vision be clearly defined once the partnership is formed and before applying for funding. A face-to-face charrette is one way to actively define a unified and sustainable vision.

## Establishing Project Team Chemistry, Culture and Trust

Since the proposed project involves multiple layers – institutions, researchers, research leadership, administrators – and many of those involved may not have not worked together previously, it is critical that all collaborators spend time getting to know and trust each other. Often international projects fail because the personalities of research teams do not work harmoniously. Equally important are regular meetings of administrators who will need to work effectively together in order for the project to be successful. If possible, funding should be used to launch and establish the project through in person meetings.

## Communication

Map out communication pathways by defining exactly who will need to talk to whom; for example, map out pathways so that researchers can talk to researchers, administrators can talk to administrators, and researchers and administrators can talk to potential sponsors. Ideally, such communication should be done face-to-face; however, using email, video or phone communication channels can be workable and less costly alternatives. A common mistake is to miss out on this step because of cost and time delays. It is incredibly valuable for teams of researchers and administrators from the various partner institutions to have a chance to form initial, positive connections that can be leveraged for further and more complicated discussions as the partnerships mature.

## Institutional Support for the Project

Major international projects usually require significant investment and support, especially during the start-up phase. In order to obtain such support, it is essential that lead project researchers discuss and advocate for the project with relevant research and administrative leaders, e.g., deans, chancellors, provosts and vice provosts. Matching funding from the partner institution is often required to make these big projects come to reality. Early endorsement from a partner's senior leadership can ensure that institutional seed and matching funding is available and dedicated to the project.

## Leadership of the Project (Institutional and Researcher)

Most sponsors require a lead institution (or prime) to be identified from among the project performing partners. In order to be considered for this role, the lead institution should have adequate experience, resources, administrative sophistication and facilities. The lead institution also needs to fully understand and be able to comply with the requirements of the sponsor. Leadership can be a thorny issue, especially when several high-profile institutions and/or researchers are involved.

In addition to identifying a lead institution, the project may identify a single lead researcher – often termed a “Principal Investigator” or “PI.” This individual must have the respect of the project researchers, the project partner institutions as well as possess the skill and sophistication to manage the project and maintain compliance. A common mistake is to appoint the PI with the strongest research record – e.g., the PI with the most number of active grants or the highest H-index – in the belief that their research credibility alone will lead to success. However, it is more important that this individual also have the bandwidth and skills to lead a major project.

## Project Feasibility, Funding Phasing and Eligibility Rules

If partners are supported from very different funding mechanisms, with different eligibility and funding usage rules, it is critical that all parties – both partners and researchers – involved understand how the different funding programs work and will impact the project. Partners should also understand if matching funding can be relied upon and if the rules of the various funders will render all sources of matching funding as eligible. Phasing – or having the project funded in several stages, or “phase” – can be problematic as some regions have programs that fund capital, operating costs and research costs support in one, single tranche in contrast to other regions which only fund one dimension (e.g., just operating costs) per sponsors. With the latter type of regions, it can often take multiple, successful awards from different sponsors before the appropriate mix of capital, research and operating funds can be secured.

## Sponsor Engagement

A crucial part of the pre-planning process is engaging the potential sponsors. Often such funders have many unwritten policies and preferences. It is important to approach a sponsor with current funding priorities that match those of the project to increase success. One needs to understand the current strategic funding areas of the various sponsors, as well as to ensure the proposed project is in line with the sponsor’s mission and funding domain. Engaging the sponsor early can help to identify and correct any flaws in the project vision.

## Special Geographical Issues

There are considerable differences between various countries’ institutional organizations, legal systems, and currency fluctuations. It is critical that the partners discuss whose legal system will be applied in case of issues and disputes. Typically, legal representatives from all partners need to be involved in making this decision. Beyond legal issues, projects can be adversely affected or even fail because of currency fluctuations, particularly losses sustained when an in-country currency weakens and it costs a partner in that country more to perform its portion of the project than originally anticipated. In order to defray such losses, representatives from financial offices of each of the partners need to ensure they have adequate hedging facilities to protect the project from non-performance due to budgetary shortfalls.

## Compliance Landscape

Compliance can be the stumbling block of many major international projects. Researchers and administrators may be very experienced in complying with their own domestic sponsors but are typically less familiar with funders from other regions and countries. Each source of funds needs to be appropriately managed according to the fund’s terms and conditions, yet joint funding should be handled in a way that ensures the continued accessibility of the numerous funds across the project. Research administrators must be very clear on all of the aspects of the project budget, taking into account what specific awards can be used for what purposes.

Another issue relating to compliance is that different countries may have different standards with respect to health and safety, animal and human ethics, and research misconduct issues. It is very important that the research project follows the correct compliance processes for the associated sponsor(s) and that all necessary certificates are in place to ensure the smooth progress of the research project.



## Agreements

It is very important to establish a documented record that describes the basis of the project at the earliest possible stage. Such a record can be accomplished through drafting, circulating and, eventually, signing, a simple, non-binding memorandum of understanding (MOU) among the partners. This agreement should define, at a high-level, the role of each partner and relevant researcher, the project vision, the communication pathways, and the lead partner and PI. (More detail on these “pre-award” agreements are detailed in Chapter 3.) Later, once sponsors are identified and funding is obtained, there is usually need for a more comprehensive agreement that lays the various issues of how the project is governed, what happens if there is a disagreement, how research funds are dispersed, how changes to the project are proposed and approved, and what legal terms shall apply (e.g., indemnification, governing law, trademark and intellectual property rights). The more work that is done earlier on to define through documenting these roles and making partners aware of the project’s parameters and their respective roles, the easier it is to deliver comprehensive agreements that satisfy the sponsors and the less likely there are to be misunderstandings or disputes as the project matures and, eventually, concludes.

## Research or Development Project

Many international projects have strong development foci and are very different from the traditional major research projects. Sponsors who support traditional research often do not fund projects with significant development activity and vice versa. It is essential that if the project has both research and development activities, those activities should be clearly separated so that the research activities can be offered to research funders and the development activities to international development funders, if possible. Securing funding support for a true hybrid project is not easy since one activity is often seen as diluting the other. In reality, the two parts of the hybrid project work well together and the research aspect can inform how to succeed on the development front.

## Peer Advice

Finally, remember that numerous previous international partnerships have been built and succeeded. Some of these global collaborations are still ongoing to this day. These past and existing international partnerships are a valuable source for lessons on what worked and what did not. To gather such insights, talk to peers involved in these partnerships, asking specifically what to do and what to avoid. Speak to potential sponsors for their advice on successful dimensions of global partnerships. Dialogue with senior researchers who have led major international partnerships. There are a vast number of experts who are willing to share their experiences and help the next generation of international partnerships succeed.



# PROPOSAL DEVELOPMENT

Preparing a funding proposal takes time and planning. It is important that each person has a clear understanding of the expectations of his/her role in the development and assembly of a funding proposal. As a research administrator, it is likely that your institution will have expectations of your role; however, international collaborating parties may have a different understanding of the support you and your team will provide. As such, it can be useful to give a brief overview of how you and your team can support putting together a funding proposal. Aspects of proposal support may include:

- Identifying and liaising with the sponsor;
- Understanding and interpreting the funding conditions;
- Reviewing eligibility and compliance of the proposal;
- Assigning academic mentors to the proposal;
- Setting up telephone or video conferences which account for time differences;
- Developing the budget and budget justification;
- Coordinating agreements between parties involved in a collaborative proposal;
- Coordinating internal and external documentation for the submission of the proposal;
- Use of internal and external funding systems; and
- Submitting the proposal.





It can be useful to connect with a research administrator at each of the institutions where the researchers are located and understand the support they will provide and how, overall, the process of assembling the proposal will work. This section addresses some key details to consider when mapping out the general proposal development process and roles.

### Lead Writer versus Team Writing

How a funding proposal is written can vary greatly from application to application. A project involving multiple institutions from two or more countries needs to consider different time zones, accounting for how this may affect the writing of a grant. In certain cases, there will be a lead writer who develops the proposal; other times several people will be working on the grant simultaneously. When working on an international funding proposal it can be useful to clearly set out who is working on what, and when. Also, time must be allocated to review the proposal, not just for compliance, but also to ensure consistency in the language used throughout. If several people are working on a proposal, also consider how the documentation will come together, who is uploading the documents if using an online submission and how to ensure everyone understands when the application is due in their time zone.

### Reviewing One Draft versus Multiple Drafts

When supporting the development of a proposal it is important to specify what you will be reviewing. Will you be providing a compliance and eligibility check? Will you be reviewing the actual written proposal? How many times will you offer to review an application? If reviewing once, then the expectation may be that you will review a final draft of the application. If reviewing multiple drafts, set out what you would expect to see at each stage of the review process.

### Suggested Changes versus Absolute “Must Haves”

When reviewing a grant application, it can be useful to have a checklist. The checklist should set out what are suggested changes, for example, those that may improve the readability of the proposal or layman’s accessibility of its contents. It is also important to set out what must be changed, i.e., what issues pose an eligibility or a compliance issue and, therefore, must be changed before the application can be submitted or the application runs the risk of rejection.

### Types of Agreements to Consider at the Proposal Stage

As noted in the previous section, institutions will often have high level agreements between themselves and other institutions, including sponsors, companies, and universities. Such agreements can be aimed at protecting both the institution and the individual researcher(s) particularly in relation to the confidentiality of information and data, intellectual property; addressing cost sharing issues or costs related to developing the proposal and conducting pre-award activities; and setting forth the expectations of research goals and delivery of outcomes. Typical agreements considered at the proposal stage include a master agreement, memorandum of understanding and a non-disclosure agreement.

**Master agreement.** Also known as an “umbrella agreement,” a master agreement is established to set out a high-level framework of legal terms and conditions to govern the work to be undertaken by an institution with another party, often a company or sponsor. Using a master agreement is preferred when there will be an overarching relationship between the parties with several, discreet projects that are later developed and initiated between the interested parties. This framework would not be preferred when only a single project is contemplated between the parties, or when the terms and conditions governing each collaboration cannot align enough to warrant the use of a master agreement because the conditions set out in the master agreement must be adhered to by all projects. If using the master agreement framework, the specificities of how the individual project to be undertaken must reference the conditions set out in the master agreement, in addition to detailing that project’s specific costs, actions, researchers and deliverables. Typically, the specifics of each individual project are addressed in addendums to the master agreement.



**Memorandum of understanding (MOU).** Sometimes referred to as a “collaboration agreement” or “teaming agreement,” a memorandum of understanding is an agreement that sets out, in writing, the overall interests and collaborative goals of the parties. It is often presented as a non-binding agreement, intended to give both parties a greater sense in security of the other party’s intent to proceed with the full relationship. A MOU often sets forth the general parameters of how the two institutions intend to work together. Typically, a MOU is created for a specific collaboration between researchers from different institutions and countries, working together to submit a funding proposal to a sponsor. Key aspects of a MOU include the following: listing the parties (i.e., institutions) to the agreement, the title and proposed sponsor of the funding proposal, goals and anticipated outcomes of the collaboration, and any agreed cost-sharing between institutions with details about differing currencies, and how the cost-sharing commitments will be met (i.e., cash and in-kind, or non-cash, support). It is unusual for a MOU to include an exchange of money and the distribution of funds is normally left to the actual award stage.

**Non-disclosure agreement (NDA).** A non-disclosure agreement can also be referred to as a confidential disclosure agreement (CDA), a propriety information agreement (PIA) or a secrecy agreement, depending on what is being protected. An NDA is a legal agreement between interested parties to ensure confidentiality when exchanging information or data. Such an agreement is developed at the initial stages of collaboration between the parties as confidential information must be exchanged or shared in order to assess whether a project is possible and build the proposal. An NDA may be mutual - where all parties must keep confidentiality - or one-way - where a specific party needs to keep information confidential. Such agreements are often established where parties desire that intellectual property, patents or information on clinical trials remain confidential.

### Budget Development for a Proposal

A funding proposal should include projected costs of the project. When preparing a budget, it is critical to review the sponsor conditions and ensure that the application is compliant. Key aspects of budget conditions include the following: amount that can be requested, number of years that funding can be requested, currency of the funding, whether sponsor expectations of a set amount of cash or in-kind funding to be provided by the institutions named on the funding proposal, whether a budget justification is required, and what can or cannot be asked for as part of the budget. The budget should align with the fiscal requirements for the proposal and demonstrate that the budget request is feasible for the project to be undertaken.

### Direct Costs

The estimated costs of a project that clearly align to the objectives must be set out in the research proposal, typically shown in two categories of cost: direct and indirect. Direct costs are those associated with a funding proposal that can be *directly* linked to the work performed with a relatively high degree of accuracy, and often include salaries, scientific equipment, travel, material and supplies, fringe benefits, sub awards and animal care. When applying for international funding, it is important to be aware that the sponsor may have different costing conditions depending on the country in which the institution or the researcher is located.

## Indirect Costs

As the converse to direct costs, indirect costs are those projected costs that *do not directly* align to the objectives set out in a research proposal. For example, if a researcher at a university is going to undertake a proposal, costs associated with the building where the research is being conducted – such as costs of electricity, renovation, heating or cooling, maintenance – are considered indirect. Additionally, costs associated with the purchase and maintenance of standard computers and office equipment as well as costs which support the administration of a grant, e.g., administrative staff salary, are all viewed as indirect costs. In large U.S. universities, the cost of supporting the libraries and scholarly resources, like museums and collections, are classified as indirect. Sponsors will often set out what types of costs it considers to be indirect. While there are many ways to reasonably represent indirect costs in a proposal, most U.S. universities apply a percentage that has been negotiated with a cognizant agency, like the U.S. federal government. Many sponsors set their own maximum rates for indirect, which often fall far below the rates most universities would typically request. When applying for international funding, it is important to be aware that the sponsor may have different costing conditions, depending on the country in which the institution or researcher is located.

## Budgeting Equally versus Proportionally

When developing a projected budget proposal with external partners, consideration needs to be given to how the fiscal costs will be shared. Will the awarded budget be distributed equally with the institutions involved? Will the awarded budget be proportioned based on the lead institution's and other parties' involvement, or amount of time each researcher has committed to the project? It is important to review the sponsor conditions for planning how the awarded funds should be distributed. Some funding sponsors may not allow for monies to be distributed outside of the country. If they do permit such cross-national funding, how will monies be shared and in what currency? Will monies be shared annually? Monthly? What are the impacts of exchange rates?

## Budget Tips for Proposal Stage

Review the sponsor's funding guidelines carefully for budget conditions. In particular, when applying for funding outside the U.S., ensure the full implications of allocation of monies to different countries are understood. Check funding limits for direct and indirect costs. Ensure the project is appropriately and reasonably costed as reviewers can easily perceive if a budget has been artificially inflated. Understand how payment will be made if the funding is awarded and in what currency. Confirm that everyone named on the proposal has an agreed understanding of what is being asked for in the budget proposal and the proposed effort being committed on their behalf. Encourage agreement at the pre-award stage to revisit the budget against project outcomes if there is a reduction in funding awarded to the proposal.

# NEGOTIATION

Discussing and agreeing to terms amenable to all parties involved in a grant, contract, or other research agreement is often referred to as the “art of negotiation”. Negotiation refers not only to settling the contractual elements of a transaction itself which manifest in written terms and conditions, but it also refers to the communication and interaction elements of the process. When international partners are involved it is crucial to be able to communicate effectively, striving to create a “win-win” negotiation environment in which each of the parties is reasonably satisfied with the outcomes. In order to help you understand and practice successful negotiation, this chapter will provide background on sponsor type, agreement type and awarding documents. Furthermore, this chapter will explore the role of a negotiator, particularly by focusing on how to better understand the needs of your international partner. Finally, this chapter will discuss how to set-up a successful negotiation process at your own institution and help new negotiators understand some of the common contractual terms and conditions that pose challenges in negotiating sponsored research agreements.

## Sponsor Type

There are different types of entities that sponsor research. The use of the term sponsored research not only refers to basic and applied research but also includes community service awards as well as instructional and teaching awards. Since the definition of sponsored research is inclusive of all a given institution’s extramural funding, i.e., funding that comes from sources outside of an institution, all international partners may receive funding from one or more of the sponsor types listed below. The international partners may be subawardees or subcontractors to U.S. institutions or the U.S. institutions may be subawardees or subcontractors to the international institution.

## Government

**Domestic.** The U.S. federal government provides grants and contracts to institutions of higher education, some in the U.S. and some in other countries. In the U.S., an international partner may receive funding directly from the U.S. government. For example, the National Institutes of Health provides funding opportunities for medical research and demonstration projects to foreign universities including those conducting clinical research.

**International.** U.S. institutions may receive funding directly from a foreign government or from a ministry that reports to a foreign government. When dealing with a foreign government the U.S. institution has to be aware of any restrictions that may apply to contracting. For example, in the State of Texas a public institution of higher education must contact the University System Office to request permission to enter into a contract with a foreign government. Approval is not automatic. Consideration is given not only to the nature of the government but also to its standing in regards to export control laws and regulations.



## Foundation

**Domestic.** Domestic foundations, which operate as not-for-profit organizations, can issue awards for U.S. institutions to work with foreign governments or foreign hospitals, depending on the foundation's mission statement. Special examination of the terms and conditions issued by the foundation is needed, as they may include the loss of intellectual property (IP) rights in such areas as the use of certain experimental drugs and vaccines that may be owned by the institution of higher education or involve a third party licensee. It should be noted that private foundations and other not-for-profit organizations may be willing to negotiate some terms and conditions. However, others are not willing to negotiate the ownership of the IP discovered during their funding period or within the scope of their funding. They may insist that ownership of all IP created using grant funds vest with them.

**International.** A converse model to domestic foundations, international foundations may give awards, subawards or subcontract to U.S. institutions. And, while U.S. entities may be eligible to receive funding from these organizations – either directly or indirectly – it is important to note that such foundations are primarily focused on seeing such funds make a positive impact in either a certain geographic location, a certain area of development, or both.

**For-Profit.** For-profit entities that award research funding include corporations and companies who have investors that want to generate a profit through the research that they can procure. Negotiation may be very lengthy and complicated as the terms and conditions may be extensive. Often, institutions of higher education must spend a considerable amount of time during the negotiation educating the for-profit entity of the typical limitations and boundaries governing research at a university or research center (e.g., the implications of Bayh-Dole on intellectual property ownership). This is especially true with international sponsors who may not understand the laws, rules and regulations that a U.S. institution of higher education may be required to follow.

## Agreement Type

The receipt of a contract, grant or other sponsored agreement from an extramural source is called an award. Awarding documents may come in various forms, yet a typical way to understand an award is by breaking it down into four critical elements: (a) Scope of the work to be accomplished by the parties, (b) exchange of money or other consideration with value, (c) rules of engagement under which all parties agree to operate in performing their respective portions of the agreement, and (d) signatures of appropriate representatives that may legally bind the various parties.

**Identification of the Type of Award.** In all negotiations it is necessary to identify the type of award. Knowing the award type, e.g., grant, contract or cooperative agreement, is critical to the understanding of the awarding documents that will be used to create a unilateral or bilateral agreement. A unilateral agreement is defined as an agreement where only one of the parties makes an offer to the other party and, when the other party requests for the offer to be fulfilled, the offering party must comply. As an example, a university catalog lists a compound for sale at a certain cost, but also stipulates that all compounds may or may not be available and, if the compound is not available, the buyer will be sent an email. This is done before any payment is sent by the buyer. There is no promise that the compound is available or when the compound will be sent. At this point, no money has been exchanged. If, on the other hand, the compound is available, the university fulfills the order by shipping the compound to the buyer, and the university can expect to be paid by the buyer. In unilateral agreements, only the promisor is bound by consideration, i.e., the benefit that a party receives or expects to receive from the deal.

In a bilateral contract, there is an agreement between the parties because each of the parties promises to do something and, once agreed to, each of the parties must fulfill their end of the bargain. Universities and foreign institutions such as foreign institutions of higher education, departments of ministry and foreign governments typically enter into bilateral agreements. Each party is obligated to either pay or to deliver, depending on its role in the agreement.

In addition, there are different types of sponsored agreements. Typically, sponsored agreements fall under four general categories, although there may be hybrids of each of the categories. The four general categories are as follows:

- **Grant.** A grant is a financial assistance mechanism where funds are provided by the sponsoring party for the purpose of carrying out and completing a set of activities. These activities are typically proposed and determined by the grantee recipient but often answer directly to the sponsoring party's goals, specific guidance and work parameters. A grant is the most common form of award received from the U.S. federal government.
- **Contract.** A contract is often referred to as a procurement mechanism, because it is used primarily to set forth a definitive scope of work and requires that certain identified deliverables be met by the contracted party within a specific period of time. Contracts often contain stricter terms and conditions, setting forth more specific obligations for both the sponsor and the recipient. It should be of note that the usage of the term "contract" to describe a type of sponsored research agreement, should not be confused with the more general legal term of "contract" which can be used to describe any agreement between private parties which creates mutual obligations enforceable by law.
- **Cooperative agreement.** A cooperative agreement is similar to a grant, however, it typically involves a significant level of sponsor participation beyond simply promising funding or other financial resources. In some cases, if the cooperative agreement involves a foreign party, the foreign party may want to work in the laboratory of the U.S. researcher so that they may work together in conducting the research.
- **Subawards.** Subawards can be either grants or contracts that are issued under a primary grant or contract. Subawards – often called subgrants or subcontracts to reflect the specific type of agreement being used – usually flow down the primary grant or contracts relevant terms and conditions onto the subrecipient party.

**Awarding Mechanisms.** There are different types of awarding mechanisms issued under a grant, contract, cooperative agreement or subaward. In addition to knowing the type of agreement, it is critical to understand these different awarding documents, many of which impact how the financial dimensions of the agreement must be handled. Some common awarding mechanisms for U.S. sponsored research performing institutions are as follows:

- **Cost reimbursable.** A cost reimbursable agreement is suitable for use when uncertainties have arisen as to the true cost of conducting the research. It is primarily used to support research and development activities. A cost reimbursable agreement requires that payment be rendered for only those costs incurred during the performance period of the award and up to an agreed amount. Such costs will be paid so long as it is established either by the contractor or the by the terms of the agreement as allowable and are within the predetermined scope and activities of the research. This type of agreement usually includes a clause that states the upper limit of the expenditures that will be reimbursed to the contractor.
- **Fixed price.** A fixed price agreement is issued when performance is based on deliverables. It provides the maximum incentive for the contractor to not only control costs but also to perform competently and efficiently. A fixed price agreement is not subject to any adjustments if expenses exceed the agreed upon amount of funding. Many times there are multiple deliverables and each deliverable will be assigned a pre-determined dollar amount for completion. When dealing with a foreign entity, especially a foreign government, fixed price agreements are usually the award mechanism issued by the U.S. institution.
- **Material transfer agreements.** Material transfer agreements are agreements in which biological compounds are exchanged for the various parties to conduct research. Normally, there is no money involved, although a legal agreement is required in order to establish the purposes of defining the scope of the research the issued biological compound can be used in, establishing intellectual property rights to the materials as well as any derivatives, and requiring that the compounds will be destroyed or returned when requested by the issuing institution. A material transfer agreement can be a standalone agreement or can be built into another agreement type.
- **Service agreements.** A service agreement – also often termed as a "work-for-hire agreement" or a "fee-for-service agreement" – is a procurement agreement which involves payment to the recipient once a defined service has been completed. Service agreements are often considered to be in the larger category of "vendor agreements," which are transactional pathways for the purchasing of goods and services.

- **Clinical trial.** A clinical trial is usually undertaken as a part of clinical medical research. A clinical trial involves a controlled study involving human beings that follows a predetermined and defined medical protocol. A clinical trial is undertaken for the purpose of testing the effectiveness and safety of a therapeutic agent such as a vaccine or a drug. A U.S. institution may have clinical trials involving foreign hospitals, clinics, or other medical facilities. In which case a subcontract or a subaward is issued to the foreign entity. However, the foreign entity must comply with U.S. clinical trial standards and receive flow-down clauses that comply with such U.S. requirements such as the use of human subjects in research. If the international institution inserts clauses into the agreement, make sure that these clauses do not contradict or negate the U.S. flow down clauses. Also, make sure that any clauses proposed by the international institution do not violate university or hospital policies and procedures and do not violate local, state, or federal law.

## Award Negotiation: Roles and Key Considerations

**Role of negotiator.** In negotiating an international contract or any large multiparty collaboration, having a single negotiator lead the negotiation discussions typically works best. The lead negotiator should act as the central point of contact for all of the necessary representatives at his/her institution, i.e., the negotiation team. Multiple people acting as negotiators often results in misunderstandings and may lead to a failed negotiation. In most large public and private institutions of higher education the lead negotiator will be an associate or assistant vice president for research, the director of sponsored programs, or an attorney who is well briefed on contract law and international law.

**Role of negotiation team members.** If multiple negotiation points are tackled and/or the negotiating institute is a large entity, the negotiation team may consist of the lead negotiator as well as representatives from the finance, technology transfer and general counsel. The Principal Investigator (PI) or other senior members of the research team may also be invited to participate. If the PI is to be included in the negotiations, the lead negotiator is responsible for ensuring the PI understands the negotiation processes, which includes effectively explaining the implications and hazards for agreeing to certain terms and conditions. The lead negotiator should also factor in the PI's motivations to finalize the award often despite less desirable terms and conditions.

**Authority to bind the contracting institutions.** It is indispensable that each negotiation team know who will be the signatory on the agreement at the other party. The signatory is the person or persons who can contractually bind the institution. If the negotiation team is not dealing directly with a signatory, the negotiations may take longer because the signatory still has to review the agreed upon terms and conditions and give approval.



### Identification of the project management

- **Key Personnel and Other Proposal Elements.** Each negotiation team needs to understand who the key personnel are from each institution with respect to the research and/or project scope. Typically, the PI of each party is automatically key personnel. Usually if the PI for the U.S. entity is involved in negotiations, the PI for the foreign institution should also be engaged and vice versa. Furthermore, a copy of the proposal should be referenced during the negotiation discussions or calls, so each party can refer to the activities and scope of the research project as the impact and potential changes of certain contractual terms are discussed. Budget-wise, each team needs to consider what activities can be excluded should the other party not want to pay for such activities.
- **Authority to authorize payment.** It is important to determine how payment will be rendered. Look at whether there will be a bank transfer or other means of payment, as well as the timing of the payment – a certain percentage at the signing of the contract, entirely cost reimbursable, or a small portion withheld until all final reports are submitted. Such details should be explicitly set forth in the terms of the grant, subaward, contract, or subcontract. It is also essential to identify who at each institution may authorize payment; this person will be the point contact if payment is not forthcoming, if expenditures are not approved, or if there is difficulty in sending payment once expenditures have been approved.

### International Collaborator

**Capacity, Payment Practices and Other Factors.** Every negotiation will be impacted by the institutional culture of the collaborators, the scope of the work, the type of sponsor, the type of binding agreement and the involvement of the research investigators. However, there are certain considerations in particular the negotiation team should consider prior to the start of negotiations.

**Prompt payment.** The U.S. lead negotiators should examine the financial history of the sponsor and/or collaborator, specifically reviewing if there have been previous issues with the prompt payment of invoices. As with all research agreements, a clear payment schedule with specific deadlines should be in the final agreement. Each party should be prepared to stop work if the payment deadlines are not met and to put such language into the agreement. In many cases when negotiating an agreement, the international partner will often request up-front payment of a certain percentage of the contract in order to pay for essential research supplies, employ graduate students for a semester, and pay the initial salaries of key personnel.

**Capacity of the PI.** There is an inherent risk that the PI at the collaborating institution may not meet the performance expectations or generate the research results expected by the sponsor or lead institution. All negotiating team members must assess the history of funding awarded to the collaborating PI as well as the nature and quality of their publications. The nature and quality of their publications will demonstrate if they have the ability to produce research results, which is needed to fulfill their contractual obligations.

**Administrative capacity.** The U.S. lead negotiators may also look at risks associated with doing business with the collaborator. Specifically, the U.S. team must look at the total amount of the international portion of the award, because if costs are disallowed by the sponsor, the U.S. partner may be liable for such unallowable costs. To help qualify this risk, the U.S. partner may need to examine whether or not the collaborating institution has the capabilities of managing the award. For example, sometimes in third world countries, robust accounting practices required to manage U.S. federal funds are typically absent. In the absence of such cost control mechanisms, one option is to use a cost-reimbursable contract instead of a fixed price contract. Such determinations about the viability of a foreign institution's administrative capacity should be made before or during negotiations, not after. In order to ascertain a foreign institution's administrative capacity, the U.S. negotiation team could send a university accounting person to the international partner for an in-person assessment of local practices and policies. Additionally, such assessments can help you determine the type of agreement to issue to the foreign institution. However, the cost of sending the accountant to assess capability cannot be directly charged to the award and may need to be funding out of indirect costs.

### International Partner or Sponsor: Culture and Customs

**Issues that may affect the negotiation.** Start with a determination of the scope of the work. Ensure that PIs at both parties review the scope of the work and agree that the scope aligns with the budget and research expectations. Also, review institutional practices and capabilities so that the U.S.-based researchers do not over commit both time and materials.

**Issues that may impede the research.** In negotiating with an international collaborator, there may arise terms and conditions to which one of the parties cannot agree. The negotiating team should always keep in mind that the end goal of the transaction is to enable collaborative research. Therefore, it is essential that parties keep open minds and do not get over anxious or committed to doing business only one way. Flexibility is a key to good negotiations. However, each party must understand that there will be certain limitations for each party, especially legal and compliance boundaries.

**Choice of language.** For most U.S. institutions, the contract will be in English and contain a specific contractual term stipulating that the contract will be interpreted legally in English (a "choice of language" term). This is because without this term, such international contracts written in a foreign language or in dual languages may be subject to interpretations which can be inconsistent with U.S. contract standards. Many times the contract terms may not have the intended meaning when translated into English.

- **Interpreter.** If the international negotiation team does not speak English, it may be necessary to have an interpreter present during negotiations. It is advisable if each entity has its own interpreter. Many times, the U.S. PI speaks the language of the country they want to contract with or the PI in the foreign institution speaks English. If neither party transacts in a shared language you may need to turn to your foreign language department to see whether they have interpreters available or if they know one of reliable interpretation services.
- **Translation.** Most U.S. institutions will assume the foreign institution is responsible for interpreting the agreement into their native language. Be cautious that the authorizing official from the U.S. institution only sign the English version of agreement. It is not advised for the U.S. signatory to sign two versions of the agreement. However, if the foreign institution requires a signed agreement in their language, either offer a dual-language version of the agreement (a side-by-side translation) or make sure that you have a translator available who can translate the foreign-language version to verify that all terms and conditions are correct.

**Right to Work Laws.** In agreements where the scope of work proposes to send U.S. personnel to work in a foreign country, the negotiators must be aware of the laws that govern the right of your personnel to work in that country. As an example, some countries only permit foreigners to work for 27 days a month and leave the country on the last three days of the month. Part of the contract review should contain a review of which country U.S. researchers may enter for the three or more days and if they will be paid for their time, transportation, lodging and food. Researchers may return to the original foreign country when the three days are up and resume their work. Inquire with the foreign negotiators about the right to work laws of their country. If it is not clear as what the laws entail, seek the help of your general counsel, who will often consult with an outside attorney who specializes in international law.

**Import and Export Laws and Regulations.** When dealing with a foreign country, negotiators must work with the cognizant export control office to determine if the country or entity you are working with falls under the U.S. Export Control regulations. This office will determine if you can enter into an agreement with the foreign country or entity or if you need to seek a license from the government. When entering into an agreement with a foreign institution taxes, tips, and use and visa fees are the responsibility of the foreign institution. Partners rely on each other to assist them with identifying costs attributable to regional and local regulations including foreign taxes, tips and use fees. The same applies to visa fees, although in some cases, such as the case of a U.S. employee obtaining a work visa for the foreign country, the cost will likely be borne by the U.S. institution.

## Defining the Scope of Work

An essential step in the crafting of any sound agreement entails defining the scope of work. The narrower the scope and the more concise the activities, the easier it is to meet the goals and objectives of the research project. If the scope is too broad, researchers may not be able to meet all deadlines and activities as set forth in the scope. At no time should the scope be increased without a written amendment agreed to by all the parties. It is important to remember that, once integrated into or appended to the agreement, the defined statement of work becomes a binding obligation.

## Establishing a negotiation process at your institution

**Terms that must be flowed down per state or federal regulations.** Often, and especially if the U.S. institution is the prime awardee on a federal grant or contract, the U.S. institution will have certain stipulations and regulations that will need to be part of the agreement that is signed by the participating institutions. These regulations, which become clauses within the agreement may include the following:

- **Conflict of Interest.** This is a requirement of most federal agencies including NIH and NSF. If the subawardee or subcontractor does not have the ability to determine whether there is a financial conflict of interest or the ability to create a management plan, they may choose to (1) request to use the U.S. institution's financial conflict of interest procedures to make that determination of financial conflict of interest and to abide by a management plan issued by the institution, or (2) establish their own mechanisms to comply with the regulations.
- **Confidentiality and Non-disclosure.** Before a U.S. institution enters into any discussion of the science being proposed, the parties need to have signed a confidentiality or non-disclosure agreement if either is divulging confidential or proprietary information in planning phases. This is essential in order to protect rights in existing and future intellectual property (IP). IP rights include legal protections for inventions, literary and artistic works, designs, symbols, and names and images used in commerce. Such rights are granted by and defined by U.S. patent, copyright, and trademark laws.
- **Institutional Review Board for the Protection of Human Subjects (IRB).** U.S. laws and regulations governing the use of human beings in research are extensive. A U.S. institution must be aware of these laws and regulations as they must be flowed down to the participating foreign institution. All collaborators must abide by the IRB regulations of the United States as applicable. The same will hold true when receiving funding or obligations from a foreign institution or sponsor, i.e., the foreign institution will require human subjects research be performed under applicable foreign law.<sup>2</sup>

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<sup>2</sup> More about these regulations can be found in the regulatory chapter.



- **“Negotiable” versus “non-negotiable” terms**

**Choice of law.** The ‘choice of law’ clause establishes which laws will govern the applicability and interpretation of the agreement and/or the conduct of the research – U.S. law (often further specified as to which state’s law) or the national or regional law of the foreign institution. Most parties prefer to have the laws of their country prevail. The parties may agree to a neutral choice of law clause or may omit the clause from the contract altogether if this presents a significant issue during negotiations.

**Warranty.** A warranty guarantees that the goods or services will be delivered as promised and allows one party to demand that corrections be made to the deliverable at a cost borne by the other party. Most U.S. institutions will not accept the obligation to provide a warranty related to research contracts. In addition, many U.S. institutions will not accept language that includes a reference to accomplishing the work or project using ‘best efforts’ because agreeing to ‘best efforts’ language in contracts can be interpreted as equivalent to providing a warranty. Often, getting beyond this language requires both parties to understand and accept the inherent risks of research.

**Intellectual Property (IP) ownership and assignment.** IP ownership and assignment can be a major challenge to negotiate, especially when dealing with for-profit foreign institutions. Specifically, U.S. institutions do not routinely relinquish or transfer ownership rights to creations before they exist, because it is hard to accurately pre-assess an invention’s potential use and fair-market value. Furthermore, if U.S. federal funding is involved – wholly or in part – ownership and assignment cannot be transferred to the for-profit institution due the statutory regulations of the Bayh-Dole Act, which require that a government use license be protected, the U.S. institution make an effort to commercialize the creation (if applicable), and seek fair-market value in the commercialization. Most federal grants are subject to the Bayh-Dole Act and title may not be released to a for-profit or any foreign institution. In addition, giving away rights to IP can be a violation of export control regulations as it can take the agreement out of the Fundamental Research Exclusion (FRE), a “safe harbor” most research universities and non-profits use to ensure their research remains available for dissemination and not subject to export control regulations.

**Resolution of disputes.** All agreements with foreign institutions should include a dispute resolution clause. Such clause would set forth the steps, in writing, of how a dispute arising between the parties under an agreement would be resolved. For example, the clause would clarify the following: Will a dispute be resolved through arbitration or mediation? Who will pay for the arbitration or mediation? Will the arbitration be binding or non-binding? In general, most U.S. institutions will accept non-binding arbitration, depending upon the venue or the specific arbitration process identified. Most U.S. institutions prefer, and some require, the arbitration to occur in the state or county of the institution in question. Requiring binding arbitrations is typically unacceptable.



**Termination.** Defining the start and end dates (often termed the “period of performance” or “PoP”) for a collaboration and appropriate termination language is essential in any agreement. A quality termination clause will describe what needs to occur if an institution chooses to terminate the agreement. A termination clause will include information on how much notice must be given to the other party before termination may take place, as well as which costs the terminating entity will be responsible for paying. In the case of U.S. institutions, a termination clause should include a reference to paying the cost of graduate or undergraduate students who are employed on the grant or contract for an entire semester or quarter and who cannot be terminated without cause in the middle of the semester.

**Indemnification.** Indemnification clauses are used to contractually agree upon how liability for injury to persons or property or liability for use of research results will play out. Negligent acts or omissions are usually exempted from such liability. Many U.S. universities do not agree to contractual indemnity provisions due to policy or local law in the case of public institutions. Foreign institutions will have their own unique country’s laws regarding liability to account for in the agreement.

**Use of facilities.** If a foreign institution wants to use facilities of the U.S. institution, a clause must be in the agreement that will allow them to come to the U.S. and work with the PI in the PI’s lab. Such a clause must include details of how facility access will function, how it is granted and what policies and processes visiting individuals agree to obey while in the U.S. institution’s facility.

**Ownership of Equipment.** In general, ownership of equipment usually vests with the purchasing entity. If the U.S. institution purchases the equipment when the project is over, the equipment remains with the institution. If a foreign sponsor wants the equipment returned to them when the grant or contract is over, the U.S. institution must make sure that the equipment is not subject to export control regulations before it can be shipped. The budget for the grant or contract must include costs to cover shipping of the equipment, including disassembly and packaging, insurance, import costs, and other costs associated with transportation.

## Academic Issues

**Publication Rights.** The freedom to publish research results is essential to research and research scientists and as a result, a publication clause is one of the most important clauses in a research agreement. At U.S. institutions the ability to publish generalizable knowledge is critical to scientific discovery. Therefore, publication rights, especially those of graduate students, in most U.S. institutions will not be waived or restricted. In limited circumstances sponsors and collaborators may be given the ability to delay publication solely for purpose of filing a patent or review of proprietary or patentable information, but the delay usually may not exceed ninety (90) days. The right to delay a publication in order to approve its content for anything other than the review for proprietary or patentable information will not be accepted.

**Use of the Institution’s Name.** Most U.S. institutions do not allow their names, emblems, shields, logos or derivatives of their names to be used without written permission from the authorized signatory of the institution. A term which defines these restrictions, usually called a “use of name” clause, will be included in the agreement. In addition, the agreement may prohibit a sponsor from making claims of endorsement without the written permission of the U.S. institution. This clause is needed to protect the name and reputation of the U.S. institution.

**Rights in Data.** Data ownership resides with the institution that has created the data. However, copies of the data may be requested by either party once the grant or contract has concluded. Each party is required to keep the original data, notebooks, videos, photographs, and other supporting materials for the period of time specified in this clause. Additionally, the prime sponsor may have the right to have copies of all the data produced under the grant or contract. Typically, the subawardee or subcontractor has the right to only the data they produce but may request access to data related to the agreement and larger collaboration.

## Reporting

- **Technical Reporting.** The technical reports, which are often required by the sponsor on a quarterly and /or annual basis and again at the end of the research project, should be addressed in the agreement. Due dates for these reports should be set forth, as well as information about to whom the report should be sent. It should be emphasized in the clause that the required dates are not optional but are in fact deadlines that have to be met.
- **Financial Reporting.** Each agreement needs a clause about how financial reporting will operate. Financial reporting is the responsibility of the institution and not the PI. Try to avoid committing to frequent (e.g., monthly) financial reporting as this can be very difficult for an institution to accomplish. Depending on the sponsor, financial reports may be required quarterly or annually, and again at the close-out of the award. When dealing with lower-tiered recipients of funding, such as subawardees, the prime grantee should be sure to stipulate a financial report is due at least thirty (30) days before the report is due to the sponsor.

**Technical direction of the research.** All changes in scope of work must be approved by the sponsor and the prime awardee, if applicable and must be in the form of a written amendment agreed to by all parties.

**Cost components.** All agreements need to have clauses that describe what constitutes an allowable charge to the project. This includes information about equipment purchases at the end of the research project, consulting agreements, and time and effort of personnel. The negotiating team should be mindful to consult with the PIs, if the PIs are not present at the negotiation, before accepting any cost restrictions.

**Payment terms.** If the U.S. institution is receiving payment from a foreign sponsor, the agreement may stipulate that payment is to be made in U.S. dollars. Regardless, it is useful to quantify the total project costs (or the awarded amount) in U.S. dollars to avoid any confusion or potential loss of funding due to a depressed currency rate.

## Payment methods

- **Sending payment(s) to foreign institutions.** Payments to a foreign institution should always be made through a wire transfer to a reputable bank in the foreign country. The name and address of the bank as well as routing information and the name of the contact person must be set forth in a clause in the agreement.
- **Receiving payment from foreign institutions.** Payments to U.S. institutions should always be made through a wire transfer to the bank affiliated with the U.S. institution. The name and address of the bank as well as routing information and the name of the contact person must be set forth in a clause in the agreement.



# AWARD MANAGEMENT

Any sound award management begins with a clear understanding of the fundamental structure of award documents. This chapter describes the main types of award actions, as well as detailing the key elements of an award with a particular focus on how those elements relate to a international partner or subaward.

## Type of Award Actions

When sponsors decide to fund a project they issue an official notification of funding which may come in the form of an award letter or a notice of award, either of which may be made in an electronic or hardcopy format. If electronic, the award notification is typically officially issued to the institution that is to receive the funding. Rarely is the PI the legal recipient of the funding. Rather, the PI's home institution is the legal recipient of the award and, therefore, only an authorized official for the institution may contractually and legally bind the institution.

Award notices will normally come to an institution in the form of an executed document needing countersignature by the recipient institution. The document will contain information detailing the terms and conditions of the award. It is not a binding document until all parties have agreed to the terms and conditions and have signed the contract. After full execution, the contract can only be altered with a mutually agreed upon and fully executed and signed amendment. In the case of contracting for research with the federal government, the Federal Acquisition Regulations ("FARs" or "FAR Clauses") are used as the contractual clauses. The use of specific clauses may vary depending on the requirements of the sponsor. The use of FAR is a sign that the contract is considered a procurement of goods or services by the government. Under this contract mechanism, in the case of higher education, the research to be conducted is considered a procurement of services.

When receiving a U.S. federal funding award notification for a grant, the award notification rarely comes in the form of a letter. Usually an electronic transmission of an award notice is issued to the recipient institution's Authorized University Official by the federal department or agency issuing the award.

**Elements of Award Notice.** A typical award notification should include the following elements:

- **The name of the research proposal or the project title.** This is an essential part of the notification as it is necessary to know exactly what research is to be conducted and a definitive title allows the research administrator to properly account for the funds.
- **The name of the Principle Investigator (PI) or Project Director (PD).** It is important that the PI or PD be named so the individual(s) in charge of overseeing the performance of the project can be held accountable.
- **The name of recipient or the awardee.** This should be the name of the institution receiving the funding and not the PI/PD.
- **The name of the awarding entity and authority.** This should include the legal name of the international organization, ministry, or institution issuing the award. It should also include addresses, emails, telephone numbers and other means of communicating with the sponsor. If the U.S. institution is the sponsor – for example when issuing a subaward or collaboration agreement to a foreign institution - the name of the pre- and post-award research administrator(s) who can amend the contract should be identified.
- **Award number and CFDA number.** If a U.S. federal award, the sponsor award number and the Catalog of Federal Assistance Number (CFDA) should be included.
- **The award amount.** The award amount including total and incremental funding should be included. It should be noted that money for funding the research will be in the form of U.S. currency.
- **The award period.** This includes the start and end date of the research.
- **Invoicing and payment details.** Information concerning the details about the process for invoicing for payment and other payment details need to be included. This would include the name, address, and email of the accounting research administrator. If using a bank wire transfer, the name of the bank and routing numbers should be included.
- **Deliverables and Reports.** The award notice should specify what deliverables are due and when they are due to the sponsor. It should also specify any reports and when they are due. Reports can include both programmatic reports and financial reports.
- **Terms and Conditions.** These are clauses that detail other terms and conditions to which the award is subject. Additional terms and conditions may be attached as part of the award notice or may be incorporated by reference. It is important to include all flow down clauses required by a sponsor in a subrecipient award or subcontract.

## Award Actions

There are various types of award actions, i.e., what is the function of the particular award. These award actions are usually specified in the award notice. However, the type of award action may be specified in the solicitation and not in the award. The following award actions may result in the issuance of an award.

**New Award.** This is an award action for new research that is funding competitively at the time of the award.

**Continuation and Non-Competing Award.** This is considered to be incremental funding which is approved during the originally funded research award period. It is usually awarded annually on multi-year projects, does not compete with other projects for funding and is based on reasonable progress of the research as detailed in PI reports to the sponsor.

**Renewal or Competing Continuation.** This action entails competing for funding with other applicants for the purpose of continuing the research that was previously funded. It includes the identification of a new award period.

**Supplemental Award.** This action provides additional funding by the sponsor during the award period. A good example of this type of award action is supplemental monies awarded by the National Science Foundation to support Research Experiences for Undergraduates.

## Other Actions

- **Amendments and Modifications.** An amendment or a modification is a written, formal change to an original award. Amendments may be issued to enact a change in any of the following: budget, scope of the research or research plan, key personnel, time and effort of key personnel, administrative requirements such as a change in reporting elements, or notification of the termination of the award for cause or not for cause. For federal grants, amendments or modifications need to be approved not only by the technical officer but also by the financial officer at the department or agency.
- **No-Cost Extensions.** A no-cost extension action is one where the agreement is being extended past the end of the award period with no added funding from the sponsor. An institution issuing a subaward or collaboration should examine its institutional policies and procedures before putting in a clause allowing a no-cost extension with a foreign institution. If the prime institution allows for the extension, it must notify the sponsor before the award period expires.

## Identification of Good Accounting Practices by the International Partner(s)

As discussed in Chapter 4, before entering into an agreement with an international partner or partners it is important to assess whether the international partner's accounting practices are acceptable to both the domestic institution and the sponsor of the research. This includes identification of the type of institution the funds will be awarded to and an assessment of the internal capabilities of the receiving institution for the following: (1) conducting the research, (2) meeting the deadlines for financial and technical reports, (3) completing the deliverables as detailed in the proposal and awarding documents, (4) processing the funding appropriately, and (5) paying all bills incurred as a result of their conducting the research.

**Assessing Award Management Capability.** This term refers to the capacity of the recipient or subrecipient to have in place administrative systems related to good financial management practices including but not limited to good property management policies and procedures and procurement standards and practices. It also includes the institution having good policies and procedures for meeting deficiencies caused by project overruns, good record-keeping practices, and sound financial reporting systems used to monitor award expenditures. It may also include an assessment of programmatic capability and include an examination of a foreign institution's past performance in completing and managing a federally funded or not federally funded award. This would include an analysis of past practices such as meeting performance deadlines, fulfilling reporting requirements and deadlines; submitting acceptable financial and technical reports; putting in place the research plan in a manner that achieves the programmatic and technical goals of the research; exhibiting a certain level of knowledge, experience and qualifications of the research staff to successfully manage the research project and administrative details; and providing the resources that are available to assist the institution in meeting the objectives of the research.

**Site Visitation.** A site visit to the international recipient may be needed to fully assess the financial and programmatic capabilities of the institution. Such a visit would need to be paid by the institution and not through the use of grant or contract funds.





## Managing the Terms and Conditions of the Award

Every grant or contract that is issued has terms and conditions that need to be met. In some cases, the proposal may serve as the basis for assessing whether the grant or contract recipient met their obligations and the terms and conditions of the award. In other examples, the terms and conditions as detailed in the contract will serve as the basis for managing and meeting the requirements of the sponsor.

## Setting up the Subaward Accounts

A U.S. institution, if using sponsor funding to award a subcontract or a subaward, must make sure that it has the permission of the sponsor to enter into a subcontract or subaward. This is especially true for using federal funding to issue a subaward. The awarding institution may decide to issue a fixed price award or a cost reimbursable award. A subaward account as a line item in the prime award may be set up to ensure that funds are available to finance expenditures. Before funds are paid to the international institution, the prime institution must review the subaward invoices. This includes comparing invoices to the budget requirements and funding categories as outlined in the proposal budget. Every invoice should include current and cumulative costs, the dollar value of the invoice, and costs incurred during the performance period. If there is any form of cost sharing or co-funding this must also be documented in the invoice. The invoice must also include attachments or receipts for expenses incurred.

## Subaward Monitoring

Subaward expenditures must be monitored in a timely manner. Expenditures have to be allowable under the terms and conditions of the award. If under a cost reimbursable grant or contract, expenditures must be verified before any payment is made or payment is transferred to the subaward. If the subaward is to receive indirect costs as part of their award, those costs should be reflected on the invoice. In addition to monitoring subaward financial expenditures, subaward programmatic results need to be monitored. Often this is the responsibility of the domestic prime PI, as that individual is the only person who can capably judge whether the research objectives and activities of the subaward meet the programmatic objectives and deliverables as described in the proposal and the awarding documents.

**Audits.** All awarding documents should contain a clause that allows the prime institution as well as the sponsor to have access to all financial documents and to have the ability to audit the expenditures associated with the award on a reasonable basis during business hours and dates. Special care should be taken when reviewing the sponsor's auditing clause so that it does not permit the sponsor to audit the entire institution, but rather limits the scope of the audit to the award. If dealing with federal auditors, most federal auditors reserve the right to audit a single award or multiple awards issued by their respective agency. However, when dealing with crafting the flow-down audit clause, craft it so that it permits as much access to the international institution's records as the main audit clause.

## Transferring Money

Money may be transferred to an international partner if that partner does not appear on any export control data base and the country in which the research will take place and the foreign institution is not under sanctions imposed by the U.S. government. Money may be transferred via a U.S. bank.

## Closeout

Closeout procedures vary from institution to institution. However, certain documentation and reports are always needed. This would include a final technical report, a final fiscal and financial report, an equipment report, other reports listed in the awarding document, and, if applicable, a patent invention report. All subawards should be sent a final release form which allows the prime institution to closeout the subaward account in a reasonable amount of time - usually 60 days from issuance of the release form.

## Uniform Administrative Guidance (UG) and International Partners

When receiving and managing a federal grant, most institutions of higher education in the U.S. must adhere to the regulations of the federal Office of Management and Budget (OMB), specifically the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (the “UG” or “Uniform Guidance”) which are codified at 2 CFR Part 200. These OMB regulations, which went into effect on December 26, 2014, consolidated eight separate circulars into a single circular that applies to universities, state and local governments, nonprofit organizations, and the tribal nations.

The Uniform Guidance sets forth regulations concerning pre-award and post-award requirements, cost principles, and audit requirements. It is a comprehensive document that must be taken into consideration when reviewing, negotiating and accepting any federal grant agreement. Many institutions of higher education not only use the UG to apply to federal awards but also to apply to non-federal awards given to the institution, since it provides a consistent framework for compliance. Some special areas of the UG to consider when preparing an award document include the following:

**Exchange Rates.** Under 2 CFR 200.440 (Exchange Rates), cost increases for fluctuations in exchange rates are allowable costs subject to the availability of funding. Furthermore, prior approval of exchange rate fluctuations is required only if there is a need for additional federal funding or the increased costs result in the need to significantly reduce the scope of the project. Under the Anti-Deficiency Act, the federal sponsor must ensure that adequate funds are available to cover currency fluctuations.

**Value Added Tax (VAT).** Foreign taxes charged for the purchase of goods or services that a non-federal entity is legally required to pay in a foreign country are an allowable expense under 2 CFR 200.470(c). As such, foreign tax refunds or applicable credits under federal awards refer to receipts, or reduction of expenditures, which operate to offset or reduce expense items that are allocable to federal awards as direct or indirect costs. To the extent that such credits accrued or received by the non-federal entity relate to allowable cost, these costs must be credited to the federal sponsor either as costs or cash refunds. If the costs are credited back to the federal award, the awardee may reduce the federal share of costs by the amount of the foreign tax reimbursement, or where federal award has not expired, use the foreign government tax refund for approved activities under the federal award with prior approval of the federal sponsor.

**Recruiting Costs.** Visa costs for recruitment are discussed in 2 CFR 200.463. Under this section of the UG, short-term, travel visa costs - in contrast with longer-term visas for work or immigration - are an allowable cost. However, the institution incurring the costs must show that the visa was issued for a specific period of time and purpose and is clearly identified as being directly connected to the work performed on a federal award. For these costs to be directly charged to an award they must fulfill the following criteria: (1) Critical and necessary for the conduct of the project, (2) Be allowable under the applicable cost principles, (3) Be consistent with the non-federal entity's cost accounting practices and non-federal entity policy, and (4) Meet the definition of direct cost as described in the applicable principles.

As an example, the Standard Processing Fee for an H-1B visa application may be an allowable cost to the research project if:

1. The fee results from a recruitment directly related to the project being charged.
2. Institution policy is to treat the cost consistently as a direct cost.
3. The federal agency guidelines do not include specific prohibitions on such fees or recruiting costs.
4. If, within twelve months after hire, the newly hired employee resigns for reasons within his/her control, the institution will be required to refund or credit such costs to the federal or non-federal sponsor.
5. Short-term visas, issued for a specific period and purpose, that are clearly identified as directly connected to work performed on an award, may also be allowable as a direct charge to a sponsored project.

### Cost Principles and Cost Accounting Standards

Cost principles are associated with federal grants and contracts. However, many institutions apply the federal cost principles to all extramural funding, including those from non-federal entities. Similar to the application of the Uniform Guidance, this provides a level of consistency for managing the compliance of all of a U.S. institution's funding. Costs associated with research funding fall into one of two cost categories: Either the cost is an allowable cost or a cost that is eligible for reimbursement or an unallowable cost that is not eligible for reimbursement either as a direct or an indirect cost. Costs that are not eligible for reimbursement by federal sponsor, commonly referred to as unallowable costs, may still be permissible charges against department or institution funds. While such costs may be paid by the institution they may not be passed on to the federal government through the indirect cost rate.

In addition to the cost principles, there are cost standards that must be met by an institution receiving federal funding before a cost can be considered as allowable. Cost standards require that a cost be reasonable, allocable, and consistently treated, as defined below:

**Reasonable.** A cost is considered reasonable if the cost of the good or service and the amount to be paid reflect the action of a prudent person. This test for reasonableness involves the standard that a hypothetical person would have bought the same item under similar circumstances and paid the same price.

**Allocable.** An allocable cost is a cost of goods or services that can be charged either as a direct or an indirect cost. A cost is allocable as a direct cost if the goods or services provided are assignable in accordance with the relative benefits directly received by the research project. It is also a cost that is incurred solely to advance the work under the sponsored agreement. An allocable cost may benefit not only the work under the sponsored agreement and but also other work of the institution. If the cost benefits more than one sponsored project then the cost must be borne by other awards in proportions that can be approximated. Allocable costs must be based on the benefit to the research. Allocating direct costs must be proportional to the benefit of two or more projects in proportions that can be determined without undue effort or cost. The benefit must be reasonable and cannot be determined because of the interrelatedness of the projects and the work involved. Costs cannot be allocated to meet deficiencies caused by overruns, to avoid restrictions imposed by law or terms of the sponsored agreement, or for other reasons of convenience.

**Consistently Treated.** Costs incurred for like costs must be treated the same, i.e., in like circumstances, as a direct or an indirect cost.

# REGULATORY AND COMPLIANCE

As noted in Chapter 1, international research projects tend to face a greater complexity in compliance regulations than faced by U.S.-only projects. There are several reasons why this is true, but one of the main challenges are the difference of international and domestic practices. One of the root sources of these differing practices is differences between the U.S. and foreign laws that apply to a research agreement. In order to manage these complexities, the U.S. sponsored programs office should establish collaborative teams with participants from their Office of General Counsel (OGC) for legal advice; Comptroller's Office for tax purposes; Office of Human Resources for employment and related issues; Office of Risk Management on issues related to liability; various ethics and regulatory committees (e.g. IRB, IACUC, Health and Safety Office), and the Office of Technology Transfer for intellectual property and material transfer issues.

This chapter attempts to provide a clear analysis of the landscape of regulations which U.S. institutions need to consider when working with international partners and provides further detail and consideration of topics mentioned in previous chapters.

## General Regulatory Requirements

The regulatory requirements discussed below generally apply to research conducted in the U.S. and the addition of an international component requires special attention to any additional host-country requirements.

**Human Subjects.** Internationally adopted standards, codes of ethics, and regulations mandate that any research involving human subjects must be ethically responsible, scientifically worthy, and conducted in accordance with applicable law. The key ethical principles of human subject protection are based in the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report. From these sources, various regulations and guidelines pertaining to the protection of human subjects were created:

- International regulations include Ethics for Researchers (EU), Facilitating Research Excellence in 7th Framework Program-FP7, and the WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants;
- U.S. regulations include 45 CFR Part 46 also known as the "Common Rule" (DHHS) and 21 CFR Part 50, 56 (FDA).

There are also many country specific regulations.

Any research involving human subjects requires review, and approval of the research by an Institutional Review Board (IRB) known in some countries as an Ethics Committee (EC), before the research begins. This requires that both the U.S. institution's IRB and a host-country IRB (if such requirements exist) approve the study. U.S. policy requires that any institution using U.S. federal funds for research involving human subjects must have an Institutional Assurance (also known as a Federal-Wide Assurance, or FWA) approved by Office of Human Research Protections (OHRP), the U.S. office that deals with ethical oversights in research conducted by the DHHS. Through the FWA and the Terms of the FWA, an institution commits that it will comply with the relevant requirements, i.e., 45 CFR Part 46.

**Collecting and Developing Genetic Materials.** Over the past three decades, international treaties such as the International Treaty on Plant Genetic Resources for Food and Agriculture, the Nagoya Protocol, and the U.N. Convention on Biological Diversity (CBD) have been signed to manage the collection and transfer of genetic materials (human, plant or animals) from one country to another. Many of these agreements are designed to provide mutual benefits to all parties and include intellectual property rights to the genetic materials, sharing of benefits from the use of such materials, and biodiversity. As a result of these requirements, many countries have enacted laws that restrict the transfer of genetic materials, including related genetic data, without prior approval from a government entity. If the research project includes transfer of genetic resources, or data, the appropriate university offices (e.g., IRB, Office of Technology Transfer, etc.) should be consulted to determine whether there are any specific requirements and to ensure that appropriate approvals are in place.

**Clinical Trials.**<sup>3</sup> Conducting a clinical trial is a complex activity with strict regulatory requirements that are all the more complex when conducted internationally. Use of data in support of a drug or device submitted to the U.S. Food and Drug Administration (FDA) that was obtained from outside of the U.S. is subject to the same strict requirements as if the data were obtained in the U.S. The major FDA requirements include competency of the investigators (e.g. qualification, training, licensure), compliance with Good Clinical Practice (GCP), IRB review of the study, and close and continued monitoring of the study. Most countries have also adopted specific rules for clinical trials that impose additional requirements and approvals. You should work with your IRB to ensure that the international clinical site meets all applicable requirements. At a minimum, the following questions should be asked:

- Are the individuals who will be conducting the study qualified (e.g., do they have local licensure and certification, as applicable)?
- Does the entity have the necessary licenses, registrations, and accreditations for the proposed work, as required by the country or other local authority?
- Does the entity have the necessary facilities (e.g., laboratories, imaging facility, etc.) and equipment to conduct the study?
- Does the entity have a history of conducting such studies with international partners?
- Does the entity have a good history of regulatory compliance for the conduct of such studies?
- Does the entity have required policies and procedures in place?
- Is the entity financially capable of conducting the study?

**Importation of Plant and Animal Samples.** U.S. Department of Agriculture has strict regulation for importation or exportation of animal, plant, soil, and food samples. These requirements are intended to prevent the introduction of agricultural pests and disease into or out of the U.S. Additionally, there are strict international restrictions on the exportation of certain animals and plants. If the research involves importation or exportation of samples research administrators should contact the relevant offices (e.g., IRB, OGC, Health and Safety) to make sure that it is permitted and that appropriate licenses are in place.

**Animal Research.** Use of animals in research is highly regulated by the U.S. Department of Agriculture (USDA), U.S. Public Health Service (PHS) Office of Laboratory Animal Welfare Assurance (OLAW), and the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). When an international project receives U.S. federal funding, any foreign organization involved in the project must comply with U.S. regulations or foreign regulations that are at least as stringent as U.S. regulations. In addition, AAALAC requires that accredited institutions follow, at the minimum, the U.S. standards of care for all animal research regardless of the source of funding or location of the research.

Any research involving the use of animals must be reviewed and approved by the Institutional Animal Care and Use Committee (IACUC). You should coordinate with your local IACUC, to ensure that all necessary approvals have been obtained.

**Shipping and Transport of Hazardous Materials.** Packaging and shipping hazardous chemicals, radioactive materials and biological materials (e.g., infectious agents and diagnostic specimens such as microorganisms, blood samples, and clinical samples for pathological testing), to and from the U.S. involves certain risks and potential liabilities. As a result, the shipment of certain materials is subject to both import and export requirements, depending upon the nature of the materials, and/or the destination and end-use of the materials. Additionally, safety regulations apply, including training requirements for individuals who package and ship such materials and packaging and labeling requirements for the materials themselves. Please consult the local Office of Environmental Health and Safety (OEHS) and Export Control Officer for guidance if a research project involves shipment of any materials to or from an international site.

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<sup>3</sup>A clinical trial is defined as a “research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.” National Institutes of Health, Notice NOT-OD-15-015, <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html>

**Health and Safety.** Researchers must ensure that they provide adequate health and safety protection for their staff while overseas. This may range from ensuring that researchers traveling abroad have appropriate and up-to-date immunizations, to ensuring researcher's safety during a natural disaster or crisis abroad, to maintaining health and safety standards while setting up a lab or conducting research abroad. In general, most institutions require that, at a minimum, the same standards as those applied to research programs at the U.S. institution be applied to all employees abroad. It is also important to note that funders may require adherence to existing health and safety standards such as Occupational Safety and Health Administration (OSHA) or the NIH Guidelines for Research Involving Recombinant DNA Molecules, wherever the research is conducted.

Research Administrators should consult their international partners and their local Environmental Health and Safety (EHS) and their international or global research offices (if one exists) to identify country-specific requirements and ensure that all appropriate requirements are in place.

**Export Control.** U.S. Export control laws apply to a wide range of designated controlled items, including materials, services, and information. Exports include not only the shipment or transfer of materials and information to another country, but also the release of technical data or information subject to export controls to a foreign national, whether it occurs in the U.S. or abroad. Export control regulations include those implemented by the Department of State through its International Traffic in Arms Regulations (ITAR), the Department of Commerce through its Export Administration Regulations (EAR), and the Treasury Department through its Office of Foreign Assets Control (OFAC).

The export of controlled items, information or software may require approval from the U.S. government in the form of an export license under the ITAR or EAR regulations. An export license permits controlled tangible items or software to be sent outside the U.S. or controlled information or software to be shared with foreign persons in the U.S. or abroad. This could include things such as biological materials, sensors and lasers, and computers. Before carrying, shipping, or otherwise sending materials outside of the United States, you should consult your institution's Export Control Officer to determine whether an export license is required.

Additionally, OFAC administers and enforces economic and trade sanctions based on U.S. foreign policy and national security goals against targeted foreign countries and regimes, terrorists, international narcotics traffickers, those engaged in activities related to the proliferation of weapons of mass destruction, and other threats to the national security, foreign policy, or economy of the United States. The U.S. Government currently has restrictions on transfer of funds between U.S. financial institutions and some countries (e.g., Iran). As a result, you may need a license to spend funds in certain countries or to exchange funds with certain foreign nationals or entities. You should consult with your institution's Export Control Officer before spending funds abroad.

Due to the complexity of these requirements research proposals should be reviewed by the institution's Export Control Officer to assist in determining whether any of the restrictions apply to the country in which research will be conducted or the equipment that is being used.

**Intellectual Property (IP).** International patent and copyright regulations vary from country to country. U.S. patent law vests ownership of IP in the inventor(s); not all foreign patent laws have similar protections. Foreign corporations/entities are generally unfamiliar with the U.S. position on retention of intellectual property and a significant learning curve in the negotiation is required. Your institution's Office of Technology Transfer should be able to provide assistance.

**Publications.** Issues relating to the publication rights should be addressed during the contract negotiation stage of an international research agreement. Most U.S. institutions do not accept any terms or conditions that limit or restrict the right of the faculty to freely publish their research findings. Most institutional publication policies will allow the funder a limited time (e.g., 30 days) to review the publication for proprietary information or trade secrets, but not the approval of the publication of the research findings. The publication provisions must be reviewed carefully to ensure that there are no unacceptable restrictions. Attention to this provision is important as some foreign government funders may require the right to review and approve any publications.

**Conflict of Interest (COI).** The purpose of conflict of interest (COI) policies is to balance naturally-occurring financial incentives held by researchers with the need for unbiased research. Step-by-step, these policies work to identify COIs, and where found, safeguard the project through “management plans” so as to prevent any potential harm as a direct result of a COI. Most often, COIs are “managed” through disclosure of the related financial interest in publications. The next level of management, for when there is a higher risk (including the presence of human subjects), may include independent reviewers of data and the manuscript, additional protections for students, recusal from certain high risk roles in the research, and in unusual circumstances, an outright ban on the project.

Research conflict of interest (COI) policies come from federal law, the project sponsor, and/or the institution, and will flow downward:



Where the language conflicts, law takes priority over the sponsored research agreement, which takes priority over an institution’s COI policy. A prime recipient’s policy will also take precedence over any subawardee’s policies. Where the language does not conflict, all policies apply. While many countries do not have specific conflict of interest requirements, if a project is funded by a U.S. government agency (e.g., NIH,) then the agency policies for COI will apply, regardless of where the project is taking place, even abroad. Unfunded research may be vetted for COIs, also, where institutional policies dictate it.

**Research Data and Privacy Protection.** In our increasingly digital world, research data is being generated in large quantities across a wide spectrum of scientific fields. This increase in available data, most of which is directly generated from human subjects, either as individual participants or as populations (e.g. spending trends, political opinions), has also given rise to concerns over the security of the data collected and the rights – particularly privacy rights – of the research subjects. To address these concerns, governments are enacting laws or regulations regarding the protection of their populations’ data in general, and research data, in specific. Unfortunately, the regulatory frameworks vary from country to country as does the scope of what data falls under each regulation. The following provides a brief summary of the two major international regulations and collaboration regions.

**European Economic Area (EEA):** The General Data Protection Regulation (GDPR) provides a legal framework that sets guidelines for the collection and processing of personal information of individuals in the European Economic Area (EEA), which encompasses all European Union (EU) member states as well as Iceland, Liechtenstein and Norway. GDPR imposes specific obligations on any entity for the collecting, storing, or processing information. For instance, the individual subjects of the affected data may request information on data collected about them, ask for correction of the data, or ask that all of their information be deleted permanently (known popularly as the “right to be forgotten”). GDPR identifies information about an individual that is considered as “sensitive,” including racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data, or sexual orientation; sensitive data is granted additional protections beyond those identified above.

**China:** By contrast China does not have an omnibus data protection law like GDPR. China regulates privacy and cybersecurity issues using three major laws and a handful of accompanying measures, and at least 10 draft standards that deal with both data flows and protection of personal information. The three major laws are the Cybersecurity Law, the National Security Law, and the Anti-Terrorism Law. The Cybersecurity Law's definition of "Personal Sensitive Data" includes personal ID number; bank account information; medical records; biological identification data; and exact geographical location and telephone records. The most significant feature of the law is the "data localization requirement" which mandates that personal information and "important data" collected or generated in China must be stored in China.

In addition to China, at least another twenty countries have formal laws restricting transfer of personal, accounting, tax, and financial data outside of the country.

Due to variations in the requirements for data protection, researchers embarking on global collaborative research should work with their collaborators to understand the requirements for the collection and storage of data in the country of their collaborator, as well as the transfer of data out the country.

Because information stored on a laptop can be at great risk for theft or corruption often researchers will commit to using encryption software which may be subject to export control requirements when crossing some borders. Please consult your institution's IT department for assistance with data privacy and security issues.

**The Foreign Corrupt Practices Act.** The Foreign Corrupt Practices Act of 1977 (FCPA), codified at 15 U.S.C. §§ 78dd-1, et seq., is the U.S. law known as the "Anti-Bribery and Books & Records Provisions of the Foreign Corrupt Practices Act" with two main provisions:

- Accounting transparency requirements under the Securities Exchange Act of 1934 (amended OCT. 13, 2009)
- Prohibition against bribery of foreign officials (§ 78dd-1 of the Act).

Any payments made to foreign government officials for "facilitating" the research needs to be carefully reviewed to ensure that it does not violate FCP, and that any payments are authorized under host country's written laws and that the payments are reasonable and for a legitimate purpose.

The Principal Investigators should establish an ongoing monitoring program whereby their primary contact person in the foreign country provides routine progress reports on the status of the project, staffing, financial reports required under the terms and conditions of award/contract and any problems that have arisen.

**Arab League Boycott of Israel.** According to a document published by the U.S. Department of State analysis the Arab League has "maintained an official boycott of Israeli companies and Israeli-made goods since the founding of Israel in 1948 ... the United States actively opposes the boycott and works on both bilateral and multilateral fronts to end it." The boycott includes prohibitions against three primary activities:

- The primary boycott prohibits the importation of Israeli-origin goods and services into boycotting countries.
- The secondary boycott prohibits individuals, as well as private and public sector firms and organizations, in member countries from engaging in business with any entity that does business in Israel. The Arab League maintains a blacklist of such firms.
- The tertiary boycott prohibits any entity in a member country from doing business with a company or individual that has business dealings with U.S. or other firms on the Arab League blacklist.

Even though the overall enforcement of the boycott by member countries is sporadic, researchers and administrators need to be aware of this boycott if conducting research in any Arab League member country. Research administrators need to review the agreement with foreign entities carefully to make sure that there is no such language in any documents.

**Material Transfer Agreements.** Material Transfer Agreements (MTAs) specify the rights, obligations, and restrictions of both the providing and receiving parties when tangible research materials are transferred from one organization to another. Key issues include ownership, publication, intellectual property and permitted use and liability. The party or office negotiating an MTA in an international setting should be particularly careful of export control issues, as discussed above.

## Unique Requirements and Considerations

The following section provides a brief discussion of some of the unique issues and requirements, which ordinarily are not encountered during the conduct of research in the U.S., that are important considerations.

**Visa.** Many countries have an entry visa process that requires the traveler to obtain the appropriate type of visa prior to entry to the country. Different countries have different application processes and requirements, stay-time limitations, and fees for each type of visa and in some instances the visa may impose specific restrictions on what the traveler may do (e.g., the ability to work, conduct research, restriction on travel within the country). It is important that the researchers be advised to contact the embassy of the country where the research will be conducted to determine the proper type of visa and the time required to obtain the necessary visas. This should be done as early in the process as possible to ensure timely completion of the required paperwork for obtaining a visa. In addition to the host country embassies, the researchers should also be advised to review U.S. government websites for additional information on any travel related restrictions or requirements.

**Immunization and Vaccinations.** Depending on the country, there may be specific immunization and vaccination recommendations that the researchers may need to fulfil prior to departure. These recommendations change depending on the regional disease outbreaks or epidemics and researchers should be advised to review the information regularly prior to travel to a foreign country, and while overseas, to determine specific needs.

**Hiring Locals or Assigning U.S. Personnel.** Recruitment and placement of staff in foreign countries, whether U.S. citizens or locals, is a complex issue that requires careful considerations. Major human resources issues may include the following:

- Host country rules regarding the employment of expatriates or local personnel triggering payment of in-country benefits or employment taxes;
- Requirement for written employment contracts;
- Mandatory participation in host country social benefits and retirement schemes; and
- Vacation and sick leave payment requirements for foreign country nationals employed for the project.

Research Administrators should consult with their Human Resources, or General Counsel Office, if the research project includes hiring of local personnel or assigning of U.S. personnel for extended periods of time.

**Procurement of Supplies and Equipment.** The research team should be asked if they intend to procure equipment or supplies in the host country, or to ship them from the U.S. If they intend to do so the research administrators should obtain as much specific information regarding the equipment and supplies as possible. Such procurements or transfers may be subject to export control requirements and must be reviewed carefully. In addition to export control requirements, in some countries purchases or ownership of equipment, or leasing of space, is considered as having established a “Permanent Establishment” that may trigger business taxation requirements. Research administrators should consult their Procurement/Purchasing and the Office of the General Counsel for guidance.

# CONCLUSION

Using a research project lifecycle as a roadmap, this publication has been developed to provide senior leadership, research administrators, and faculty at U.S. institutions with a detailed overview of pre-award and post-award issues likely to be encountered when dealing with research in a global setting. Based on the guidance provided herein, the authors hope that these individuals feel better prepared to understand the complex challenges of working with international entities – from finding appropriate partners, planning the work, engaging in the research project and ensuring compliance and coordination throughout. For each of these stages of an award's lifecycle, there are many more resources that can be explored for greater detail and guidance.





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