

FRONT COVER

INTRODUCTION

Negotiation is the ***interaction*** between partners that occurs throughout the different levels of development of a research partnership. Often regarded as a difficult process to navigate, the process of negotiating is in fact based on a set of skills which can be learned and mastered with time.

Key to a successful negotiation is understanding that, with the right approach, almost ***anything is negotiable*** and appreciating that a ***fair*** and ***mutually beneficial relationship*** means that partners enter negotiations with mutual ***respect, and balanced power***. This is particularly important when partners might appear to be different levels of bargaining power.

Negotiation is not a dry technical process that can be easily documented but rather rests in softer, more tacit interpersonal skills. This includes core values such as ***adaptability, effective communication, empathy, trust, honesty, openness, curiosity, creativity, innovativeness, good faith, patience, respect and tolerance***. All these traits are vital to a dynamic and collaborative research environment.

As a negotiator in a potential research partnership, you have the right to ask for your ***fair share of the benefits*** of a joint endeavour. While it won't always be a 'win-win' situation in partnerships, the ***overarching goal of negotiations*** in research contracts should always be to strive toward ***a mutually fair and beneficial partnership***.

This booklet aims to provide guidance for better negotiation outcomes in a ***3-stage approach, based upon the lifecycle of a research contract***. The approach suggests some enabling guidance on improving negotiations in the research collaborative environment, with emphasis on the softer, more tacit skills rather than specific technical areas.



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CLARIFY YOUR NEEDS AND BOUNDARIES

Prior to engaging in the process of partner identification and partnership development, the question of how your organisation intends to benefit from collaboration, and any restrictions and limitations your organisation may have in such collaborations needs to be clearly mapped out. Mapping out both what you can bring to and, importantly, what you want out of a partnership needs to be evaluated. To be an effective negotiator, you need to have a good sense of your asks, and also of your boundaries.

Establishing your organisation's **needs and boundaries** includes having an understanding of:

- your current capacity and capacity gaps (training, resources, equipment),
- your expectations and needs from a partnership
- your organisation's internal policies, principles, values and priorities in relation to other organisation(s).
- an understanding of the reputational risk of failure
- a clear mandate from your organisation for pursuing a partnership

By going through this process, you not only establish what you might need to ask for, but you also start to recognise more clearly your limitations and your possible 'fall back' positions in the negotiation process.

Moreover, you can win the **internal support** you need to strengthen your position in negotiations, while further assisting you in knowing how far you can go (your **negotiation limits**) and whether you are able to take on the partnership. It is a **good practice in negotiations** process to know that your organisation is completely behind you, and allows you to refer upwards when it is strategically sensible.

IDENTIFYING POTENTIAL PARTNERS

The identification of potential partners should be based on your identified needs and boundaries. This will mean that in identifying your potential partner, you gather **all available information about them, map out what offer you and review their fit in terms of their aims and objectives** (including information on their interests, needs, priorities, policies, opinions, strengths, weaknesses and resources in order to argue on the basis of logic, and evidence).

In addition to this, you need to assess whether they share the same values and mission as your organisation, or whether they are likely to subvert your objectives. What is their opinion on issues that are important to you and what are the likely limits they will go to in negotiations? This may mean investing considerable time in getting to understand their perspective and what they want out of the potential partnership as well as what resources they have to offer (i.e. conducting a ‘suitability match test’). It is definitely worth researching contacts you have who may have entered into partnership with them in the past to gain additional insight.

An additional tip to consider is whether there are organisations who are able to help you identify partners based on your identified needs. Especially helpful is when these partners can then also act as a neutral, trusted broker during the negotiation process. An example of a mechanism for partnership facilitation is the WIPO:Research Partnership Hub, administered by Bioventures for Global Health (BVGH).

Once you have identified a potential partner, it is important to **build a mutually agreeable platform for negotiations**. Key to this process is building a strong relationship. The values of **trust, availability, flexibility, openness and honesty, accuracy, transparency, consistency, and timeliness**, should underpin your interactions with the potential partner.

CASE STUDY IDENTIFY YOUR PARTNER

Dr. Dennis Liotta is Professor and Director of the Emory Institute for Drug Development. Dennis and his colleagues developed an antiviral drug called Emtriva™ which is now used by more than 90% of all HIV-positive patients in the United States. Dennis was interested in connecting with an expert in dengue biology, and used WIPO RE:Search and Bioventures for Global Health (BVGH) as a mechanism for doing this.

Dennis believed the RNA-dependent RNA polymerase inhibitors he had developed had promise as new therapies against dengue fever. “My lab has developed polymerase inhibitors among other antivirals, but different viruses have different RNA-dependent RNA polymerases, so it wasn’t clear whether or not the inhibitors would demonstrate sufficient activity against dengue polymerases. We knew we needed to connect with experts in dengue biology that could help us test our compounds,” says Dennis.

BVGH met with scientific administrators and program officers at the National Institutes of Health (NIH), including Dr. Cristina Cassetti, Program Officer for Acute Viral Diseases. She explained that the NIH, more specifically the National Institute of Allergy and Infectious Diseases (NIAID), could help support Dennis’s drug discovery efforts. A teleconference was arranged to connect Cristina and Dennis so they could discuss the dengue project and how Dennis could gain access to in-kind support from NIAID. One critical aspect of the support offered by NIAID was its ability to perform in vitro antiviral screens against the four dengue virus serotypes.

Following the discussion, the NIAID and Emory signed a ‘non-clinical evaluation’ agreement that would allow NIAID-funded contractors to test the compounds in vitro for efficacy against dengue viruses. Some of the compounds are looking promising against Rift Valley fever virus and Dennis is now considering how to collaborate to develop them further.

This simple case study illustrates how important it is to research potential partners, and see how they match and can meet your needs. It also illustrates how having a ‘neutral broker’ such as BVGH to facilitate the relationship can be especially invaluable.

KNOW YOUR PARTNER: TYPES OF RESEARCH PARTNERSHIPS

Different types of partnerships may raise different kinds of contractual issues. The type of institution and the sector they are positioned in (for example, private or public) will influence the extent to which the issues covered in this guidance document factor into the contract negotiations. A research partnership taking place between a private and a public organisation will have different parameters to one between two public institutions. A private-public partnership is increasingly seen as an effective model for achieving health gains, but can raise particular issues around research ownership, benefit sharing and intellectual property. It is important to be aware of the context of the partnership and the parameters or drivers of each partner’s research agenda.

The interaction point between two or more partners in a partnership will be influenced by the different requirements of each organisation in terms of the rationale or purpose of the research, the intended contributions or input by each partner, the expected outputs or benefits for each partner, and the policy and legislative context in which each institution operates. Note, too, that partnerships are often between more than two organisations; there are networks and multiple pathways through which contributions are made. It might be helpful to identify other partnerships involving local or similar institutions, and find out what challenges were encountered in negotiating and implementing the contract and how these were resolved. (Marais, D. 2013, p8).

CLARIFY YOUR OBJECTIVES

Prior to engaging in negotiation you must clearly set out your needs, how you expect to benefit from the collaboration, and what you bring to the collaboration. You should try to identify and fully cost your financial needs, what access to the benefits of research (e.g. publications) you think is fair and what opportunities for capacity building there might be.

It is good practice to establish a range for negotiations such as ideal, acceptable and minimum set of objectives. Intuitively, you should only be prepared to disclose this information with a potential partner as negotiations progress, always starting with the ideal objectives.

For example, if a partner is not willing to meet with your ideal set of objectives, then you can negotiate your next level of objectives. However, where a potential partner is not willing to accept your minimum set of objectives, this can also be used as a useful red flag. You will have to decide whether at this point to walk away from negotiations. So, by establishing a full range possible objectives, this provides you with a frame of how far to go with negotiations and when to present the next level, and when, if needed, to end negotiations.

The risk of maintaining negotiations where a potential partner does not accept your minimum objectives or presents a completely different set of objectives means that you place your research activity and institution at a great disadvantage (wasting resources; financial or otherwise). Remember that not every negotiation you enter into will end in a partnership. The trick is to know when a potential partner represents a risk or burden rather than an opportunity, and then to appropriately close the negotiation.

In addition to this, it is important to note that both sides have strengths and weaknesses and in order to engage in a fair and equitable negotiation process, it is good to be aware of what these are and how they affect each partner. For instance, what do you offer that they lack or what do they have which you lack? It is important to remember that they see something of value in engaging with you. Having a mutual understanding of what each partner's objectives are, and the benefits each partner contributes will help in achieving a mutually beneficial outcome.

CASE STUDY THE PATH EXPERIENCE

All projects come with their own unique challenges, particularly when multiple partnerships are involved. In the case of the START project, PATH was able to avoid some common pitfalls by carefully selecting its partners and being very clear about its objectives and what it could offer, and also what PATH needed from the partnership..

For example, because PATH came forward with links to clinical researchers and policy-makers, and because it had a solid understanding of the specifications that any new cervical-cancer-screening test would need, PATH was able to attract two top-tier industry partners that had the expertise and capacity to move product development forward. These partners were attractive to PATH because they owned proprietary control of the key reagents needed for their specific technologies. This allowed the project to avoid the even more uncertain, complex, and lengthy negotiations necessary to bring multiple IP holders into a workable product development project.

PATH also provided access to well-characterized, highly sought-after clinical specimens from countries outside the industry partner's normal research networks. In addition, PATH offered the opportunity for major field-based clinical assessments of final products, assessments that would be sufficient for product registration in those countries.

As a result, the two industry partners realized that working with PATH would provide a unique opportunity to reengineer their product (in the case of one partner) or develop a new product (in the case of the other partner) to address lower-price market segments, thus gaining valuable inroads into the challenging but attractive markets of India and China. Without the PATH program incentives, it is unlikely that either company would have undertaken these major efforts to adapt and develop their technologies for use in developing countries.

(Taken from Krattiger A, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez and SP Kowalski. 2007. Editor's Summary, Implications and Best Practices (Chapter 17.17)).

PREPARATION IS KEY

Preparation and due diligence is essential before entering into any kind of negotiation with a potential partner. Take the time to **assess your negotiating position** as and gather information about your potential partner. Information can involve a thorough investigation of **facts, figures, documents, pro forma contracts, priorities, information** about partnerships the funder has already engaged in, and any additional knowledge from your contacts that could potentially have weight on a negotiation.

No matter what your style of negotiating, it is important to have prepared **relevant data and material** in negotiations to support or convey your negotiation points in a factual and evidenced based manner.

CASE STUDY

TUBERCULOSIS (TB) IS NOT A NEW DISEASE

Modern genetic analysis suggests that humans infected with *Mycobacterium tuberculosis*, the causative agent of TB, may have migrated from Africa more than 50,000 years ago. As populations grew and distributed themselves across the world, TB came along for the ride. Existing tuberculosis treatments are decades old and are primarily restricted to the developed world. Eighty-five percent of the world's people battling TB live in Asia and Africa, with many having limited access to life-saving medication.

iThemba Pharmaceuticals, a company based in South Africa, is working on a special class of compounds, known as isocitrate lyase inhibitors, to target TB. Scientists at iThemba had characterized a library of novel isocitrate lyase inhibitors that demonstrated activity against *M. tuberculosis* during in vitro testing. In order to move into the next phase of discovery, **their team needed access to computational chemistry capabilities. Sorting through thousands of compounds to select a lead candidate capable of becoming a clinical drug requires extensive testing, which can take years to complete.** One approach to accelerate compound selection is to use predictive computer models. These computer models are used primarily by large pharmaceutical companies to increase the likelihood of success for products in their early clinical pipelines.

During an introductory phone call with BVGH, the **iThemba scientists summarized their work on TB and inquired about gaining access to computational chemistry support. BVGH approached AstraZeneca, who had already expressed its willingness to provide WIPO Re:Search members with access to internal computational and predictive chemistry resources.** AstraZeneca's research center in Bangalore, India focuses almost exclusively on TB and malaria research and development. Their scientists are highly skilled in the precise type of computational support iThemba needed. A conversation was facilitated between AstraZeneca scientists and iThemba researchers. **Within a couple of months, a Confidentiality Agreement had been signed between the two organizations, allowing the isocitrate lyase inhibitor project to begin.**

Results from the computational analysis will guide iThemba's efforts to select and develop the best lead candidate for further development. **Without the ability to analyze their compounds using AstraZeneca's computational models, the researchers in Cape Town, South Africa would face years of complex, expensive experiments, delaying the development process.** WIPO Re:Search partnerships are speeding the research and discovery of new drugs to treat diseases of poverty.

UNDERSTANDING INTERNAL PROCESSES

Learn what you and your partner organisations' **internal processes and procedures** are. For example, **knowing who is the authorized person for entering into negotiations**, who has the legal authority to sign contracts, etcetera. You want to be sure you are dealing directly with the relevant person, or with a person who has delegated authority to enter into negotiations.

By doing so, you are able to establish whether there is an internal policy or criteria to admit or deny projects before starting the partnership or how you wish to approach your negotiations to potential partners and ultimately you pave the way for **creating interest** in negotiating in research partnerships.

Looking at this issue from a slightly different angle, having agreed institutional procedures and policies also puts you in a stronger position in negotiations. For example, having a developed capacity building strategy, helps you to understand quickly your organisation's prioritised capacity building needs. You can refer directly to your organisations policies and strategies during the negotiation, given your asks greater weight.

CASE STUDY

THE AFRICAN AGRICULTURAL TECHNOLOGY FOUNDATION APPROACH TO IP MANAGEMENT

Execution of agreements for smallholder farmers in Africa, yields of major staple crops (maize, sorghum, millet, cassava, cowpea, bananas/ plantains) have remained stagnant or even declined in the past 40 years. Numerous biotic and abiotic stresses have contributed to this dire trend. Local research efforts to overcome these stresses have been hampered by declining support for agricultural research, limited access to elite genetic material and other technologies protected by IP rights, and the absence of commercial interest in these crops from private owners of agricultural technologies.

The African Agricultural Technology Foundation (AATF) is a new initiative addressing the challenge of reversing the negative trend in agriculture by negotiating access to proprietary technologies and facilitating their delivery to smallholder farmers in Sub-Saharan Africa. **AATF believes it is essential and indeed good IP management practice to finalize all contractual terms, set them out in writing, and have an agreement duly signed by the authorized representatives of the parties before commencement of any engagement. Therefore, AATF ensures that all arrangements with third parties associated with the access to or the creation, use, or exploitation of IP protected materials are appropriately documented.**

Documentation for the Cowpea Improvement Project, for example, will, in the end, involve several agreements between AATF and its collaborating partners. First, AATF obtained a license from Monsanto, and thereafter sublicensed the licensed Bt gene to CSIRO and IITA in order to introduce the Bt gene into the cowpea genome. The AATF, potentially, will sublicense the resulting successful transgenic events to African agricultural research institutions, which will introgress the Bt gene in cultivated cowpea varieties. These varieties would then be licensed to commercial, nongovernment, humanitarian, or public institutions charged with disseminating the improved cowpea varieties in Africa.

(access online via <http://www.iphandbook.org/handbook/ch17/p18/> on 23 April 2014)

SEEK ADVICE



Make sure you seek advice, if needed from different organisations that might be able to provide assistance with the contracting process. For example, pro bono organisations exist such as Public Interest Intellectual Property Advisors (PIIPA) are a network of pro-bono IP lawyers, PIIA who may be able to help you think through elements of the draft contract and their implications. The World Intellectual Property Office has a vast range of resources for thinking through intellectual property considerations. BVGH, as mentioned earlier, can help to identify, and then introduce, possible partners. The Council on Health Research for Development (COHERD) has a range of publications aimed at research organisations with limited contracting capacity.

Try to map all the internal components of your organization which you may need to access in order to put a contract in place (e.g., a business office, the tech transfer office, the legal office). According to different issues contained in the contract, and the capacity of your organisation, you might need to identify who else might be helpful in your institution – e.g. financial, legal, clinical areas. Be sure, if it is mandatory, to consult a specialist area (such as a research ethics committee where human subjects are involved). In addition to this, if your institution does have a legal unit, or an individual with responsibility for legal affairs, it is good practice to involve them from the earliest possible stage of negotiations. They can provide useful assistance with the terms in the contract phase to during negotiations but in order to do so need a complete understanding of what the partnership is designed to achieve.

Other valuable skills that could be sourced are those from other institutions in your local and regional networks – other scientists, accountants and project managers who may have experience in negotiations and contracting in the research environment.

EXAMPLES OF
IMPORTANT
SOURCES OF HELP
Public Interest
Intellectual Property
Advisors (PIIPA), Council
for Health Research
and Development
(COHRED), World
Intellectual Property
Organisation(WIPO),
World Health
Organisation(WHO),
BIO Ventures for Global
Health(BVGH)

CASE STUDY

Research institutions in African countries offer local scientists an opportunity to be a part of the global movement to develop effective and affordable products for neglected tropical diseases – diseases that these researchers and their communities are intimately more familiar with than developed world researchers. They personally see the devastating results these diseases can have in their communities and often have suffered from them individually. Yet, while these diseases cause the greatest burden within these regions, African institutions frequently lack experienced staff and resources to facilitate moving a new discovery through preclinical and clinical development and manufacturing to commercialization.

To address this gap in research and development, IP Australia, a branch of the Australian government, provided funds to WIPO to financially support sabbatical arrangements for African researchers at international pharmaceutical and academic institutions. Through the WIPO Re:Search consortium, BVGH identified African scientists who could benefit from further training and matched them with international organizations that could provide that training and experience. BVGH learned that Novartis had an interest in building relationships with researchers from African countries and institutions. BVGH presented the sabbatical program to Novartis and they quickly responded with interest in hosting one or more researchers from African academic institutions at its Basel, Switzerland headquarters. BVGH went to work to identify senior African researchers who were interested in spending three months with Novartis in Switzerland. Two scientists were selected: Dr. Fidelis Cho-Ngwa, Associate Professor of Biochemistry, University of Buea, Cameroon, and Dr. Wellington Oyibo, Associate Professor, College of Medicine, University of Lagos, Nigeria, who have backgrounds complementary to programs at Novartis.

Fidelis and Wellington were enthusiastic about gaining a broad experience at a large pharmaceutical company. Novartis organized telephone interviews with each candidate to ensure alignment of expectations. Following the interviews and review of submitted written proposals, the administrative planning got underway for visas, travel plans, housing, and local temporary healthcare. "I see this as an opportunity not only to gain invaluable experience and knowledge from a world-class company like Novartis, but to develop relationships and collaborations that I can leverage to advance my research upon my return to Cameroon," says Fidelis. "The chance to participate in a sabbatical with Novartis was an amazing opportunity – one which I will utilize to gain skills and knowledge to fill the gaps in product development at my home institution. I am also excited by the opportunity to transfer my new skills to my students at the University of Lagos," says Wellington. The sabbatical opportunity has been a fruitful experience for all. Both Fidelis and Wellington have built relationships with Novartis scientists that will continue long after their return home. Plans to collaborate beyond the sabbatical are already being explored and planned. "We are extremely happy that we had the opportunity to host both Wellington and Fidelis. They have been wonderful colleagues to our team here in Basel, and we have enjoyed learning from their perspectives and insights. Building relationships and sharing our capabilities with researchers in Africa is core to our values and desires to develop new products to treat infectious diseases," says Petra Keil, Head, Global Public Policy at Novartis.

STYLES OF NEGOTIATION

There are many styles of negotiation. Ideally, **direct communication** of interests, expectations, beliefs, and concerns is the best approach. This approach can also mean disclosure and/or exchange of certain documents/information, perspective, and possibly mutual brainstorming of different methods to reach joint solutions, and to encourage open, honest discussions.

Consider a principle-based approach to negotiation: "principled negotiation, which focuses on differences in interests, is an effective tool for much dispute resolution. It concentrates on creative problem solving and fair accommodation of diverse interests" (Bammer, 2008, p. 880). Focus on how different goals and diverse perspectives can be integrated to achieve cooperative objectives and outcomes.

Cross cultural and cross-linguistic differences can often cause people to misunderstand each other and thus the need to approach negotiations with the notion that partners will have different styles in negotiating, is important to bear in mind. Most importantly partners need to respect each others different approaches, and continue in the spirit of **adaptability, effective communication, empathy, trust, honesty, openness, curiosity, creativity, innovativeness, good faith, patience, respect and tolerance**.

Negotiations should involve a joint decision making process, by all partners with decisions clearly indicated, accepted, and clearly documented.

CASE STUDY THE IMPORTANCE OF STRONG INSTITUTIONS

Given the abundant obstacles to equitable agenda setting, the strength of the LMIC institution in a HIC-LMIC partnership stands out as the primary factor affecting the successful negotiation of research agendas that are both mutually beneficial and rooted in LMIC priorities. Currently, many partnerships are premised on the assumption that all those involved are well-intended, well-informed, culturally sensitive people, and that these qualities are sufficient for equitable agenda setting. While good intentions and respect facilitate smooth agenda-setting processes, they cannot substitute for the advantages that strong LMIC institutions enjoy in partnership negotiations. In the context of research partnerships with high income partners, strong institutions are characterised by a realistic awareness of their own strengths and weaknesses; sound administrative systems; and relatively stable finances. Most importantly, they have a clear institutional mandate and agenda. Bradley, M. (2008). On the agenda: North-South research partnerships and agenda-setting processes. *Development in Practice*, 18, 673-685.

STRATEGIES FOR DIFFICULT NEGOTIATION

There are instances in negotiations where partners cannot agree or for some reason negotiations are disrupted, put on hold, or dropped completely. When this takes place you should plan on how they could be handled. Ideally, you should have a strategy established beforehand, identifying what you think likely pressure points will be, and how to approach conflicts.

If, in such an instance, a partner holds a strong position that they are not willing to move away from, it could mean that instead of issuing an ultimatum (i.e. take-it or leave-it approach) - which could halt or dissolve negotiations, it is at this point that should you clarify and rationalise your approach to your partner on the basis of the evidence and documentation you have collected, or in the light of your organisations existing policies and strategies.

Then, you might consider reentering the negotiation with an alternative/fall-back position (also known as BATNA, best alternative to negotiated agreement). The key is to have an acceptable approach which is acceptable to you, and does not

lose focus on your main objectives and interests, which brings both partners to a fair and mutually beneficial outcome so that neither is disadvantaged

Although it is good practice to try and find ways to agree during negotiations, there are instances when you cannot put off bringing up difficult and significant issues that could potentially cause major obstacles to a research activity. Thus by tactfully bringing up these issues early during the negotiation phase, you are able to deal with each other's perspectives and open discussion for solving potentially detrimental problems later by exploring solutions early. You can also more easily create the opportunity to engage in joint identification of solutions, leaving enough time to seek agreement internally.

CASE STUDY

STAGE 2: CONTRACTING

FINALISING NEGOTIATIONS

Formalise all negotiations in writing and ideally in formalised contract. This will bind all partners (institutions) to its requirements by the signatures of all authorised signatories to the contract. Where arrangements are made and are not formalised in writing, it may give rise to complications and misunderstanding between partners. Therefore it is strongly recommended that negotiations be finalised in writing, even if not in a formal contract.

For the same reason, be simple, clear and precise while discussing the terms of the contract through any means, especially written. Your words might become the means through which the terms of the contract are interpreted. Conversely, if you do not understand a concept in the negotiation, an 'ask' of your partner, or a term or phrase in the contract, have it clarified, and documented. The implication is that a relationship can break down where there is misunderstanding and no clarity over even the most minor issues in negotiations. If you don't understand something now, a third party may have difficulty interpreting it later.

It cannot be over emphasised that the signatures on the contract are the authorised signatories to the contract.

Written agreements which are translated into contracts are an important mechanism in formalising what is agreed to during negotiations. This ensures that all partners understand each other. A contract is thus not just a piece of paper that must be signed but rather should be viewed as a vital document that continues to exist and is referred to during, and often after the lifespan of the partnership itself.

It is important to read the contents that all agree to, sign it and then keep a record and store the signed contract in a secure, accessible place. Fundamentally, all that is negotiated must be recorded and eventually formalised in a contract which aims to speak to what was agreed to by all the partners during the negotiation process. This becomes enforceable, and should be honoured throughout the lifecycle of the research project. This includes being sure to set out and agree on the deliverables (such as potential benefits of intellectual property(IP)) and being clear about expected outputs of the research including the status of IP that arises from the research agreement, authorship, data ownership.

CASE STUDY

CONTRACTING

Compile a historical record of all the information and communications shared during negotiations. Make sure all conversations (for example, emails, Skype, etc.) are kept stored. They represent the intentions of both parties and can be also useful if any clarification is necessary or to a third party or a new partner to understand the agreement afterwards. Remember that people leave and join organisations regularly as part of normal attrition and recruitment and may not be able to be consulted with again or may not understand what has happened before they joined.

What has been negotiated should end in a signed contract. Understand clearly the obligations and the final objective before looking for a model of contract. Be aware of alternative contract models. They may also have unnecessary clauses or absent terms to be completed or added. Examine prior contracts to understand what you might need to obtain to fulfill the contract. Remember to seek advice.

Many funders often prefer to use their own template agreements but it is always good to check if this is the appropriate type of contract and indeed addresses your needs. Simply because it is a pro-forma contract does not mean its terms are not negotiable.

Be sure that the contract/agreement is not in direct conflict/contradicts any of the interests/objectives that have been established in the pre-contracting phase. If there is a conflict then this should be weighed against the legitimate expectations of both partners and a decision should be made to either pursue further negotiation or to 'let-it-go'.

A good place to start for help with contract basics is the "Lambert Review" (see xxx) for a set of standard agreements/contracts. This project was set up to assist in collaborations taking place between Industry and Universities.

It is important that each partner carefully reads and confirms the terms of the contract to confirm that which was agreed to during negotiations is clearly communicated in writing before it is finalised and signed. Ultimately a written contract should conform to what was agreed/intended during negotiations.

If the contract is more complex prepare a checklist with the necessary information you will need. Improve this checklist and create others according to the new agreements you discuss.

CASE STUDY

The University of Washington (UW) sprawls across several dozen acres of scenic real estate in Seattle, Washington. Long an academic powerhouse of scientific research, UW is home to scientists who are committed to discovering new, promising drugs to treat malaria. While attending a conference, Jennifer spoke with Dr. Wesley Van Voorhis, Professor of Medicine and Head of the UW Allergy and Infectious Disease Division. The nascent WIPO Re:Search consortium was growing and the two discussed UW becoming a member. "Having the University of Washington's Department of Medicine as a South Lake Union neighbor makes it particularly convenient for BVGH to explore various partnership ideas and proposals with faculty. Not only is its infectious diseases group (or Division) among the top in the world, UW is also known for its bioengineering and chemistry strengths. Each of these groups represents critical components necessary for product discovery and development. Most importantly, there is important and innovative R&D ongoing for diseases of poverty," says Jennifer. Shortly thereafter, UW officially joined WIPO Re:Search as a Provider and User Member. The Partnership Hub wasted no time identifying synergies between UW scientists' research and those of other WIPO Re:Search members.

BVGH successfully connected UW researchers led by Wes with experts working in GlaxoSmithKline's (GSK) Malaria Discovery Performance Unit (DPU) in Tres Cantos, Spain. It was agreed that Wes's team would send their 1294 compound to the Tres Cantos lab to be re-profiled through a battery of tests performed by GSK researchers. Over the next few weeks, as calls were held to arrange the compound's transfer, both groups discussed previous screens performed by the UW scientists on the GSK Tres Cantos Anti-Malarial Set (TCAMS). These screens had been commissioned by another WIPO Re:Search member, Medicines for Malaria Ventures (MMV). MMV provided financial support and guidance to UW on the discovery of protein kinases targeted by the TCAMS anti-malarials discovered by GSK and MMV continues to work with and support Wes's team.

GSK is devoted to maintaining its open, collaborative approach to malaria drug discovery by offering unrestricted access to the dataset and compounds. Through the TCAMS and other GSK initiatives, GSK hopes to stimulate more neglected diseases drug discovery and partnerships that will fill the pipeline for diseases of poverty and ultimately eliminate these diseases," says Nicholas Cammack, Senior Vice President, Diseases of the Developing World, GSK. Previous work completed by Wes's group identified 80 compounds in the TCAMS that appeared to target specific enzymes, called protein kinases, within the malaria parasite. Inhibitors of these kinases were predicted to result in a reduction in transmission.

SETTING TIMEFRAMES

Be aware of timeframes and deadlines for preparing and finalising offers/submissions.

Negotiating is a process that requires the luxury of time. The more time you have, the more opportunity to create solutions to barriers, and to reach a mutually acceptable conclusion. It must be emphasised that it is always good practice to set negotiating timeframes for partners to work within as this can impact a project's commencement point and hence the project deliverables.

Timelines are also critical when considering the execution and closure of research activities, as well as when the payment of funds are made and received, deliverables completed and a researcher's opportunity to make timely and relevant publications based upon the outcomes of the research.

CASE STUDY

STAGE 3: POST CONTRACTING

EXECUTING THE CONTRACT

Throughout the lifecycle of the research project, research partners should ensure that everything relates back to the requirements of the contract and what has been negotiated. For example, when payment is received, deliverables and timelines.

Post contractual means that the agreement is already signed and the obligations now need to be fulfilled by all parties of the contract. If there is another person in your institution who will conduct the project established through the agreement, make sure that the obligations are well understood by that person. If necessary, make a short resume of the agreement with a list of what your institution needs to delivery, by when and what to expect.

Pay attention to the validity of the agreement. If there is a need to extend the obligations, it can to be done through a simple document, such as an addendum, while the contract is still in place to effect a no-cost extension. Otherwise, it may mean setting in place an entirely new agreement which can be a difficult and lengthy exercise to carry out, and risk re-opening issues which were considered settled in the original contract.

CASE STUDY

CLOSE-OUT OF A RESEARCH PROJECT



CASE STUDY

At an American Society of Tropical Medicine and Hygiene (ASTMH) conference, Jennifer and Roopa met with Drs. Frederick Duncanson, Senior Director and Infectious Diseases Clinical Lead, and Michael Everson, Associate Director-Clinical Research, of Eisai. Fred and Mike described some of the challenges Eisai was having with an anti-fungal compound it had developed. The compound was highly protein-bound and had bioavailability and solubility limitations. They were interested in obtaining the opinion of other scientists who had experience with this type of compound to see if they might have recommendations or advice to share.

The University of Kansas (KU) was a relatively new member of WIPO Re:Search and had considerable expertise in drug formulation development and problem solving. An introduction was made by BVGH and the parties entered into a Confidential Disclosure Agreement to move discussions forward. Eisai provided extensive information regarding the various approaches it had tried to Dr. Michael Baltezor, Director, Biotechnology Innovation & Optimization Center, University of Kansas. Michael determined that Eisai had covered every approach that his lab would have taken. The Eisai scientists were pleased to hear they had already considered the approaches Michael would have recommended and expressed appreciation for a second opinion from KU's formulation experts.

When a contract reaches the end of its life-cycle, the partners still have various legally binding obligations toward each other. For example, in some instances, **confidentiality clauses** may outlive the specified contract period. The extent to which each party fulfils its obligations may directly affect the success of future deals, so both administrative and management staff must be familiar with the obligations of all parties.

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- See also** <http://www.iphandbook.org/index.html>
- See also** http://www.wipo.int/sme/en/index.jsp?sub_col=sme-cs
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