Where there is no lawyer: Guidance for fairer contract negotiation in collaborative research partnerships

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TABLE OF CONTENTS

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Key words: fair research contracting, negotiation, collaborative partnerships, intellectual property rights, technology transfer, capacity building, data and sample ownership, indirect costs, legislative frameworks

Disclaimer: The content of this document is intended as guidance and should not be seen as a substitute for relevant national or international legislation or policy directives. Readers are also advised that, wherever possible and practical, they should seek expert legal advice when entering into legally binding contractual agreements.

For more information, go to http://www.cohred.org. See also http://www.cohred.org/FRC

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Fair Research Contracting

Recent snapshot surveys of research institutions in the African and Asian regions have revealed some significant gaps in the contracting and contract management capacity of low- and middle-income country (LMIC) institutions in these regions. Many institutions seemed to lack awareness of the many legal issues around research contracting and reported having no specialist legal expertise, with the result that contractual terms and conditions were often poorly understood. Better contract negotiation awareness and expertise in LMIC institutions will help improve the distribution of benefits of collaborative research, such as overhead costs, data ownership, institutional capacity in research management, technology transfer, and intellectual property rights. This booklet is about optimising the benefits of research to institutions through better contracts and contracting between institutions. Although this initiative started by focusing on collaborative research between LMIC institutions and high income country (HIC) institutions, the guidance presented here is equally relevant in the growing field of south-south collaborative research.

WHAT DO WE MEAN BY FAIR RESEARCH CONTRACTING?

In recent years, the importance of local research and innovation for the development of sustainable solutions to address health problems in LMICs has increasingly been recognised. There has also been a sharp rise in research partnerships between low- and middle-income institutions and high income institutions. These partnerships provide a great deal of potential for building strong research infrastructure in lower income settings. However, such sustainability is only achievable if research funding also allows for capacity building and sharing of other benefits from research partnerships which leave the low income partner in a stronger position.

The growing volume of research conducted in and with LMICs is welcome but also brings with it a number of new challenges for research institutions and government departments in those countries. A greater volume of global health research has likewise resulted in increased complexity of legal arrangements accompanying funding and benefit-sharing – but often without a corresponding increase in legal and negotiating resources in LMIC institutions. Calls for low income country researchers to share greater amounts of biomedical and public health data can only be achieved through increased data management capacity, greater protection of local knowledge, and adapted models of intellectual property rights. Perhaps not surprisingly, LMICs are also increasingly asserting their rights to intellectual property and calling for fairer technology transfer arrangements.

To keep up with these developments, capacity building efforts should be fore-grounded in all collaborative research partnerships. The Council on Health Research for Development (COHRED) is a key partner in increasing the research competitiveness and innovation capabilities of LMICs in this highly competitive global research environment. Strengthening LMIC institutions' ability to negotiate fair research contracts with their higher income partners is a critical part of this. Without fair research contracts, a major global opportunity is lost to transfer the kind of research capacities and benefits to LMIC institutions that would enable them to engage in research and innovation on their own terms. For these reasons, improving research contracting capacity in LMICs is not merely a matter of fairness. It is key to developing a thriving research and innovation sector in LMICs, which will advance sustainable health, equity and development.

BACKGROUND TO THIS GUIDANCE DOCUMENT

This fair research contracting guidance document is the culmination of work COHRED has been engaged in with key partners over the past few years. The rationale for developing this guidance was to highlight the key issues for consideration when entering into formalised research partnerships, and to provide tools and resources for negotiating fairer research contracts. Although the issue of inequitable research partnerships is not new, previous work has not addressed the crucial role that equitable contracts and contract negotiations play in defining the nature of research collaborations, in building the foundations for successful long-term partnerships, and in enhancing the research systems of LMICs. Previous work often called on the HIC partner to abide by principles of fair partnership. The essential difference in this guidance document is that it aims to shift the locus of control of research benefits to the LMIC partner. At the current time, there are no such efforts focused on "where there is no (intellectual property) lawyer". There have been sporadic attempts at levelling the playing field through, for example, attempts by HIC institutions to transfer patents to LMICs. However, in general, many LMIC institutions simply do not have the necessary contracting or legal expertise available to negotiate the technical terms of such arrangements.

Existing efforts in this field mostly direct their appeals towards high income research partners to engage in 'good partnerships'. In contrast, our initiative is aimed at strengthening LMIC institutions to negotiate better partnerships which support their research and innovation capabilities, reducing dependence on goodwill as the main mechanism for achieving fair outcomes. By developing tools which place contracting knowledge and skills directly in the hands of institutions and government departments who currently have limited expertise in this area, the fair research contracting initiative will be instrumental in helping to level the playing field in global health research partnerships.

This guidance document aims to clarify the problems experienced in research relationships between high income and low income institutions (including south-south collaborations and public-private partnerships). In particular, we focus on issues that can be effectively addressed by developing and implementing guidance on research contracting in which the rights, responsibilities and requirements of all partners are recognised and addressed in an equitable and transparent manner.

WHAT ARE THE KEY ISSUES?

Experience suggests that high income institutions that collaborate with or commission research from lower income institutions often include implicit and explicit conditions which comparatively disadvantage those institutions. This is not only related to institutional policies, but can be a consequence of the funding source for the collaborative research or, where institutions are sub-recipients, of inflexible terms and conditions in the primary funding agreement. It applies similarly when a for-profit business engages in partnerships with research institutions, for example. Consequently, international research partnerships are likely to have less impact on sustainable research institution building in LMICs than is possible with good contracts. Post-research benefit sharing, obtaining a fair share of any intellectual property rights, the need for capacity building (not just of researchers, but also of institutional or governmental research managers) and technology transfer are some of the key issues that LMIC governments and institutions need to be better equipped to negotiate.

Without adequate legal capacity, contract negotiations can lead to agreements which disadvantage the LMIC partner. The disadvantages may allow for only a limited role for the LMIC partner in the academic aspects of the work – for example, restricted rights in authorship of publications and ownership of intellectual property – and little technology transfer or capacity building for the sustainable development of local research and innovation systems. In addition, these partnerships can result in LMIC institutions being financially disadvantaged by entering into contracts that may not cover the true cost of the work, with the knock-on effects of drawing research activity away from national priorities.

Results from a number of recent straw poll surveys, conducted by our partners in LMIC institutions, made it clear that negotiating fair contracts which enable country ownership and stronger research and innovation systems remains a central issue for these institutions. Many organisations in LMICs across a number of different regions lack access to legal expertise, while their ability to negotiate mutually beneficial research contracts is further hampered by a lack of contract management ability, financial know-how, managerial and administrative structures. The result is that the research partnerships that these organisations engage in risk perpetuating a situation in which LMIC institutions remain only junior or nominal partners in collaborative health research or, worse, make substantive contributions to scientific deliverables but nonetheless receive inadequate compensation or control over the results. .

We have identified five key issues that, when properly negotiated by both partners, can lead to substantially improved outcomes for LMIC institutions. In the long run, an environment in which all partners are able to negotiate fair contracts will enhance research and innovation for health and bring global health benefits.

Intellectual property rights
Exclusive ownership of intellectual property rights (IPRs) are frequently claimed by the high income funder or partner. An appropriate balance of IPRs needs to be identified where these rights are used to facilitate the development of local research capacities, and research results are made available and accessible in lower income settings.

Capacity building & technology transfer
Capacity building refers to strengthening the ability of an institution to carry out its key functions, from research management and financial control to greater training and development of scientific and professional staff, to 'bricks and mortar' infrastructure, to being able to negotiate fairer research contracts to ensure benefit sharing that results in sustainable research and innovation.

Ownership of data & samples
A common issue is the claiming of exclusive data or sample ownership by research sponsors, even though the materials have been collected by the LMIC institution from its own population. Debates on the issue of data sharing and ownership are ongoing.

Compensation for indirect costs
Linked to capacity building, this refers to the overhead costs that LMIC partners incur when the research project is housed and conducted within that institution. Not providing adequate funding for such costs within the research contract circumscribes the potential for capacity building in the LMIC institution.

Research contracts in (legislative) context
The issue of lawyer or no lawyer assumes that there is a legal or institutional contracting framework to begin with. However, this is not always the case. Similarly, contracts often describe ways of settling disputes, but it is not always easy to identify a neutral body for dispute settlement or to settle such disputes without incurring substantial costs. Most draft contracts have indemnification clauses but many are one-sided or, at best, potentially confusing to an institution without adequate legal staffing and, at worst, unacceptable for many LMIC institutions from a financial and risk management point of view.

Using this guidance document

The issues identified above can promote or hinder equitable collaboration, depending on how they are dealt with in the contractual agreement. They are the focus of this guidance document. Each section begins with a brief description of the issue, highlighting why it is important. The two objectives of each section are to equip readers with a deeper understanding of the issue (Understand) and to guide readers through some of the main points to consider when contracting around each issue (Consider). Where relevant, examples of clauses relating to each issue are included. In each section, there are references on where to go to find out more, case studies, tips, and examples of best practice.

This guide has been designed to offer broad guidance in practical terms on some of the key challenges faced in fair research contracting. It is not intended to assert rigid rules or procedures, but rather to suggest considerations to think through as you engage in negotiations with research partners. It is hoped that this guidance will add to existing good practice documents by translating good partnership principles into pragmatic actions for fair research contracting.

This guidance document is just the beginning. As we move into the next phase of this initiative, we plan to make this guidance more web-based and interactive. The guidance presented here will continue to be improved and updated as we receive feedback from you, the users. We invite you to submit comments on this fair research contracting guidance here http://www.cohred.org/FRC, or by emailing Danny Edwards at edwards@cohred.org.

Strategies for Negotiation

WHAT ARE THEY ABOUT? WHY ARE THEY IMPORTANT?

A solid, equitable contract is the bedrock of a fair research partnership. Negotiating fair contracts is, however, a process. Contracting guidance cannot replace building mutually respectful relationships based on good communication and trust, which require a longer-term investment on the part of both partners. This goes beyond having technical know-how to greater individual and institutional capacity for negotiation. A critical part of negotiating fair research contracts is recognising that every partner has something to bring to the table to negotiate with. Negotiation is often regarded as a mechanism that becomes necessary when a conflict of interest or dispute arises between parties which needs to be resolved. When we think about it in the context of collaborative research, however, we prefer a wider view of negotiation as a dynamic, flexible process that defines the parameters of both the contract and a mutually beneficial partnership.

Different types of partnership allow for different levels of negotiation. Where research occurs under a grant award, for example, the conditions are usually prescriptive and leave less room for negotiation than a research collaboration in which all parties are engaged in the work of the partnership and responsibilities are equally shared. Understanding the parameters of the partnership – including knowing what your partner expects you to contribute to and to get out of the partnership – is critical for knowing where the potential for negotiation lies. **This section highlights key points to consider when engaging in the negotiation process** and provides a broad overview of the main drivers of different types of research partnerships.

Understand

Although developing a research contract is largely a once-off process, negotiation is a process that might begin with defining the conditions of the contract, but continues throughout the life of the research partnership. Respectful negotiation and ongoing discussion are crucial to the building of trust and to ensuring that the concerns, interests and needs of each party are addressed. A number of principles of fair research partnerships have been identified and are applied here to the fair negotiation of research contracts (see KFPE (2012) and Costello & Zumla (2000)). This guidance document is based on the understanding that it is important to have a contract in place that outlines how key components of the research partnership will be fairly handled; negotiation is the tool for making this happen.

Negotiation is not about ensuring that every partner is the same; it's about engaging in frank and transparent discussion about how each partner can expect to contribute to and benefit from the collaboration based on their capacities and resources. Striving for equality does not mean that you are striving to be the same. Rather, it means that you strive to share responsibilities and benefits in a way that supports all the institutions engaged in the partnership. Equally, it is important to be clear about what is and what is not negotiable. Some decisions are out of the hands of both partners. Prior to entering the negotiation process, it is important to take time to understand the motivations, expectations and the needs of your partner. Negotiation also involves identifying the various stakeholders who need to be involved in the contracting process and clarifying the roles and responsibilities of each partner upfront.

KFPE's principles of partnership

1. Set the agenda together
2. Interact with stakeholders
3. Clarify responsibilities
4. Account to beneficiaries
5. Promote mutual learning
6. Enhance capacities
7. Share data and networks
8. Disseminate results
9. Pool profits and merits
10. Apply results
11. Secure outcomes

(KFPE, 2012)

TIP: 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, 2008, p. 682)

Guidelines for equitable partnership practice: The Partnership Assessment Tool

The Canadian Centre for Global Health Research (CCGHR) have developed a toolkit which is designed to provide additional support for fair partnerships. The Partnership Assessment Tool (PAT) draws upon the previously developed principles and checklists for partnerships, but contains a number of unique features…While contracts and other such agreements are essential formal arrangements between partners, the PAT plays a different role; it provides guidelines for equitable practice within the partnership throughout its duration, and provides a means through which to negotiate potential difficulties or "road blocks", thus protecting the partners and maximizing the benefits obtained from the collaboration…Barriers related to inequity and power are hard to break down. The CCGHR team argue that it is essential that the persistence of inequitable LMIC-HIC research partnerships be acknowledged, and that LMIC partners in particular have a tool to guide their negotiations within research collaborations. Open, frank discussion and honesty are encouraged. Simply by engaging in these conversations, steps will be taken toward equity in partnerships.

(Adapted from Afsana, Habte, Hatfield, Murphy & Neufeld, 2009).

Consider

Identify your needs and motivations for engaging in the partnership and assess the contract based on your **expectations of the outcomes** based on these motivations. What would need to occur for you to consider the partnership a success?

Although it is often a reality that LMIC institutions – and indeed, many HIC institutions – are under-resourced in some area of research capacity, such **institutions will always have something to offer that their (perhaps better resourced) partner stands to gain from the partnership.** Each partner will have unique knowledge and skills that can be brought to bear on interactions within the partnership. Ownership of skills and capacities by all parties is critical. Partners from high-income institutions will have skills and resources to contribute that should not be overlooked in attempts to make everyone appear 'equal.' But these research partners also stand to gain an enormous amount from working with LMIC partners. These contributions can be made explicit and used as leverage in the negotiation process. As holders of cultural and locally relevant knowledge and as gatekeepers of participant communities, LMIC partners can make invaluable contributions to research programmes in which they partner with HIC institutions. The questions for you to answer are *what is our strength?,* and *where do we want to add to at this stage in our development?*

Do not treat individual research projects as separate events, but keep the **whole picture** in mind. Collectively, all collaborative research projects should add up to make your institution better able to conduct, manage, evaluate, use and communicate research and engage in contracts that enable you to do so. Further, it is important to anticipate what achievements, benefits and tangible outcomes might result from the partnership and incorporate these considerations into the contract, where possible.

Check **institutional policies and records** for existing research contracts prior to negotiations. This might offer useful information on what clauses have been approved before and which clauses were unacceptable, and will save time in the negotiation process. Similarly, familiarise yourself with internal procedures for contract approval.

Consider **what contributions are within your institution's capacity** to commit to – in terms of funding, time and resources. Where extra support (finance, training, infrastructure) will be needed in order for you to make these contributions, discuss possibilities for building this support into the contract. The implicit promise of research collaboration is that each partner has the opportunity and agency to provide input to the partnership, in whatever form this input might take. Given the inevitable constraints under which less resourced partners might be operating, considerable effort should be spent early on to negotiate how the partnership might address these gaps.

Select the **right person / people from your team to negotiate.** Negotiation is a set of skills involving good human and relationship management skills, an ability to consider the perspectives of all partners, and to present a particular position with the right balance of authority and diplomacy. Consider building multidisciplinary teams with individuals who can contribute diverse skills and experience to the contracting process.

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.

Consider cont...

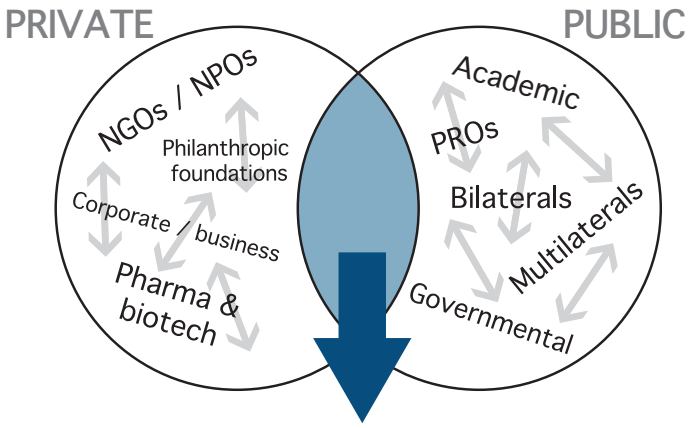
Clarify the **roles and responsibilities** of each partner. It is also important to identify the different role players and stakeholders who will need to be involved in the contracting process. Who will manage what? Who do you need to liaise with at your own institution? What established structures and procedures are in place to facilitate the contract negotiation process? Different roles and responsibilities will come into play at different stages of the process.

Keep track of the **correspondence and discussions** that set the terms of the negotiation. Summarise discussions , save e-mails, and highlight changes made to terms and clauses in the contract and the reasons given for them. If any doubt arises when implementing the contract, the historic record of the negotiation might help to clarify the issue. The spirit of the negotiation can be an important supplement to the written agreement. It is also an important part of the learning process and will be useful for the next negotiation.

Assess how compatible each partner institution is with the other. Although each partners' interests might not be completely congruent, they should at least be compatible in that they both share the goal of improving health (for example). **Institutional compatibility** is particularly important where there might be high staff turnover. Ensuring that collaborative contracts and agendas are negotiated by institution-wide teams, rather than only by senior management or individual researchers, can ensure your institution's position in the partnership.

Consider the **context**/s in which the research is intended to occur. When negotiating the research agenda of the partnership, for example, consider whether and how this addresses your national research priorities. Consider what terms may need to be negotiated with respect to the participant communities that will be involved in the research, and your responsibilities towards these communities.

Assess the **risks and benefits** of each partner's contribution and consider whether this is acceptable to all. Be aware that these do not have to be the same for each partner: each will benefit from the partnership in different ways.



Know your partner

As the figure to the left illustrates, 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.

Consider cont...

Be aware of the **power differential** between partners, where it exists, and the ways in which power might operate in the partnership. Power can create a barrier to successful negotiation and compromise. Where time and energy is invested in obtaining or maintaining power, less can be invested into the work of the partnership. A solidly negotiated research contract should reduce the negative impact of power differences between partners.

Different **levels of collaboration** are required to make a partnership work – not just between two people or two institutions, but between people and departments within each institution. At different times in the research contracting process, for different reasons, these levels of collaboration will become salient – and can impact on the negotiation process. While discussions may start off between researchers at respective institutions, negotiations will likely move to a point where staff in the research office, finance department, legal department or technology transfer office may need to become involved.

Discuss the difficult issues before entering into the partnership, and agree on at least a broad strategy for how they should be handled. **Clarifying expectations upfront** can counter such difficulties, as will an appreciation that partners will have both shared and individual objectives and that this is okay. 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.

"'You do not necessarily have to share the interests of another partner, but you do have to understand them, and you do have to accept them' (Director of a Southern university-based research institute)" (Migot-Adholla & Warner, 2005, p. 4). Stewardship, efficiency and transparency are highly valued by funding agencies – all of which require a number of capacities to be in place in their LMIC partners. Situated in the middle of these two positions are primary award recipients – frequently institutions in high income countries – who are concerned with protecting their own interests (maximising return on investment) and minimising their own risk. If not handled explicitly, this could result in a typically defensive or restrictive position when negotiating contracts with LMIC partners. Get to know your partner and what you can expect from them. As far as possible during the negotiation process, encourage all partners to reveal their strategic interests and assess how far these are aligned with shared partnership objectives – or where modifications might be necessary.

WHERE TO GO TO FIND OUT MORE: RECOMMENDED RESOURCES

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Intellectual Property Rights

WHAT ARE THEY ABOUT? WHY ARE THEY IMPORTANT?

In order to understand the relevance of intellectual property (IP) in the context of fair research contracting, it is important to be clear about what IP actually is. Firstly, IP is not a stand-alone issue nor is it only about patenting, licensing, trademarking, copyright and commercial issues. IP is much broader and is applied in a variety of contexts, including science, technology, trade/competition, research, innovation and development. More specifically, IP is an idea which develops into what is commonly referred to as an invention or innovation. Once an invention has been created, the inventor can choose to bring into play various intellectual property rights (IPRs). IPRs allow the inventor to exercise certain controls over the invention, and derive value from it. Four common elements arise from an IPR:

1) ***ownership*** of the IP;
2) ***access and use of*** the IP;
3) ***rights*** and ***responsibilities*** attached to the IP;
4) ***mechanisms*** available to ***manage*** and/or ***negotiate*** disputed issues around IPRs

Underlying these factors is the issue of which laws and/or policies are available to protect IPRs and whether these, if they exist, provide adequate protection or enforceability of such IPRs.

Intellectual property can be a complex area to engage with. This can be particularly true in the context of negotiating fair research contracts in research and innovation where LMIC institutions engage in partnerships with HIC institutions. However, as detailed in the previous section, it is critical that the risks and benefits for all parties in a research partnership are clarified upfront. It is thus important for all partners to have a satisfactory level of awareness about IP and IPRs in general, and about the protections available to LMIC institutions in particular.

Exclusive ownership of IPRs has frequently been claimed by the high-income partners (including bilateral or multilateral organisations) in research contracts. Similarly, IPRs, when used inappropriately, may hinder the development of local research capacities through, for example, preventing open access to research results. On this reading, one could assume that the exercise of IPRs is invariably bad for the LMIC partner. However, as significant research results begin to emerge from LMICs, the protection of IP created by LMICs becomes more important.

Many LMIC institutions do not have the necessary IP protection mechanisms available to them, such as national legislation and institutional policies to protect their IP rights in agreements they enter into with HIC institutions. Similarly, there may be a lack of understanding about why certain IP rights should be sought, and what the longer term value of exercising control over IP might be.

Some of the reasons that LMIC institutions may be at a disadvantage when negotiating IP ownership include:

1. Lack of awareness of what IP is;
2. High dependence on HICs for funding;
3. Lack of adequate support structures, such as technology transfer and research or legal offices;
4. Lack of capacity regarding the risks/benefits involved in negotiating IP in research partnerships;
5. Lack of awareness of international standards, national frameworks, and/or institutional IP policies.

As a result, LMIC institutions may be unable to safeguard their interests in IP when engaging in research partnerships. To this end, research collaborations tend to weigh heavily in favour of HIC institutions, while LMIC institutions are disadvantaged due to inequitable contract negotiations. It is for this reason that LMIC institutions need to be aware and able to ensure that their IP interests are protected and they do not contract on 'any terms.' **In this section, we clarify the notion of intellectual property and provide guidance on the various factors to consider when negotiating IP in research contracts, as well as the legal protections available for research partners.**

Understand

Protection and enforcement of IP can vary from country to country. In order to encourage member countries to establish a consistent level of IP protection, the World Trade Organization (WTO) established the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement. The TRIPS agreement sets out a uniform set of general principles applicable to IP protection and enforcement, which member states commit to upon joining the WTO. The TRIPS agreement covers principles such as the trading system, international property agreements, intellectual property rights, enforceability of these rights, and settling of disputes relating to intellectual property. Those member states who have agreed to the TRIPS agreement commit to incorporating these principles into their national legislative frameworks and to establishing policies that enforce this model of IP protection. It is useful to note that the TRIPs agreement allows for a degree of flexibility in the application of its requirements, in order for countries to implement IPRs which suit their context. Further, there are exemptions from the requirements of TRIPs for specific time periods for certain countries, such as the Least Developed Countries (LDCs). An extension to an existing exemption was recently agreed at the WTO TRIPS Council, which means LDC members of the WTO do not need to apply TRIPS in their national IP legislation for an additional 8 years from 2013. The text of the decision recognises the need for "flexibility to create a sound and viable technological base" for such countries.

Intellectual property takes a number of forms. It could be an invention, a literary work, some music, a design, a shape, a trade name, trademark or a trade secret. Protection of IP is achieved through the application for and exercise of intellectual property rights. IPRs can be divided into the following main categories: copyrights, patent rights, trademark rights, trade secrets, geographical indications, protection of undisclosed information and anti-competitive practices in contractual licences. The consequence of having an IP right is that ownership is conferred to an individual or institution to own and use exclusively, save for certain exceptions.

Inventions in the form of products, information or processes are protected by ***a patent right.*** A patent right provides for exclusive ownership over an invention, which means that no other person or organisation may make, sell, distribute, copy or use a patented intellectual property without the owner's permission for a period of between 10 and 20 years. However, an owner of a patent may assign, sell, share or transfer the right to another via licensing agreements. Patent rights have certain limitations, however, as they are only enforceable in the country where the patent right is registered. In other words, if the patent is not registered in a particular country, the invention may be commercially exploited without infringing on the owner's exclusive right. ***Copyright*** covers a broad spectrum including literary works, reference works, newspapers, publications, computer programmes, databases, films, musical compositions and choreography, artistic works, architectural works, advertisements, maps and technical drawings, research findings, and so on. Copyright protection gives the owner the exclusive rights of use and prohibits the reproduction, recording and translation of the works without the owner's permission.

Determining issues relating to IP such as ownership, use, rights, and responsibilities, enforceability and management, depends on what has been negotiated at the outset between partners entering into a research collaboration, and formalised, in most instances, into a written contractual agreement. Data ownership is frequently considered as an IP right, although in some instances, it is not. For further guidance we refer readers to the section on ownership and sharing of data and samples in this guidance document.

Best practice example:
The Danforth Centre

The Donald Danforth Plant Science Center (Danforth Center) is a not-for-profit research institute with a global vision to improve the human condition through plant science. Their best practice model is based on respect for protection and sharing of IP (intellectual property) rights, interinstitutional and international collaborations and scientific partnerships. Their philosophy, entrenched in their overall mission, is not to infringe or misuse the IP rights or materials entrusted to them. This is evidenced in the way they draft agreements.
(http://www.iphandbook.org/handbook/ch17/p10/)

TIP: Harnessing IP

In trying to move the focus in discussions away from patents alone, participants at the FRC Bellagio meeting highlighted that IP is about more than just patents and is not always (only) about commercial benefit. For example, the importance of clauses about data ownership or sharing and publications should be considered in all guidance. Trade secrets are another means of information protection which could be considered when the information has commercial value for the institution but the maintenance of a patent is too expensive. IP can also be useful as a tool for protecting the interests of research participants and low- and middle-income institutions and countries. (COHRED, 2012)

Recommendations for funders

In line with the development agenda that aims to capacitate LMIC institutions to engage in research and innovation, HIC partners should aim to ***be flexible in IP negotiations*** where there is a need to discuss further the risks and benefits of exclusive or jointly owned IP rights. While the risk of losing exclusively owned IP is an issue, it would be beneficial for all partners if there was a move away from exclusively owned IP toward increasing transfer of technology to least developed countries.
It is critical in ***balancing interests*** to approach IP management as ultimately a mechanism to protect the interests of both HIC and LMIC institutions in research innovation and public benefit.

Consider

Establishing a basis of trust and mutual benefit in research partnerships is fundamental to negotiating fair research contracts. It is crucial for LMIC institutions to consider and discuss from the outset the various expectations that would arise from the research collaboration, which includes discussion on how IPRs should be handled. The following considerations are key for LMIC institutions in discussions with high income partners – whether in high income countries or in south-south collaborations or public-private partnerships – when negotiating IP issues in fair research contracts:

1. NATURE AND PURPOSE OF THE RESEARCH

Describing the nature and purpose of the research and identifying potential IP that may result is an important part of establishing legitimate expectations. Research partners could consider:

a) What you both bring to the table (background);
b) How the work of the research partnership will build on this;
c) What comes out of the partnership (foreground); and
d) Any new IP that is generated as a result of the partnership (sideground).

Discuss and build these considerations into the contract, including who will have rights in respect to these IP. This may go as far as detailing the potential IP results of research and breaking these down into individual components. This will ensure that, right from the start, you have identified the specific IP issues that may arise from your collaboration and you can properly apportion and manage any IP rights and benefits arising from the exploitation of those resources.

2. INTERESTS OF ALL PARTIES, RELATING TO THE RESEARCH (INCLUDING CONFLICT OF INTERESTS)

High income institutions are often in a far greater bargaining position, with greater legal capacity, and thus it may seem as though their interests outweigh the interests of low or middle income institutions. It is thus critical that institutions entering into research partnerships clarify issues around IPRs and benefit sharing upfront in a contract, to minimise conflict of interests later on. To resolve such conflict, some partners set out in their policy documents dispute resolution provisions. It is useful, then, to negotiate upfront good practice measures around each partner's rights and responsibilities and obligations, and to outline, in the case of conflicts of interest later on, what procedures have been agreed on for dispute resolution.

3. EXISTENCE OF IP LAWS, INTERNATIONAL NORMS, NATIONAL LEGISLATIVE AND INSTITUTIONAL IP POLICY

Check what national legislation exists in your country with respect to IP. Where your institution or country lacks a national legislative framework and /or institutional policy relating to IP protection and enforcement, you may consider looking to existing international norms and standards that relate to contractual terms and conditions. Although this will not be legally binding where your country has not acceded to the relevant treaties and conventions, it is nonetheless a useful starting point when thinking through clauses in contracts with research partners, particularly those from another country. Refer, for example, to WTO's Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, other effective national legislative frameworks from developing countries (e.g. South Africa's Intellectual Property Rights from Publicly Financed R&D Act (2008)), and related policies. Other international sources include the following treaties: the Paris Convention for the Protection of Industrial Property, the Berne Convention for the Protection of Literary and Artistic Works, the WIPO Copyright Treaty (WCT), the Patent Cooperation Treaty (PCT).

CLAUSES

Rights of ownership of IP
A typical clause on ownership of IP rights specifies that the IP is owned by the research partner/s, either exclusively or jointly.

Confidentiality
A confidentiality clause describes in detail the information that must be kept confidential and by whom.

Rights and obligations
A rights and obligations clause describes the contractual duties that must be adhered to and respected by each party to the contract.

Conflicts of interest/ Dispute resolution
A dispute settlement clause describes the process that will be followed in the event that a conflict arises in the contract. The World Intellectual Property Organization (WIPO) offers a fully established service for such procedures for mediation and arbitration.

Consider cont...

4. OWNERSHIP OF IP

Clarify upfront with partners ***who will own the IP.*** Discussions around who will own the IP, exclusively and jointly owned, are at the heart of this section. Establish how important ownership of IP is to the respective partners. Generally, a right of ownership rests with the institution that is hosting the research. Researchers, students, and staff employed by the LMIC institution who create IP in the course and scope of their work do so under the express or implied agreement that ownership of the IP belongs to that institution. This is normally established by way of a ***Participation Agreement*** or found as a clause in a general Conditions of Service contract. Obtaining, holding and exercising such rights should promote a mutually beneficial outcome, and the equitable sharing of benefits. Joint ownership of IP rights is one other method of ensuring that a research partner can retain a form of control over their IP, but this method has limitations and may not always be an appropriate benefit-sharing mechanism. For example, joint ownership does not necessarily create an entitlement to receive benefits from the other owner's exploitation of the common IP rights. In some jurisdictions, joint ownership of patent rights does not require one owner to share economic benefits derived from ownership with the other owner.

5. DISCLOSURE OF IP

In most instances, the term disclosure, in research contracts, refers to the disclosure of IP. Establish when and how partners will disclose (i.e. declare and describe to another party) any IP brought to and arising from the partnership. Consider establishing confidentiality arrangements pertaining to the IP. Privacy and confidentiality issues may also apply where research activities involve the creation and publication of papers or information which has copyright implications.

6. RIGHTS AND RESPONSIBILITIES PERTAINING TO THE IP

Identify each partner's rights with regard to the IP and their responsibilities regarding fulfilment of the IP. If one of the partners to the research contract fails to fulfil their responsibilities regarding agreed upon IPRs, then this is known as a breach of duty or infringement. Consequences of this breach are usually included in the contract.

7. MANAGEMENT OF THE IP

Management of IP arising from the research partnership might include all the components described in this section, or it may pertain to a specific aspect of IP, such as licensing. For detailed guidance on IP management, readers are referred to the Intellectual Property Handbook (Krattiger, Mahoney & Nelsen, 2009), an online resource providing comprehensive guidance regarding all aspects of IP management.

8. COST IMPLICATIONS OF IP

Consider whether the acquisition and further protection of IP rights will involve any costs, and who will be responsible for covering these costs**.** Some IP (e.g. patenting) has significant cost implications, which may involve significant risks for the primary research sponsor in particular. When including benefit sharing and IPR clauses, consider the cost implications if there is likely to be patenting and licensing potential of products and technologies arising from the partnership.

9. PUBLIC BENEFIT

Identify, where relevant, what your obligations are to make your research findings available for public benefit. It is widely agreed that public funds should lead to public goods. However, this depends on the jurisdiction you and your partners are operating in, as well as the funding source.

Benefit sharing

The term benefit sharing is often understood in the context of sharing genetic resources and intellectual property (under international standards such as the *Convention on Biological Diversity*) with developing countries and regions. The concept is also frequently used to refer to the ethical obligation to ensure that reasonable benefits are received by LMIC participants and their communities as a result of their participation in clinical trials and research studies (*International Ethical Guidelines for Biomedical Research Involving Human Subjects*). However, we highlight here that benefit sharing in the context of international collaborative research can also refer to the sharing of research benefits between research partners – particularly with LMIC institutions. Notwithstanding the standard IP issues that can be negotiated as a research benefit, research partners can discuss alternatives that extend beyond the traditionally accepted approaches to benefit sharing. Benefit sharing is not limited to those research benefits of monetary value but can also be of non-monetary value (such as sharing of research results; publications; opportunities to visit partner sites; conference attendance; collaboration for further grant opportunities; transfer of equipment or materials; or strengthening capacities for technology transfer). Often research partners opt for benefit sharing in the form of capacity building in various forms, which might be made explicit in the research contract, or may occur in implicit ways throughout the duration of the research partnership.

WHERE TO GO TO FIND OUT MORE: RECOMMENDED RESOURCES

A number of resources on IP are available at: http://www.wipo.int/about-ip/en/

CREST Expert Group on IPR (2006). CREST cross-border collaboration decision guide.

Krattiger, A., Mahoney, R.T., & Nelsen, L., et al. (Eds.) (2009). Intellectual property management in health and agricultural innovation: A handbook of best practices. MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Lambert Toolkit for university-industry collaboration: http://www.ipo.gov.uk/lambert (in high income settings)

WIPO (n.d) A brochure on intellectual property rights for universities and R&D institutions in African countries. Geneva: WIPO.

WIPO (2004). *Intellectual property handbook: Policy, law and use.* Geneva: WIPO.

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Simons, J.J. (1999). Cooperation and coercion: The protection of intellectual property in developing countries. Bond Law Review, *11,* Article 5.

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Ownership & Sharing of Data and Samples

WHAT IS IT ABOUT? WHY IS IT IMPORTANT?

Within collaborative research, there is increasingly the expectation that the data and samples (tissue samples, biospecimens, genetic material and other biological samples) generated within the partnership will be shared, subject to legislative, contractual and ethics restrictions, both among partners and with other interested parties outside the partnership. A common issue in collaborative research is the claiming of exclusive data or sample ownership by funders or high income partners, even though the data have been collected by the low- or middle-income institution and the biological materials have been collected from participants in LMIC populations. The notion of open access to genetic and other biological samples has become commonplace in genomics research, but there are also growing calls for open access to public health data. It is generally accepted that the products (data and samples) from publicly-funded research should be made freely available to encourage further research and maximise the benefits of such research to society. The increasingly global, cross-border nature of research will have a significant impact on issues of ownership, management, sharing and access to research data. In particular, it highlights issues of equity and fairness with respect to the capacity of LMIC researchers to collect, analyse, manage and store such data in ways which also maximise the benefits to themselves, their institutions and their study populations.

In addition to ensuring that the interests of LMIC researchers are protected, the sharing of data and samples adds another dimension for consideration: protecting the interests of research participants. The notion of ownership – and sharing of benefits derived from the research – extends beyond the rights of those who have collected the data, to the perceived, symbolic ownership of data and samples of participant communities. Negotiating conditions around data release and access, then, is ultimately a risk-benefit analysis. Good practices are emerging: there is a multitude of guidance from the field of genomics research and a growing body of literature regarding sharing of datasets. **The guidance presented in this section pertains particularly to data ownership and sharing**, although many of the principles apply equally to sharing of biospecimens and samples.

Understand

There are undoubtedly good reasons to share data, including facilitating the discovery of new knowledge, more effective use of existing data, public health benefits, increased visibility and enhanced opportunities for partnership. But there are a number of issues to consider when entering into research partnerships where the expectation is that the data will ultimately be made available as open access. Some of the concerns include misinterpretation and misuse, fear of marginalisation from loss of recognition and control over the data, governance challenges relating to sharing costs and benefits, risk of identity disclosure and potential stigmatisation of study participants, and legislative vacuums in many LMICS with respect to policies and procedures for data sharing and protection of privacy. Data or sample sharing is frequently included under the umbrella term of intellectual property, and is usually associated with some form of benefit sharing. We refer readers to the relevant sections in this document for further guidance on intellectual property rights.

When contracting around the sharing of research data, researchers need to consider the legislative, ethical and practical implications of how they negotiate ownership, control, access, storage, management (maintenance) and use. Ownership refers to who owns the rights in relation to the relevant data; control refers to any restrictions or conditions that apply to use of the data; storage, management and maintenance of the data refers to the practical systems and capacities required to archive and manage the data; access and use refers to the terms and conditions under which access to and use of the data is permitted. Determining who has rights of ownership (and can therefore confer on others rights of access and use) can be complex. "Whether these parties can be said to own or control the data will depend upon various factors including the circumstances in which the data has been generated, obligations relating to maintenance and management of the data and the operation of laws (such as copyright and confidentiality) which confer legally enforceable rights exercisable in respect of the data" (Fitzgerald & Pappalardo, 2007, p. 28). These issues need to be clarified upfront in the research contract.

Case Study: MalariaGEN's policy on building capacity for data sharing

The Malaria Genomic Epidemiology Network (MalariaGEN) is a partnership of malaria researchers in over 20 countries supported by the Grand Challenges in Global Health Initiative. In MalariaGEN, a number of attempts have been made to address the more exacting challenges (of data sharing), in addition to material transfer agreements and research contracts. First, the network developed a capacity building scheme in which young researchers from all partner sites were trained in the analysis of genomic data. Second, the network recognised the need to enable all contributing researchers to analyse their own data before it was made publicly available and incorporated this into the MalariaGEN Data Release Policy (http://www.malariagen.net/home/downloads/16.pdf). Third, the network sought to develop software that allows the remote analysis of genomic data – meaning that Malaria-GEN researchers anywhere in the world could analyse data without the need to invest in expensive in-house infrastructure for data analysis and storage. (De Vries et al., 2011).

Tip: Levels of Access

Ownership and access rights are often confused. Giving access to one's data does not mean giving the data away. The owner may retain ownership rights over the data to varying degrees, depending on the level of access granted. Levels of access include open access, licensed access, restricted licensed access and managed closed access. The level of access granted will also determine how much input is required of the data owner in terms of management and maintenance.

Best practice: INDEPTH Data Sharing and Access

The INDEPTH Network is a network of health and demographic surveillance systems in Africa, Asia and Oceania. To facilitate access to the longitudinal data generated by its 19 member centres, INDEPTH has established iSHARE to achieve its goal of making its data widely and freely available to all researchers and decision-makers. The INDEPTH Data Access and Sharing Policy (iDASP) can be found here: http://www.indepth-network.org/images//idasp.pdf

Guidance from Funders

A landscape survey of the twenty funding organisations making up the Joint Funders' Initiative revealed that about half have dedicated policies on data sharing and management – while the other half lack clear guidance on data sharing for grantees. Data sharing requirements – such as time frames for data release – seem to vary substantially from funder to funder. Funders' guidance typically covers five broad areas: 1. Data management plans; 2. Time frames; 3. Use of public databases and central repositories; 4. Ethics and confidentiality requirements; and 5. Compliance.

Consider

Frameworks: Policies & legislation

Consider developing an institutional data sharing and access policy, if you do not already have one. The policy can help guide how you negotiate with partners on data sharing issues. Institutional data sharing policies should cover:

- The kinds of data to which the policy applies (Note: not all data generated in research projects will be suitable for reuse due to, for example, ethical or legal restrictions). A research contract can specify which data, materials etc will be shared across the partnership, and which will remain exclusively in the domain of individual researchers or institutions (clauses about the ownership of research data and materials that will be retained at the end of the research project, with terms about if and how this data will be made available).
- Conditions under which data will be shared.
- Roles and responsibilities of researchers and data managers.
- Responsibilities of users (e.g. protecting confidentiality, citation of source of data, reasonably involving producers of data in research outputs such as publications).
- Time frame for sharing. A limited, defined period of exclusive use for the originators of the data is considered reasonable.
- Plan for storage and management of data (see **data management plan**).
- Consider the culture of your institution and incorporate current practices and academic conventions around data sharing and use. Data is often considered a researcher's intellectual capital, and appropriate career development and other incentives should be considered to encourage data sharing. Include how credit / acknowledgement will be distributed among partners and incentives for researchers to share data.
- When drafting policy or negotiating data sharing clauses, consider also the legislative frameworks that govern how data can be managed and shared in accordance with national laws (e.g. privacy laws, intellectual property or patent laws, copyright law, protection / freedom of information laws, public records legislation). Also be aware whether there is any discordance between legal and ethical guidance.

In a **data/information management plan**, outline practical procedures and structures required for implementing the policy – and consider these requirements when negotiating data sharing arrangements with research partners. The data management plan is usually required along with project proposal submissions. A data management plan might include:

- How data is to be collected, analysed and stored.
- Database or repository infrastructure.
- Quality assurance measures.
- How data will be managed and disseminated.
- Data security measures.
- How and when access / future use will be made possible.
- Projected costs involved in i) preparing data for storage (e.g. cleaning and anonymising the data) and ii) maintenance and ongoing management (some institutions charge access fees to cover the operational and administrative costs of maintenance, for example, but be aware that this may not be possible in cases of publicly-funded research).

Many funders have data sharing policies in place which will need to be adhered to once you have signed a contract – review these before entering into partnership, inquire about flexibility around terms, and negotiate according to your institution's needs and capacities. A hyperlinked index to various data sharing policies is included in a table at the end of this document.

CLAUSES

In addition to the partnership contract, there are a number of contractual agreements pertaining to ownership and sharing of data and samples. Each of these agreements can be stand-alone, or relevant clauses pertaining to conditions of use, confidentiality protections or commercial arrangements can be included in the overarching research contract.

Material Transfer Agreements (MTAs)

A contract which governs the transfer of tangible research materials between parties involved in a research project, when the recipient intends using these materials for their own research purposes. It usually specifies the rights and obligations of the provider and the recipient with respect to the transferred materials, including which materials will be transferred, the work to be done on the materials, the conditions of storage and management. There is usually an agreement about collaborative opportunities for the provider in the analysis (e.g. authorship on publications), and MTAs are thus an important means of protecting the interests of researchers who collect and supply the data/materials, in addition to the rights of study participants.

Confidentiality Agreements (or Non-Disclosure Agreements)

A contract which covers the transfer of confidential information between parties for certain purposes, but which restricts the disclosure of such information to third parties. It will identify the information to be treated as confidential, the rights of the provider of the confidential information, the obligations of the parties with whom the information is shared, and the consequences of failure to comply.

CLAUSES *(Continued)*

Access Agreements
A contract which outlines the terms under which access will be granted to data, when a decision has been made to share such data with one or more party. It will specify who has permission to access the data and the purposes for which the data may be used. There will also usually be conditions that prevent the transfer of access rights to third parties. Intellectual property clauses are typically included in such agreements – either to refer to the holders of intellectual property rights or to declare that the data providers retain no rights to intellectual property.

Licensing Agreements
A contract in which the provider of data grants a license to another party to use the data for certain purposes, while the provider retains ownership of the data. The contract will identify the data / materials that are covered by the agreement, the work that is permitted on the materials, and any restrictions on the person to whom the license has been granted. It will also usually specify conditions for informing or compensating the provider for certain outcomes of use.

For diagrammatic examples of these agreements, we refer readers to Fitzgerald and Pappalardo (2007).

Consider cont...

Governance and monitoring requirements

- Identify what data management processes and structures will be necessary to store and share data.
- Consider what oversight mechanisms and regulatory structures will need to be in place – such as Data Access Committees (see INDEPTH Data Sharing and Access box). Consider making provisions for the establishment of such structures in partnerships that will make heavy demands on data management and sharing.

Capacity: Operational and technical considerations

"The Swiss Commission for Research Partnership with Developing Countries contends that the organizing principle here should be capacity-building. It is not that research ownership is important as an end in itself, but rather as a means to garner increased funding or human capital. For that reason, there should be discussion amongst collaborators as to what types of research ownership are most important in developing local capacity—publication in journals, inclusion on grant proposals, or technical training" (Chokshi & Kwiatkowski, 2005, p. 12).

- What technological systems and infrastructure are needed for collecting, storing and disseminating data?
- What skills and capacities do researchers need in order to collect, clean, archive and analyse data?
- Where possible, make provisions in the contract for training, skills transfer and capacity building so that data producers are also capacitated to be data users.
- Consider sustainability needs: ensure that data management is recognised in contracts as an essential component of the research project. Consider what costs will be involved in managing and maintaining the data after the research project is completed.

Ethical issues / protections for participants

Sharing data or biological materials changes researchers' responsibilities towards research participants. Be aware of these ethical responsibilities and the additional demands they may place on your researchers and Institutional Review Boards (IRBs).

- It will be important to maintain the trust of your research communities, so it is reasonable to insist that secondary users assume the ethical responsibilities that come with the privilege of accessing shared data.
- Consider the Research Ethics Committee (REC) or Institutional Review Board (IRB) capacity required to review the ethics relating to release and future use of data. In the absence of Data Access Committees, IRBs are sometimes expected to take on oversight or regulatory functions regarding secondary users. Regulation of data access is often not within the capacity of many LMIC IRBs.
- Consent for future use adds a component to standard consent forms.
- Consider privacy, anonymisation of data, confidentiality protections, and identifiability / discrimination risks.
- Consider including requirements for feedback of results by third parties to participants, as well as benefit sharing in the results of research.

Commercial aspects

When negotiating to share samples in particular, consider the commercialisation potential and include clauses about intellectual property rights and the sharing or distribution of eventual benefits – not just to the primary researchers and their institutions, but also to the participant communities.

WHERE TO GO TO FIND OUT MORE: RECOMMENDED RESOURCES

Fitzgerald, A., & Pappalardo, K. (2007). *Building the infrastructure for data access and reuse in collaborative research: An analysis of the legal context.* Brisbane: Open Access to Knowledge (OAK) Law Project. [For a comprehensive approach to data sharing, and diagrammatic examples of data sharing agreements, we refer readers to this source]

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Jentsch, B., & Pilley, C. (2003). Research relationships between the South and the North: Cinderella and the ugly sisters? *Social Science & Medicine*, *57,* 1957-1967.

Kaye, J. (2011). From single biobanks to international networks: developing e-governance. *Human Genetics, 130,* 377–382.

Kuula, A., & Borg, S. (2008). *Open access to and reuse of research data – The state of the art in Finland.* Tampere: Finnish Social Science Data Archive.

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Rathgeber, E.M. (2009). *Research partnerships in international health: Capitalizing on opportunity.* Stakeholders meeting on strengthening research partnerships for neglected diseases of poverty, GTZ, Berlin, 16-18 March 2009. WHO/ Federal Ministry for Economic Cooperation and Development.

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Schroeder, D., Cook-Lucas, J.M., Arnason, G., Andanda, P., Kimani, J., & Fournier, V. (2013). Donating human samples: Who benefits? Cases from Iceland, Kenya and Indonesia. In D. Schroeder & J. Cook Lucas (Eds.), Benefit sharing: From biodiversity to human genetics (pp. 95-127). Netherlands: Springer.

Vickers, A. (2006). Whose data set is it anyway? Sharing raw data from randomized trials. *Trials*, *7:* 15.

Walport, M., & Brest, P. (2011). Sharing research data to improve public health. *The Lancet, 377,* 537-539.

World Economic Forum (2011). *Global Health Data Charter.* Geneva: World Economic Forum.

Capacity Building & Technology Transfer

WHAT IS IT ABOUT? WHY IS IT IMPORTANT?

Capacity building in relation to research partnerships refers to a wide range of areas of potential focus, from the capacity to define national research agendas and set priorities, to greater training and development of scientific and professional staff, to 'bricks and mortar' infrastructure, to being able to negotiate fairer research contracts which build sustainable research and innovation capacity. While capacity building was once understood simply as a technical process of transferring knowledge, skills and technology, it is now understood more systemically, recognising also the importance of building the capacity of institutions to produce and use knowledge. This shifts the focus to capacitating an enabling environment in which research occurs, coupled with a growing appreciation for country or institutional ownership of capacity development initiatives. As such, capacity building is not just a box to be ticked but a long-term process that requires significant commitment and resources from all partners.

- **Capacity** is understood as the ability of people, organisations and society as a whole to manage their affairs successfully.
- **Capacity development** is understood as the process whereby people, organisations and society as a whole unleash, strengthen, create, adapt and maintain capacity over time.
- **Promotion of capacity development** refers to what outside partners –domestic or foreign –can do to support, facilitate or catalyse capacity development and related change processes. (OECD, 2006).

Any effort to build capacity should consider how such efforts best fit the current circumstances and needs of the partner institution. As such, in negotiating fair research contracts, it is important for institutions to be able to communicate their capacity needs to their partners. For the purposes of this guidance document, aimed at partner institutions, the focus will be on individual and institutional capacity considerations, while recognising that building these capacities can contribute to national system capacity. In COHRED's work, we focus on *system optimisation,* rather than on capacity building per se, to acknowledge that, irrespective of sector or level or organisation, there is always prior capacity in place. System optimisation avoids the notion that capacity building is a one-sided transfer from 'capacity builder' to 'capacity recipient.' Instead, the goal is to enable partners to identify where the gaps might be and to determine how best to fill them in order to maximise what works.

Understand: Capacity Building

There are various ways in which capacity can be developed as part of a research partnership. Capacity building can be seen as incorporating a wide range of activities aimed at addressing gaps in the ability of institutions to produce, manage, use, implement and scale up their research endeavours. It occurs in research partnerships in formal and informal ways. Some research partnerships are explicitly about capacity building, others exchange knowledge and skills as part of meeting the objectives of the research project. There is increasingly a move towards making capacity development an explicit component of all research partnerships, in part as a means of realising the ultimate goal of institutional ownership of their research and development agendas, and building long-term, sustainable capacity to meet their own research and development objectives.

Capacity development is not just a one way process. The term capacity building can imply that the exchange of 'capacity' is one-sided, rather than a partnership of mutual benefit. Both or all partners stand to benefit in different ways from the interaction. What is often overlooked in capacity development efforts is that LMIC institutions have existing skills, resources and knowledge systems that can provide valuable insight and contributions to the research process. The rationale for this section is to respond to the needs of the less capacitated partner, but this should not create the impression that the capacities of the high income institution will not also be enhanced in different but important ways by engagement in the research partnership. This section focuses on ways in which low and middle income partners can negotiate for greater commitment to building capacity for long-term development. Ultimately, with greater capacity, all partners will benefit in the long term from stronger institutions.

Example of best practice: Capacity 'exchange' in an international collaborative research partnership

A research partnership formed between South African and American researchers to design and implement a prison intervention to reduce the rate of HIV is an example of a successful collaboration in which all partners benefited from mutual capacity building efforts. Clear and direct institutional support on both sides of the partnership, involvement of both teams in all stages of the planning and decision making process, and joint control of the budget were key aspects of this collaboration that resulted in strengthened capacity at the South African site. Recognising that both partners had particular expertise to contribute to the project, a mutual respect for the talent of all partners was identified as a critical starting point in skills and knowledge transfer. In this partnership, special consideration was given to proportional distribution of power, resources and decision making, towards the achievement of mutually agreed upon goals.

(Reddy, Taylor & Sifunda, 2002)

Capacity Components: Research Capacity Strengthening (RCS) grid

Type of intervention / Level of intervention	Individual	Institution	Research system	Socio- economic & political	International collaboration & linkage
'Capacity building'	Master level training	Grants management	Priority setting Strategy development	Increase demand for research	Good partnerships (e.g. alignment & harmonisation)
'Capacity strengthening'	Doctoral level training	Merit-based promotion system	Research ethics review capacity	Civil society engagement	Fair research contracting
'Performance enhancement' * equity-focus	Networking researchers, peer reviews	Research communication	Monitoring & evaluation of output & impact	Focus on health, equity & socio-economic development	Focus on research competitiveness

The actions listed in this grid are selected examples of capacity strengthening at each level.
Many more actions can be undertaken in each cell.

(Adapted from Ghaffar, IJsselmujden & Zicker, 2008).

Understand: Technology Transfer

Part of capacity development is building an institution's technological and innovation capability to take research results from 'bench to market'. Technology transfer is a term used to describe the processes by which technological knowledge, in its various forms, moves within or between organisations. Technology transfer is traditionally understood as a commercial or trade-related process in the innovation chain involving the acquisition and use of technology and the knowledge and skills needed to operate it. In the context of research partnerships, it can also be understood as the process of technological learning and benefit from technical exchanges in the partnership.

In this guidance document, technology transfer is understood as a way of governing the transfer of certain kinds of capacity, and is addressed here in three broad ways: the informal transfer of technical know-how and technological capabilities during the course of the research partnership; the process of transferring technology from one institution to another to enable the partner institution to use the technology for their own application and production (horizontal technology transfer); and the process of moving research results from 'bench to market', usually with the support of Technology Transfer Offices (TTOs) (vertical technology transfer). The latter two typically involve a structured process of technology transfer in which licenses and intellectual property rights are granted to allow partners to use various technologies for production and commercialisation purposes. It is important for institutions engaging in research partnerships which involve technology transfer to know and exercise their rights with regards to benefit-sharing and ownership of intellectual property rights. This section takes a general approach to these issues, and we refer readers to a substantive body of guidance on technology transfer to find further information on the nuances of such arrangements.

Much technology transfer occurs between willing partners in voluntary transactions of informal collaboration, learning and exchange of knowledge and know-how between individuals in different institutions (Maskus, 2004). For technology transfer to result in successful innovation, an institution needs to have sufficient absorptive capacity – that is, an enabling environment and a certain amount of pre-existing infrastructure and skills to optimise their ability to replicate, use, adapt and benefit from the technology. It is important to be aware that your organisation is unlikely to simply be a passive 'user of technology'. Every institution will have certain strengths, opportunities and needs that it can build on to use, adapt, learn and build capacity in technology. Any form of technological capacity building should take these into account. Increasingly, many LMIC institutions are engaging in their own technology transfer processes, as evidenced by the growing trend of universities partnering with industry to move research results from the academy to the market. This calls for intra-institutional coordination and is facilitated by the establishment of, for example, TTOs.

"To achieve sustainable transfer of knowledge, the transfer process must be based on a genuine partnership that is founded on the concept of reciprocal exchange. An equitable, participatory, and knowledge based approach in which everyone plays a role is essential. Along with the technology itself, a thorough understanding of the principles underlying the technology needs to be transmitted for independence to be achieved" (Harris & Tanner, 2000, p. 818). Ultimately, technology transfer should enhance the technological capabilities of the LMIC partner.

Definitions of Technology Transfer

There is no universally recognised definition of what 'technology transfer' means. Technology transfer may mean different things to countries and institutions at different stages of development. Some useful approaches to understanding technology transfer are presented here.

Technology transfer is a broad set of processes covering the flows of know-how, experience and equipment…It comprises the processes of learning to understand, utilise and replicate a technology, including the capacity to… adapt it to local conditions (WIPO, 2005)

Technology transfer encompasses the transfer of technical information, tacit know-how and performance skills, technical materials or equipment, jointly or as individual elements, with the intent of enhancing the technological capacity of the recipients. Such transfer can take place within a variety of domains, including public and private, institutional and individual, formal and informal, through partnerships and joint ventures, and within and across national borders (Sampath & Roffe, 2012).

Horizontal technology transfer refers to the movement of an established technology from one operational environment or organisation to another (SciDev.Net: www.scidev.net)

Vertical technology transfer refers to the transmission of technologies from generation (R&D) phase to operational application to commercialisation (SciDev.Net)

Technological learning refers to the process of accumulating the capability to innovate (SciDev.Net)

Technological capability refers to the ability to make use of knowledge to acquire, assimilate, adapt and change existing technologies and develop new products and processes (SciDev.Net)

Consider

This section highlights points to consider with regards to capacity building components when negotiating research contracts. The goal is to formalise these arrangements so that capacity strengthening becomes an explicit part of the research partnership.

Identify the **capacity building needs** of your institution. Capacity needs assessments can be an important way to begin the dialogue with partners. Identify indicators for capacity building at the start of the partnership (see, for example, ESSENCE (2011) and Bates et al. (2006)).

Consider developing an **explicit capacity building plan**, based on a needs assessment, where components of the plan can be built into the contract. (Refer to **Capacity Components** box).

Prioritise your institution's capacity needs and consider what could be incorporated into the existing project / partnership. Be clear about why capacity strengthening is needed, what purpose the capacity is being built for, and who the capacity will benefit.

Does the contract assume an enabling environment and existing infrastructure? Are there provisions for this if it does not exist or is insufficient? Try to secure **explicit commitment from the partnership to strengthen capacity** of partner institutions.

Be sure to clarify what kinds of capacity building are planned for during the partnership and ensure that **all partners are on the same page** in understanding what will be provided / developed / shared / transferred. Focus on **'capacity exchange'** – how can each partner complement the other?

Local ownership and control are critical to any capacity strengthening process. Ensure that capacity building efforts within the partnership are aligned with existing institutional strategies and resources for capacity strengthening. Reinforce what already exists and works, and anchor capacity building in institutional priorities, initiatives and structures.

When engaging in more than one research partnership, consider how to **harmonise capacity building efforts**. Where possible, try to balance external funding sources with domestic sources of funding.

Capacity building is often incorporated into the 'indirect costs' of a research project. See the section on compensation for indirect costs for guidance on negotiating a fair share of core funding that will enable realistic and sustainable capacity building efforts. Try to find other ways in which capacity can be built into the research partnership, **beyond what might be allowed for in indirect costing.** It is in the interests of all partners that each institution in the partnership is equipped to work effectively and is able to contribute fully to the success of the project.

Identify and partner with institutions and **research sponsors that make capacity building an explicit component** of their funding partnerships.

For capacity building to be sustainable, decision makers from local partner institutions should be given **equal say in how resources are allocated** and managed. This will often require coordination and communication between different sectors or institutional departments.

Case study: South – South technology transfer

With the growth of the so-called BRICS economies (Brazil, Russia, India, China & South Africa), south-south partnerships between LMICs are becoming more common. A classic example of south-south technology transfer is the launch in 2012 of Africa's first fully public antiretroviral factory in Mozambique, in partnership with Brazil's Oswaldo Cruz Foundation: http://www.panapress.com/Brazil-to-produce-ARVs-in-Mozambique---12-836035-66-lang2-index.html

Case study: A funder's approach to capacity building

The Special Programme for Research and Training in Tropical Diseases (TDR) structures its research capacity strengthening activities according to the needs of each country / institution. TDR works on the principle that, to achieve long-term outcomes, what is needed are comprehensive capacity building programmes that provide continuing professional development, support, and an enabling environment, rather than scientific training alone… Research capacity strengthening (RCS) is both explicit and embedded in its programmes: "Everything we do is RCS, and we try not to waste any opportunities – even if a scientific research project is being funded in the north, then we will try to bring in a fellowship for someone from the south" (Ghaffar, IJsselmuiden & Zicker, 2008, pp. 64-65).

Consider cont...

Consider **pooling skills and resources** across institutions in networks to attract funding and benefit from combined capacities.

Capacity development should **take into consideration all the individual, institutional and systemic capacity components.** Even where capacity building focuses only on particular components, this will inevitably have an impact on other components, so the relationships between these components need to be understood.

Is there scope for including **training (formal or informal) components** into the contract? Identify opportunities for workshops, conference attendance, short courses and academic programmes.

Include strategies to promote the **retention of a critical mass** of skilled and experienced researchers, managerial and support staff. Examples include career pathways, job security, networking opportunities, and so on. This may require a change in the mindset of research sponsors, to allow the use of core funds towards these purposes.

Is there scope for engaging with partner institutions for **proposal writing and grant management training / workshops**? Capacity for resource mobilisation is critical to the sustainability of research institutions.

What can be built into the contract in terms of **institutional capacity building**? Move beyond focusing only on individual capacity building, to include institutional components (See **Capacity Components** box).

Identify ways in which **capacity building can be incorporated into the success of the research project.** Frequent communication is needed, for example, if the partnership is to be successful; this may mean investing in the communication infrastructure of less capacitated partners. This includes increasing individual and institutional access to information.

Recognise the potentially **powerful position** that your institution occupies. High income partners and research partners require your involvement in the partnership to engage in locally-based research, for example. Recognising your position in these terms can empower your institution to insist on equal partnership with explicit capacity strengthening components.

Where technology transfer is an important component of the partnership, consider establishing a **dedicated technology transfer and support team.** (See **Technology transfer resources** box).

Negotiate for **mutually beneficial arrangements** which balance the concerns and interests of technology generators/suppliers and those institutions that rely on transfer of technology and technical know-how for their technological development (Roffe & Tesfachew, 2002).

The implementation process of technology transfer takes time and requires ongoing follow up in which **the 'technology donor' serves as a long-term resource** for scientific consultation, technical guidance and provision of relevant information and materials (Harris & Tanner, 2000).

For comprehensive guidance on technology transfer considerations, readers are referred to existing guidance listed in **Technology transfer resources.**

Technology transfer resources

Where no technology transfer office or support exists, there are initiatives that seek to address this by providing resources and guidance on aspects of technology transfer, management of innovation and IP. See, for example:

Southern African Research & Innovation Managers' Association (SARIMA)
SARIMA builds capacity and promotes best practice in the management, administration and support of research and innovation. Resources include training on aspects of technology transfer and IP management.

The Association of University Technology Managers (AUTM)
Based in the United States, AUTM's objective is to support and advance academic technology transfer globally.

The Brunswick Agreements
A number of template agreements - including material transfer agreements - for use between two universities or similar not-for-profit organisations.

The Intellectual Property Handbook (iphandbook)
The IP handbook is an online resource providing comprehensive guidance regarding all aspects of IP management. Technology transfer is addressed in a number of ways, including TTO functions and examples of technology transfer and licensing agreements.

The Lambert Toolkit
The Lambert Toolkit contains model agreements for university and industry partners looking to engage in collaborative research.

World Intellectual Property Organization (WIPO)
WIPO provides a number of resources for navigating the transfer and licensing of technology. Its *Exchanging Value* training manual is particularly aimed at non-specialists.

WHERE TO GO TO FIND OUT MORE: RECOMMENDED RESOURCES

Capacity building resources:

Bates, I., Akoto, A., Ansong, D., Karikari, P., Bedu-Addo, G., Critchley, J., & Agbenyega, T. (2006). Evaluating health research capacity building: An evidence-based tool. *PLoS Medicine, 3:* e299

ESSENCE (2011). P*lanning, monitoring and evaluation framework for capacity strengthening in health research.* Geneva: TDR/ESSENCE

Ghaffar, A., IJsselmuiden, C., & Zicker, F. (2008). *Changing mindsets: Research capacity strengthening in low- and middle-income countries.* Geneva: COHRED, Global Forum for Health Research and UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR),

OECD (2006). *The challenge of capacity development: Working towards good practice.* Paris: OECD.

Technology transfer resources:

Krattiger, A., Mahoney, R.T., Nelsen, L., et al (Eds.) (2007). *Intellectual property management in health and agricultural innovation: A handbook of best practices.* MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

Lambert Toolkit for university-industry collaboration: http://www.ipo.gov.uk/lambert (in high income settings)

Brunswick Agreements for collaboration between universities and similar non-profit organisations: https://www.arma.ac.uk/resources/brunswick-agreements (in high income settings)

Resources available on the website of the Southern African Research & Innovation Managers' Association (SARIMA): http://www.sarima.co.za/

WIPO (2005). *Exchanging value: Negotiating technology licensing agreements.* A training manual. Geneva: WIPO.

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Maskus, K.E. (2004). *Encouraging international technology transfer.* UNCTAD-ICTSD Project on IPRs and Sustainable Development. Geneva: ICTSD & UNCTAD

Nuyens, Y. (2005). *No development without research: A challenge for capacity strengthening.* Geneva: Global Forum for Health Research.

Potter, C., & Brough, R. (2004). Systemic capacity building: a hierarchy of needs. *Health Policy and Planning, 19,* 336-345.

Reddy, P., Taylor, S.E., & Sifunda, S. (2002). Research capacity building and collaboration between South African and American partners: The adaptation of an intervention model for HIV/AIDS prevention in corrections research. *AIDS Education and Prevention, 14,* Suppl B, 92-102.

Roffe, P., & Tesfachew, T. (2002). *Revisiting the technology transfer debate: Lessons for the new WTO working group.*

Sampath, P.G., & Roffe, P. (2012). *Unpacking the international technology transfer debate: Fifty years and beyond.* ICTSD Programme on Innovation, Technology and Intellectual Property. Geneva: International Centre for Trade and Sustainable Development.

White, M.T. (2007). A right to benefit from international research: A new approach to capacity building in less-developed countries. *Accountability in Research, 14,* 73-92.

Compensation for Indirect Costs

WHAT IS IT ABOUT? WHY IS IT IMPORTANT?

There is broad disagreement as to what is meant by ***indirect costs*** in research contracts. Most research funding scenarios require a full costing budget, which is made up of both direct and indirect costs of all research and related expenses. However, there are many instances where the indirect costs are not fully accounted for, if at all. While direct costs refer to those expenses that relate directly to project activities (e.g. salaries, travel, equipment and material supplies), indirect costs are those expenses which enable research institutions to carry out the underlying operations (the 'get-up') of research, and include costs such as rent, utilities, management costs, administration and financial service costs, maintenance, and legal and IP support. Indirect costs are also known as overhead costs, institutional levies or taxes, facilities and administration (F&A) costs, core funding, or non-specific/ discretionary costs. The percentage of indirect costs in relation to direct costs is known as an indirect cost rate.

Difficulties can arise where some research sponsors allow indirect costs in the full costing project budget and others do not. There is a great deal of variation among funders regarding allowable indirect cost rates. Further, the indirect cost rates that LMIC institutions are allowed to claim are generally much lower than those permitted to institutions in high income countries. While some research sponsors and high income partners do allow for indirect costs, they may also place a limit (also known as 'compliance costs') on the maximum allowable costs for these expenses carried by the research activity, leaving a great burden on less capacitated institutions to make provisions for carrying out the research in already low-resourced settings.

Because LMIC institutions very often lack supportive institutional structures and budgeting capacities, they are at risk of underestimating the full cost of research, running research projects at a loss and not being able to sustain their research environments. LMIC institutions are under tremendous pressure to grow and sustain their research environments. Often they are not in a position to fund research and as a result depend largely on high income partners for funding and support. The inadequacy of accurate costing around the full extent of indirect costs in research budgets has a direct impact on the sustainability of the research activity itself and the research environment as a whole. There may also be pressure on low income partners to provide a high income partner or research sponsor with a reduced cost budget in an attempt to bring costs in line with keeping with grant application requirements or conditions. This is not conducive to fair research contracting and very often benefits only the research sponsor or the partner directly in charge of budget allocations.

Against this backdrop, it is important to create an awareness of what indirect costs are and to strengthen the capacity of LMIC institutions to accurately determine and negotiate for indirect costs in a full costing with high income partners or research sponsors. **This section gives a general overview of the importance of taking indirect costs into account when calculating a full cost budget, and the different ways of calculating indirect costs.** We also provide some key pointers to consider when including indirect costs in a budget.

Understand

Indirect costs are those overarching costs that are utilised to sustain the research activity before, during and after research output has been delivered. Research staff engaged in the research environment should be able to accurately define and allocate such costs to a research costing (budget). Ultimately, a costing culture needs to be fostered whereby full costs (i.e. **the real cost of carrying out research activity**) are recognised and accounted for when budgeting. In some instances, LMIC institutions lack policies on the minimum conditions for calculating indirect costs. Thus the aim of this section is to provide a basic overview for establishing an **effective *costing culture.***

There is no single approach to establishing indirect costs. It is important that all partners work toward transparency and accountability. In determining accurate budgeting and financial planning, being open, realistic and accountable about indirect costs goes a long way towards fostering a trusting and mutually beneficial relationship between research partners. Similarly, where LMIC institutions lack policies and practices on how to determine indirect costs, high income partners that have access to such material should consider creating an enabling environment that makes way for negotiations on how to best resolve the issue of allocation of appropriate rates for indirect costs, to the mutual benefit of all concerned. In this section we broadly address indirect costs as they relate to research contracts. For excellent guidance on calculating indirect costs, we refer readers to the ESSENCE (2012a) *Five keys to improving research costing in low- and middle-income countries* good practice document.

TIP: Methods for calculating indirect costs

You may be able to recover indirect costs by either allocating the costs into direct costs, or making use of discretionary funds for administrative costs, training/ development of researchers and project oversight allocations. Below are a few ways that indirect costs can be distributed in a budget to incorporate a cost recovery by distributing them in direct costs.

Approaches to calculating indirect costs include:

1. Using total direct costs
- Divide the indirect costs by total direct costs to determine the indirect costs rate;
- Apply the indirect cost rate to total direct costs in a research project.

2. Using modified total direct costs as the basis of direct costs
- Determine the indirect costs;
- Determine the total direct costs;
- Determine the specific costs that should be taken into account (often this means the total direct costs excluding capital expenditure for equipment, charges for patient care, rental costs for off-site facilities, scholarships and fellowships, plus a portion of subcontracts over a certain value);
- Set the indirect-cost rate by dividing the indirect-cost pool by the agreed set of direct costs.

3. Using remuneration only as the basis of direct costs
- Determine total salaries and wages of all staff whether working directly or indirectly on the project (also consider whether to include or exclude fringe benefits);
- Determine the indirect costs;
- Determine the remuneration-distribution base (by subtracting the remuneration included in the indirect costs from total remuneration costs);
- Set the indirect-cost rate by dividing the indirect costs by the remuneration distribution base, and apply this to salaries and wages in a research project.

From: ESSENCE (2012a). *Five keys to improving research costing in low- and middle-income countries.*

Example of Best Practice: South Africa's Full Costing Model

South Africa is so far the only country in Africa that has used legislation to encourage research institutions to move towards full costing. The Intellectual Property Rights from Publicly Financed Research and Development Act, (No. 51 of 2008) came into effect in August 2010. Its primary goal is to ensure that intellectual property generated through the use of public funds is used to benefit the people of South Africa. The Act applies only to projects and research contracts that are fully or partially state funded (in other words, the Act does not apply when funders cover the full cost of the research). In terms of the Act, the National Intellectual Property Management Office (NIPMO) was established, and has called on all publicly funded higher education institutions to develop their own full-costing policies as a step towards developing a nationally accepted full-costing model.

(From ESSENCE (2012a): *Five keys to improving research costing in low- and middle-income countries)*

Recommendations for funders

In general, current indirect cost percentages are not sufficient to build capacity. Funders could consider:
- Site visits to get to know the realities of the environments in which their grantees are working.
- Indirect cost rates should be updated periodically to ensure that the institution's costing remain accurate and in line with research environment sustaining costs.
- Policies and practices should facilitate dialogue and collaboration for negotiating consensus on what are fair indirect costs.
- Allow for easier and more accessible grant application processes and offer support to those institutions that lack adequate financial systems and structures.

Consider

Determine your institution's internal or indirect costs for conducting and supporting research. Having a **clear institutional policy** around research costs is an important tool for ensuring consistency across grants negotiated at your institution, and provides leverage for negotiations with research sponsors. That said, an institutional policy on indirect costs should be flexible enough to accommodate the requirements of different research partnerships.

Cost your institution's research activities at a reasonable and current market value, and review these periodically. Being transparent and upfront about these costs will assist in contract negotiations around budgets and finances. Where research funds are in a different currency, be aware that exchange rate fluctuations will affect the total amount received over time.

Think about **allocating your indirect costs in a number of different ways** – for example, as a percentage of the total direct costs, as a proportion of a specific set of direct costs, or calculating indirect cost rates based on remuneration costs only. The methodology for calculating indirect costs will be based on your institution's policy around indirect costing.

Ideally, **separate direct costs from indirect costs**. Although there will be times when they need to overlap in order comply with funders' conditions on indirect costs, it is preferable to treat the direct running expenses of a particular project as different from those operational expenses that enable your institution to house and run such projects.

Be clear on **where the funding recovered from indirect costs will go** and how it will be used in your institution. Researchers are often unaware of how this funding is allocated within their own institutions.

Develop **good financial mechanisms** to strengthen financial and administrative reporting procedures. Build staff capacity in budgeting and financial planning for your research activities. Adopt good accounting principles and practice for determining, allocating, implementing and accounting for such costs. Research sponsors are more likely to agree to indirect cost rates if there is evidence of strong managerial and financial systems.

Establish **whether partner institutions are flexible on indirect costs.** It is always worth finding out how flexible a funding organisation's indirect cost rates are and whether there is room for negotiation. Establish whether there is a fixed, pre-determined methodology or rate that partners provide on indirect costs. More specifically, where the rate is too low, there needs to be some negotiation with the research sponsor or high income partner on adjusting the rate of indirect cost allocation. This is where having a clear outline of institutional costs will be useful. Establish whether funders' rates for indirect costs can be adjusted in line with current market rates toward promoting sustainable research environments.

Focus on **how investments in infrastructure will benefit your organisation's beneficiaries.** Even within the confines of a "cost conversation," you can emphasise how infrastructure investments may actually reduce the costs of serving beneficiaries over time (Gregory & Howard, 2009).

Tip: Calculating indirect costs

Universities in the United Kingdom have been encouraged to have an understanding of the full economic costs (fEC) of their research activity, and to be transparent in the way that they account for these costs, in order to ensure the sustainability of the sector. Since September 2005, UK universities have been calculating the fEC of individual research projects. Under the fEC model, traditional definitions of direct and indirect costs no longer apply. Instead, costs are to be classified as:

Directly Incurred Costs: actual costs that are explicitly identifiable as arising from the conduct of a project (e.g. staff salaries, equipment, materials, travel).

Directly Allocated Costs: costs of resources used by a project that are shared by other activities and based on estimates (e.g. principal and co-investigator costs)

Indirect Costs: non-specific costs charged across all projects that are based on estimates (e.g. human resources and finance services, library costs).

Taken from Wellcome Trust Grant Policy: Full economic costs
Also see EUA (2008).

WHERE TO GO TO FIND OUT MORE: RECOMMENDED RESOURCES

ESSENCE (2012a). *Five keys to improving research costing in low- and middle-income countries.* Geneva: ESSENCE.

ESSENCE (2012b). *Research costing practices: Bridging the gap in the funding of health research in low- and middle-income countries.* Geneva : ESSENCE.

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Research Contracts in (Legislative) Context

WHAT IS IT ABOUT? WHY IS IT IMPORTANT?

The issue of lawyer or no lawyer assumes that there is a legal or institutional contracting framework to begin with. However, this is not always the case. Furthermore, research contracting is often not considered a legal issue. Research institutions negotiating research contracts are less advantaged when they do not have an adequate legislative framework they can utilise as leverage to negotiate complex arrangements in global research partnerships. Moreover, lack of legal expertise, contract management capacity and budget preparation expertise can adversely affect the outcomes of a research contract. When research partners lack legal capacity, both in-house and in the broader national context, to negotiate and evaluate their contracts, they are limited in applying enforcement and protection mechanisms when disagreements arise from contracts that are not carefully crafted. In addition, research contracts often include clauses such as dispute settlement and indemnification but many of these are either one-sided (often in favour of the sponsor or high income partner and unacceptable to LMIC institutions from a financial and risk management point of view) or, at best, potentially confusing to an institution without adequate legal staffing.

Having national legislative frameworks pertaining to different aspects of the research contract can have a significant bearing on the terms and conditions drafted in a contract. For example, the IP laws of a partner country will to some extent determine the way that IP clauses are drafted in their contracts. In this section, we present **guidance on contracts as legal documents.** There is no uniform legal system governing contracts; the laws governing contracts can vary from country to country and may, in some cases, not exist at all. As a result, research partners engaged in international research contracts may have a difficult time negotiating these kinds of contracts where they concern two or more countries.

This section aims to provide some guidance on contracting in contexts where there is no clear legislative framework. We provide an overview of the different types of contractual agreements that exist, and outline some of the standard clauses and provisions that can be included when negotiating contracts, such as dispute resolution and confidentiality.

Understand

There is no universal legislative framework that applies to research contracts for all countries. In some countries, contracts may be governed by specific legal codes; in others, there may be various sources of law that the country derives its legal framework for contracts from. These legislative frameworks may have roots in a number of sources. For example, a country's legal framework governing intellectual property could be determined by international law, treaties and conventions. But in instances where there is no such clear-cut legal framework, a country's laws may be rooted in common-law, judicial precedent, custom, and customary law, with no specific protective mechanisms such as intellectual property law. In other countries, there is a relative legislative vacuum. In addition, there may be lack of institutional policies around contracting.

While there is no general applicable international law governing contracts, there are international norms that can aid in formulating specific terms in a contract, such as intellectual property (IP) law. IP law has been developed to such an extent that there is now a universal set of principles, the TRIPS agreement, which many countries have committed to implementing in their national legislative framework and policies. But this is not the case for all countries, and this inconsistency can cause a significant challenge for those partners who enter into research contracts with inadequate legislative framework to guide the contract negotiation process, specifically around terms and conditions concerning intellectual property. In the context of this lack of legal uniformity, this section aims to outline standard terms and conditions that can be found in contract agreements.

Where a country has legislation pertaining to relevant issues covered in a contract, this will have significant bearing on the enforceability of the terms of that contract. However, in some contexts, a partner country may have no clear legislative framework. In such cases, partners will look to the contractual terms and conditions that have been agreed upon. The provisions in a contract are legally binding, so it is important to be clear from the outset what you are agreeing to.

Below is a comprehensive outline of standard agreements and the kinds of clauses that can be thought through in contract negotiations. However, the template provided here is only a guide; it should ideally not be implemented as is but rather serve as a starting point for partners to negotiate and renegotiate, if necessary, to the benefit of all parties. While having a strong legislative framework can influence what can and cannot be included in a contract, a partner country that does not have an adequate legislative framework can still enter into a contract without being obliged to sign on 'any terms'. There are many ways that a contract can be negotiated to ensure that all parties benefit from the agreements they enter into.

Tips

- Take into consideration each partner country's laws such as their patent law, copyright law, and other specific legislation relating to IP, as well as any regulation of contracts, national legal provisions covering discharge of contract and potential dispute settlement methods (e.g. mediation, arbitration).
- Negotiators are normally advised to think first about the practical arrangement or partnership that they want to enter into, and then to think about how that arrangement should be expressed in legal terms. This includes deciding what law will govern the contract (choice of law clause). A choice of law clause is best decided on up front in the negotiation process, particularly when contracting in international partnerships.
- Where there is difficulty deciding which partner's (country) law will apply, partners could elect to choose a third country law to govern the contract. But bear in mind that this is likely to be more costly.
- The WIPO website "Lex" is a "one-stop" search facility for national laws and treaties on intellectual property of WIPO, WTO and UN member countries.

Consider

There are many kinds of agreements used to protect the interests of partners entering into research contracts. A contract is essentially an agreement on a set of legally binding rights, obligations and responsibilities between two or more parties. Contracts often describe these rights and obligations in provisions known as clauses - for example, a clause describing the procedure for settling disputes. Disputes will inevitably arise in managing contracts and intellectual property, so there is a great need for provisions such as dispute resolution to be carefully drafted in the negotiation of contracts so as to avoid or minimise conflict that could hinder successful collaboration. Dispute resolution clauses are often selected years before an actual dispute arises, by people who are not involved in the issues later on in the life of the contract or who have limited awareness of their specific implications in a dispute-resolution development (Min, 2007). More detail on dispute resolution clauses in particular is thus provided in the box to the right (**Dispute resolution**).

Types of contracts

Note: for the purpose of research contracting, the terms contract and agreement are used interchangeably.

In the context of negotiating fair research contracts, the contract, while an important legal consideration, should ideally maintain the themes of mutual benefit, trust, respect and good communication. A contract is a promise or undertaking containing mutual obligations of the provider and recipient that can be enforced by law. The concept "mutually agreed terms" indicates some kind of agreement (Tvedt, 2006, p. 4). The contract system rests upon the basic assumption that those entering into the partnership have partly overlapping interests and so are likely to negotiate a relatively balanced agreement.

Below is a list of some of the different types of agreements which may either be stand alone or clauses within larger contracts:

1. **Participation agreement:** a contract whereby researchers accept a policy which assigns all rights in any intellectual property to the institution they are employed or contracted by. (This may also be stipulated in a researcher's employment contract).
2. **Service agreement:** a contract whereby a consultant agrees to perform certain tasks and sets out to meet very specific outcomes, as determined in the contract by mutual arrangement.
3. **Confidentiality agreement/non-disclosure agreement:** a contract or part of a larger contract that covers the information pertaining to the research that must be kept secret. This type of agreement is put in place either before sharing exclusive information with another party or seeking such information from another party. It can be a separate agreement between disclosing and recipient parties, or may be included in a research agreement as a term.
4. **Materials transfer agreement (MTA):** a contract that sets out the conditions relating to use of materials that are only handed over to another party after the MTA is agreed to by the owner of the IP. It includes the use and methods to make the materials, where relevant, and often refers to transfer between partners of biological specimens and samples.
5. **Co-development agreement/collaboration agreement:** a contract that involves the specific contributions of multiple parties who contribute to a mutual outcome. Two key aspects of a collaborative agreement are that i) it is a legally binding document and ii) it includes a budget (documented evidence of funding that the parties contribute).
6. **Licensing agreement:** sets out certain permitted uses of materials or rights that the provider is entitled to grant, such as agreements to license the use of associated traditional knowledge or other IP rights.

Dispute resolution

Certain fundamental practices can be adopted in a contract in anticipation of dispute settlement. A dispute resolution clause might cover aspects ranging from general disputes to specific contentious issues. This does not mean that disputes will not arise between parties but if they do, the dispute resolution provision should provide guidance on how conflict will be handled. Two established mechanisms for dispute resolution are mediation and arbitration. These processes are far more cost effective than a lengthy litigation process.

The various mechanisms for resolving disputes should be considered and agreed upon, with a view to what is appropriate and effective, particularly in partnership with partners with limited capacity in terms of effective formal legal systems.

WIPO offers assistance on dispute resolution issues, through the WIPO Arbitration and Mediation Centre. Other options include the "Rules for Arbitration" of the International Chamber of Commerce (ICC) which were developed specifically for business disputes in an international context and are published in thirteen languages. The International Court of Arbitration (ICA) organises and supervises arbitration procedures and helps in overcoming obstacles. The Court will endeavour to ensure that the award is enforceable in national courts if required. Another advantage of the ICA is that the parties have the opportunity to choose the law under which their dispute is considered and also the location and language of the arbitration.

Consider cont...

7. **Research agreement or Research and Development (R&D) agreement:** defines various inputs to research or to research and development, including financial, material and intellectual contributions. Also specifies various responsibilities in relation to the conduct of research and development of new products or processes, and sets out how the monetary and non-monetary benefits from this research and development should be managed and shared. Some agreements are part of wider Co-operative Research and Development Agreements (CRADAs) as a common tool in biotechnology research. In essence, the parties agree to contribute various resources, such as existing IP, personnel, research facilities, in the collective pursuit of a shared research and development objective.
8. **Patent licence, technology licensing and licence agreement:** a contract that allows a party to use, make, sell or further develop a patented (and/or trade-secret-protected) innovation of another party. Patent licenses may be specific to one or several patents. Technology licences usually include the transfer of know-how (which may or may not be a trade secret) and sometimes materials.
9. **Research agreement and distribution agreement:** a contract that can contain any of the agreements listed above.
10. **Memorandum of Understanding (MOU):** a document whereby parties entering into a partnership agree to an intended common purpose or set of goals. This is sometimes seen as more of a moral agreement rather than a legally binding agreement, and thus it is usually not intended to have the enforceability of a legal document. Although useful as an overarching agreement that sets out the working principles between parties, it should contain a clause stipulating that any specific projects or collaborative work will be subject to individual written agreements.
11. **A Memorandum of Agreement (MOA) or cooperative agreement:** a document whereby parties willingly work together on an agreed upon project or meet an agreed upon objective. The purpose of an MOA is to have a written understanding of the agreement between parties.

Standard to all these contracts or agreements listed above are the following elements:

1. Broad purpose of the agreement.
2. Preamble, and 'whereas clause'.
3. Parties to the agreement.
4. List of terms and definitions: clearly describe the meaning of commonly used terms in the contract.
5. Clauses, which can include:
    - disclosure/non-disclosure;
    - confidentiality;
    - exclusivity,
    - liability;
    - payment;
    - dispute resolution;
    - indemnification: indemnification is usually a legally binding undertaking to protect a party from financial loss. This clause can be described as a form of direct compensation for any loss incurred.
    - intellectual property provisions: partners should describe all kinds of IP (existing and potential) included in the research collaboration, to the extent of ownership, protection and access;
    - publication.
6. Term and Termination.
7. **Jurisdiction** (where disputes will be resolved): The choice of law governing the agreement has significant implications in international agreements. There is often a lack of information about the procedures in many countries. It is therefore necessary for a research partner to carefully consider the jurisdiction under which the contract will be governed as this will have bearing on legal processes and costs.
8. **Warranties and notices:** carefully consider your institution's ability to provide warranties in stating ownership of IP.
9. **Illegal/unenforceable provisions:** If a court of competent jurisdiction considers an agreement and finds any provision invalid, illegal, or unenforceable, that provision is considered severed from the contract. The remaining legal provisions will still be enforceable. In other the words, but for the illegal and unenforceable provisions, the contract remains intact.
10. **Choice of law:** the choice of law clause describes where parties to a contract wish to have an agreement interpreted and adjudicated.
11. Name, address and capacity of individuals to whom official communication is to be sent.
12. Signatories of authorised representative (i.e. officials who are able to bind the organisation).

WHERE TO GO TO FIND OUT MORE: RECOMMENDED RESOURCES

A Collaboration between the National Cancer Institute and the CEO Roundtable on Cancer (2008). *Proposed standardized/harmonized clauses for clinical trial agreements.*

Min, E.J. (2007). Alternative dispute-resolution procedures: International view. In A. Krattiger, R.T. Mahoney, L. Nelson et al. (Eds.) *Intellectual property management in health and agricultural innovation: A handbook of best practices* (pp. 1415-1427). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A.

Mahoney, R.T., & Krattiger, A. (2007). Agreements: A review of essential tools of IP management. In A.Krattiger, R.T. Mahoney, L. Nelson et al. (Eds.) *Intellectual property management in health and agricultural innovation: A handbook of best practices* (pp. 675-687). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A.

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Recommended WIPO contract clauses and submission agreements.

Steinbock, M.B. (2007). How to draft a collaborative research agreement. In A. Krattiger, R.T. Mahoney, L. Nelson et al. (Eds.) *Intellectual property management in health and agricultural innovation: A handbook of best practices* (pp. 714-724). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A.

See also www.IP-helpdesk.org

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Jurčys, P. (2012). International jurisdiction in intellectual property disputes. *JIPITEC*, *3*, 174-226.

KFPE (2012). *A guide for transboundary research partnerships: 11 principles.* Berne: KFPE.

Knowledge Transfer Working Group of the European Research Area Committee (2012). *European Research Area Guideline: Intellectual property (IP) management in international research collaboration agreements between European and Non-European partners.*

OECD Global Science Forum (2009). *Investigating research misconduct allegations in international collaborative research projects: a practical guide.* OECD.

Tvedt, M.W. (2006). Elements for legislation in user countries to meet the fair and equitable benefit-sharing commitment. *The Journal of World Intellectual Property*, *9*, 189-212.

UNCTAD-ICTSD (2005). *Resource book on TRIPS and development: An authoritative and practical guide to the TRIPS agreement.* Geneva: UNCTAD-ICTSD Capacity Building Project on IPRs.

Useful TRIPS resources available on the WTO webpage: www.wto.org/english/tratop_e/trips_e/trips_e.htm

Williams, B.A. (2000). Consensual approaches to resolving public policy disputes. *Journal of Dispute Resolution*, *8,* 135-152.

WIPO (2013). *Results of the WIPO Arbitration and Mediation Center international survey on dispute resolution in technology transactions.* Geneva: WIPO.

Repository of Policies & Templates

Policy / Organisation	Broader research & grant management	Intellectual property & ownership of samples	Data sharing and management	Technology transfer & capacity building	Budgeting for indirect costs	Sample agreements
Africa Centre				Capacity building policy		
Astra Zeneca			Data privacy policy			
Bandim Health Project			Data sharing policy			
Canadian Institutes of Health Research (CIHR)	CIHR grants and awards guide Guide to collaboration	Intellectual property assessment form	Best practices for protecting privacy			
Canadian International Development Agency (CIDA)					Overhead compensation policy	
Center for Disease Control & Prevention (CDC)		Contract templates Policy on IP licensing	Standards to facilitate data sharing and use Policy on releasing and sharing data Guiding principles for data sharing			Confidentiality disclosure agreement Material transfer agreement
Department for International Development (DFID)	Research consortia terms of reference		Open and enhanced access policy			
European & Developing Countries Clinical Trials Partnership (EDCTP)	General terms for grant agreements	Policy on IPRs			Budgeting guidelines Financial management guidelines	
INDEPTH Network		IPR & authorship terms	Data access & sharing policy Collaborator data sharing policy Data sharing agreement			Confidentiality undertaking
International Centre for Diarrhoeal Disease Research (ICDDR,B)			Data access policy Data licensing application agreement			

Policy / Organisation	Broader research & grant management	Intellectual property & ownership of samples	Data sharing and management	Technology transfer & capacity building	Budgeting for indirect costs	Sample agreements
International Development Centre (IDRC), Canada	Grant terms & conditions Additional grant terms & conditions	Patent policy			Guidelines for acceptable project expenditure	
National Institutes of Health (NIH)	Grants policy	Grants policy	Grants policy Data sharing policy & implementation Data sharing chart		Grants policy	
Stellenbosch University, South Africa				Exploitation of IP policy		Nondisclosure agreement Material transfer agreement
The Global Fund	Guidelines for grantees Grant standard terms & conditions				Guidelines for budgeting	
The Wellcome Trust		Policy on intellectual property Exploitation of trust-funded IP agreement	Policy on data management and sharing			
United States Agency for International Development (USAID)		Guidance on intellectual property rights				
University of KwaZulu-Natal, South Africa	Grants and contracts policy	IP policy Intellectual property agreements			Position statement on overhead and indirect costs	Material transfer agreement IP disclosure form
World Health Organization (WHO)	Terms and conditions for WHO collaborating centres					
World Intellectual Property Organisation (WIPO)		Guidelines on developing IP policy Brochure on IP for African countries				

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