

MEETING REPORT

“Where there is no lawyer...”: Towards fair contracts and contracting in research for health

COHRED Fair Research Contracting Meeting
Bellagio Center, 22 – 26 October 2012

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Acknowledgements

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Key words: fair research contracting, negotiation, capacity building, sustainable research and innovation systems, low- and middle-income countries, intellectual property, technology transfer, research financing

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Executive Summary

Background

The negotiation of equitable research partnerships is now, more than ever, a central issue for low- and middle-income countries (LMICs). One of the core obstacles to sustainable research and innovation system building in LMICs is the difference in legal expertise and contracting capacity between LMIC institutions and their high income partners. The principle driving COHRED's fair research contracting initiative is to level the playing field through equipping LMICs with the legal resources and capacities needed to negotiate fair partnerships.

In 2011, COHRED successfully applied to the Rockefeller Foundation's Bellagio Study and Conference Center for support to hold a meeting entitled *"Where there is no (intellectual property) lawyer: Towards fair contracts and contracting in research for health."* This meeting enabled us to bring together a group of just over twenty people who were capable, interested and well-positioned to design, implement, advocate for and disseminate the outcomes and follow-on actions of this meeting. They came with a wide range of contracting experience, representing perspectives from research institutions, development partners, foundations, donor agencies, non-governmental organisations (NGOs), academic institutions, the private sector, and legal groups.

Summary of the meeting

Work in the year leading up to the Bellagio meeting focused on identifying and critically reviewing those aspects of research contracts identified as unfairly weighted against LMIC institutions in research contracts. These issues were identified as:

1. Benefit sharing
2. Ownership of data and samples
3. Intellectual property rights
4. Technology transfer and capacity building
5. Compensation for indirect costs
6. Insufficient legislative frameworks governing contracts
7. Conflict resolution

The objectives of the Bellagio meeting were to:

1. Review and test out the key issues in fair research contracting identified above
2. Critically review and build potential solutions, in the form of:
 - i. Model contracts, checklists, modules
 - ii. A manual or guidance document for contracting / negotiation training and support
 - iii. Web-based intellectual property advisory service
 - iv. Global advocacy for adoption of best practice

Perspectives on research contracting challenges and enabling strategies were presented by participants on the first day of the meeting. Over the next two days, participants began to develop potential solutions for addressing the challenges identified. The discussion focused on developing model contracts and checklists, and on contracting and negotiation guidance, which would both become the basis of a web-based toolkit and advisory service. Based on the form that these outputs began to take during working group sessions, plans for advocacy and dissemination were outlined on the final day of the meeting.

Taking action

A group of diverse and interested partners at the Bellagio meeting committed to forming a consortium to support COHRED in driving this initiative. On behalf of their organisations, participants pledged support for the pooling of model contracts, needs assessments and surveys of institutional networks. They also offered to provide their expertise, advice and case studies of what has worked and what has not. This will be backed up with financial assistance to move the initiative forward.

A number of recommendations emerged from this meeting:

1. Move beyond an ad hoc, institution-by-institution approach
2. Build LMIC capacity to negotiate on their own terms, for sustainable development
3. Understand contracting needs and develop guidance based on this
4. Sensitise all stakeholders to the consequences of lack of contracting capacity
5. Unpack the contrary incentives that drive LMIC institutions to agree to contracts on any terms
6. Make products (checklists and negotiation guidance) and (advisory) services accessible on an interactive web-based platform
7. Identify funders and high income partners to champion this cause
8. Foster social entrepreneurship by engaging the private sector and pharmaceutical industry

1 Background

Why fair research contracting?

NEGOTIATING EQUITABLE RESEARCH PARTNERSHIPS remains a central issue for low- and middle-income country institutions (LMICs). The Council on Health Research for Development's (COHRED) fair research contracting (FRC) initiative aims to identify best practices for the research contracting (negotiation) process that would be useful in the following three situations: i) where there is no lawyer, ii) where there may be lay personnel who could be trained, and iii) where there is a lawyer or legal expertise.

The growing volume of research in LMICs is welcome, but brings with it a number of new challenges for research institutions and government departments dealing with research in those countries. In particular, experience suggests that, on occasion, high income institutions proposing to either collaborate with or commission research from lower income institutions, insist on a number of preconditions that disadvantage these institutions. The necessity for LMIC institutions to have access to the legal resources and capacities to negotiate fair partnerships with their funding partners has become more important than ever.

The issue of inequitable research partnerships is not new, and is not limited to the health sector. Although best practice guidelines have been developed, implementation strategies – the key to ensuring that guidelines change practice – appear limited. 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.

The fair research contracting initiative seeks to clarify the problems experienced in research relationships between high income and low income institutions and, in particular, to focus on those 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.

Why now?

The world is ever increasingly focused on research and innovation, and this research is increasingly multi-centre, multi-country, and multi-regional. As these collaborations transcend national borders, the complexity of technology transfer and intellectual property arrangements has multiplied. The negotiation of equitable research partnerships is now, more than ever a central issue for LMICs. For this reason, COHRED committed to restarting the fair research contracting project in 2011.

In the past few years, the importance of local innovation and R&D to develop sustainable solutions has increasingly been recognised. However, such sustainability is only achievable if research funding allows for capacity building and sharing of other benefits from research partnerships which leave the low income partner in a more empowered position. With the growing focus on of the EU and other high income partners on economic growth and innovation¹, having strong, accountable partnerships with LMIC partners is important in driving the research sector for mutual benefit.

1. For example, the EU 2020 Innovation Flagship Initiative

The past few years have seen a growing emphasis on country ownership for sustainable development, home-grown solutions, and an increasingly open global village which has increased the complexity of technology transfer arrangements and intellectual property rights (IPRs) – while LMICs are struggling to keep up in terms of capacity to produce local solutions and in establishing the legislative frameworks to navigate these complex arrangements in global partnerships. Calls for researchers to share biomedical and public health data are matched by an increasing need for capacity, the protection of local knowledge, and for new models of IPRs. Perhaps not surprisingly, developing countries are now actively asserting their rights to intellectual property and are also calling for fairer technology transfer arrangements – as evidenced at the multi-lateral level by the establishment of the Development Agenda Group at the World Intellectual Property Office.

To keep up with these developments, capacity building efforts should be fore-grounded in all collaborative research partnerships. COHRED is a key partner in increasing the research competitiveness and innovation capacity of LMICs in this highly competitive global research environment. Building LMICs' capacity to negotiate fair research contracts with their high income partners is a critical part of this.

At the current time, there are no such capacity building efforts focused on “where there is no IP lawyer”. There have been attempts in the north to give patents to the south, but institutions in the south simply do not have the necessary contracting or legal expertise available. The principle driving this project, then, is to level the playing field. COHRED has connected with and gathered data from a number of countries on a number of continents concerning issues related to research and innovation for health. With this data and through our preliminary work in the research contracting area, we have identified seven areas (listed below) that seem to require addressing most urgently in interactions between high income and low – and middle income partners.

On their own, these issues have received a great deal of air time. However, much of the available guidance seems

to have been generated in and by the north, and tends to focus on how northern institutions can navigate these issues in partnership with other northern institutions, or with their southern counterparts (see for example, the Lambert Review or the newly revised KFPE guidelines on research partnerships). Generating such guidance from the perspective of the global south is part of what makes COHRED's fair research contracting project innovative. We are not aware of other initiatives similar to this – placing tools and knowledge in the hands of institutions and governments in LMICs rather than focusing on the goodwill of higher income partners. We focus on building capacity for LMIC institutions and governments to be able to define partnerships and contracts on their own terms. In COHRED's philosophy, this self-sufficiency is what constitutes real development.

Lead up to this meeting

In 2006, the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) brought the issue of contracting practice to the attention of the WHO's Advisory Committee on Health Research, by highlighting the difficulties they faced in negotiating ‘equitable’ contracts with research sponsors. COHRED was asked to lead an *International Collaboration on Equitable Research Contracts* to examine this issue in more detail and plan a collective response. The first phase of this response was finalised in May 2009 with the publication of an editorial in the Bulletin of the WHO, raising awareness on the issue.

Given that negotiating equitable research partnerships remains a central issue for LMICs, COHRED committed to restarting this project in 2011. A think tank convened by COHRED in March 2011 asked a core group of partners in this project to review those aspects of research contracts identified as unfairly weighted against LMIC institutions in research contracts. These issues are presented in Table 1 below.

In April 2012, in Cape Town, a fair research contracting workshop was held at Forum 2012. At this workshop, attended by an experienced and multi-disciplinary group, the previously identified issues were reviewed and preliminary work was done to begin to identify solutions.

ISSUES IN RESEARCH CONTRACTING

Distribution of research benefits: Benefit sharing is more than simply sharing intellectual property rights. It can be seen as an umbrella condition including technology transfer, individual or institutional capacity building, and strengthening (aspects of) national research systems.

Ownership of data, samples & publications: A common issue is the claiming of exclusive data ownership by funders, even though the data have been collected by the LMIC institution. Debates on the issue of data sharing and ownership are ongoing.

Sharing of intellectual property rights: Exclusive ownership of intellectual property rights (IPRs) has frequently been claimed by the high income funder or partner. Similarly, IPRs may hinder the development of local research capacities and deny open access to research results. On the other hand, as significant research results begin to emerge from some LMICs, it is important that their IPRs be protected.

Capacity building and technology transfer: Capacity building in relation to research partnerships refers to a wide range of areas in which such efforts should be focused, from the capacity to define national research agendas and set priorities, to being able to engage in pharmaceutical innovation and research & development, to being able to negotiate fairer research contracts.

Adequate compensation for indirect costs: Linked to capacity building, this refers to the overhead costs that LMIC partners incur, and for which minimal provisions are made, 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, beyond the research project itself.

Compensation for insufficient national legislation governing contracts: 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. One point of entry into the fair research contracting project might be to collect, through HRWeb, evidence from countries to determine what is actually in place, thus enabling us to support countries more clearly by developing or building on their national or institutional frameworks.

Conflict resolution: Contracts often describe ways of settling disputes. However, it is not always easy to identify a neutral body for dispute settlement. Most draft contracts have indemnification clauses but many are one-sided or, at best, potentially confusing to an institution without adequate legal staffing.

2 Objectives, Participants & Process

FOLLOWING 18 MONTHS OF PRELIMINARY WORK, the FRC Bellagio meeting aimed to briefly review the challenges experienced in research partnerships between high income and low income institutions and to focus on ways in which those issues could be effectively addressed by developing and implementing guidance appropriate to local and global contexts. The objectives of the meeting were therefore to:

- 1 Review and test out the key issues identified in fair research contracting from preliminary work,
- 2 Brainstorm around solutions to address the challenges identified, focusing in on 2-3 concrete, actionable solutions
- 3 Critically review and begin to build on potential solutions, in the form of:
 - a. Model contracts, checklists, modules
 - b. A manual or guidance document for contracting / negotiation training and support
 - c. Web-based 'IP-advisor' service
 - d. Global advocacy for adoption of best practice

The outcomes from the Bellagio FRC meeting are expected to culminate in an interactive space on COHRED's Health Research Web (HRWeb) where guidance on process and content is available to countries and institutions negotiating research contracts.

To ensure that the work at Bellagio had momentum beyond the three day meeting, COHRED brought together a talented, multi-disciplinary group who were well positioned to design, implement, advocate and disseminate the outcomes and follow-on actions of the meeting. Participants at the Bellagio meeting came with a wide range of contracting experience, representing diverse perspectives from research institutions, development partners, foundations, donor agencies, non-governmental organisations (NGOs), academic institutions, the private sector and other groups.

One key factor in the success of the meeting was its Chatham House Rules format, resulting in candid, transparent discussions around contracting issues on both sides of the field. Participants' willingness to share both successes and shortfalls in past experiences ensured that

all delegates had a thorough understanding of factors that could influence contracting in partnerships for research. Innovative suggestions and practical, actionable steps were generated, as well as plans for how to package these and make them available. Participants' expertise, perspectives and experiences were invaluable in informing this process. (See Appendix 1 for a complete list of meeting participants).

The open space facilitation approach to the meeting allowed us to make the most creative and involved use of the knowledge and expertise of meeting participants. In open space meetings, participants determine meeting content through a relatively rigorous, creative process, and may adjust it as the meeting proceeds. The open space meeting format ensured that all issues raised could be addressed by those participants most qualified and capable of getting something done on each of them. The professional facilitation of Liesl Schoonwinkel from Facilitators without Borders, with support from COHRED's Debbie Marais, was key to ensuring a smooth meeting process, as was the input from the COHRED writing and administrative team (Danny Edwards and Florine Jobin).

3 Overview of Issues Presented

THE MEETING AT BELLAGIO WAS A VALUABLE OPPORTUNITY for peers working in this area to share their ideas and thoughts with colleagues, and to build something bigger by combining their efforts – ultimately improving the ability of research institutions in resource-poor settings to negotiate stronger, fairer contracts. To secure the continuing success of Bellagio – both at the meeting and beyond – participants were asked to do preparatory work in the months preceding the meeting. This work, presented on the first day of the meeting, enriched and directed the discussions which followed. It is discussed briefly here.

Carel IJsselmuiden from COHRED first outlined why this remains a critical issue in research partnerships, and drew participants' attention to the objectives of the current meeting. A number of participants conducted valuable 'straw poll' surveys of institutions in their regions and networks regarding contracting capacity and experiences. For example, Jeannette Quarcoopome of the INDEPTH Network's Health and Demographic Surveillance System (HDSS) Centres suggested that many members had not

autonomous centres). Similar findings were presented by Jens Hinricher of the ICDDR,B, following a regional survey of collaborating institutions in South and South-East Asia. The majority of institutions reported having no specialist legal expertise, with the result that contractual terms and conditions were often poorly understood.

Gaps in contract management capacity also existed in many grantee institutions of the European & Developing

Countries Clinical Trials Partnership (EDCTP), including legal assistance, budget preparation support, and dedicated contract negotiation capacity. Charles Mgone of the EDCTP highlighted some of the consequences of this lack of capacity, ranging from delays in starting projects, inability to finish projects within the agreed budget, and mistrust between grantees and funders – with the consequent risk of perpetuating the cycle of dependence on high income partners. In general, these brief surveys raised awareness among those surveyed about the importance of contracting capacity. There was agreement amongst

meeting participants that continuing and expanding on these surveys could reveal further valuable information about the current status of capacity in many regions.

Echoing these findings, Bakari Bakari from the IFAKARA Health Institute, believed that the research contracting



considered research contracting as a legal issue. Access to legal capacity, both in-house and externally, seemed to vary greatly between member sites, from strong capacity to negotiate and evaluate contracts (at well established centres) to average (usually those affiliated with an academic institution), to weak (at independent or semi-

deficiencies experienced by IFAKARA were symptomatic of challenges faced by many other institutions in LMICs: a shortage of contract negotiation skills, legal and financial knowhow, managerial and administrative structures, and an institution's financial resources, which in turn influenced their negotiating power. With regards to research financing, Judith de Kroon of the Netherlands Organisation for Scientific Research (NWO), presented findings from the ESSENCE Group that recovering research costs was a major challenge for institutions in LMICs that were seeking to develop and maintain sustainable research environments. In response to this need, ESSENCE has published a guidance document presenting five keys to improving research costing in low- and middle-income countries.

Bakari Bakari's previous experience working in a high income country funding institution provided a perspective on capacity from the 'other side.' 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 the north – who are concerned with protecting their own interests (maximising return on investment) and minimising their own risk. This tends to result in a typically defensive or restrictive position when negotiating contracts with LMIC partners – further highlighting the need for contracting capacity to be strengthened in LMIC institutions. Gerald Keusch from Boston University pointed to the effects that lack of awareness, legal constraints, and economic considerations have on research collaborations from the perspective of developed country institutions. He recommended following a strategy of focusing on regional partnerships amongst resource poor institutions, where there is at least one large capacity player in the region willing to truly partner.

Intellectual property (IP) issues were also presented as a major challenge in negotiating fair research contracts. Pamela Andanda from the Faculty of Law at WITS University reviewed some of the prominent examples of these issues, showing that exclusive ownership of IP (IP protection), exclusive data ownership, specimen / sample ownership, and disagreements over dispute resolution are issues typically faced by LMIC partners in Africa and other regions. A more in-depth review of how technology transfer arrangements are impeding national innovation and development in Macedonia was presented by Bratislav

Stankovic, of the Public Interest Intellectual Property Advisors (PIIPA) group. Foreign firms are currently the major players in new technology innovation in Macedonia, with a dearth of local public-private partnerships and little government investment in research and development activities. In contrast, Jie Chen, of the School of Public Health at Fudan University, explained how IP protection policies in China have created an enabling environment for



national innovation and development, showing that IP can be positively harnessed to shift a country from an economy of production to an economy of innovation. Keeping the focus on the pharmaceutical industry – in this case, in the United States – Adel Mahmoud from Princeton University drew attention back to the fundamental importance of ethical considerations in protecting the individuals and communities who participate in clinical trials and related research from which intellectual property may emerge.

Participants were reminded that intellectual property issues extend beyond patents and products to data and publication rights. Jeanette Quarcoopome highlighted that data sharing issues are a major challenge faced by the INDEPTH Network's HDSS Centre members. Increasingly, there are calls for open access to public health data. The call by the Joint Funders' Initiative for more equitable (public health) data sharing was outlined by Mary Bassett, from Doris Duke Charitable Foundation (a member of the aforementioned Initiative). 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 quite substantially from funder to funder.

A number of participants presented strategies, programmes and policies employed by their institutions and countries to facilitate research contracting that is geared towards capacity building and development. These included approaches to equitable contracting for regional development by the National Research Foundation (NRF) of South Africa, as described by Albert van Jaarsveld, and by the International Development Research Centre (IDRC), as presented by Michael Clarke. Renata Curi from FIOCRUZ presented a summary of Brazil's cooperation policies, which have a strong emphasis on capacity building and sustainable development in partner institutions. Renata's presentation set the scene for a common theme that found its way into much of the discussion during the meeting: shifting the focus from technical assistance to technical cooperation among all partners. Providing technical checklists are only valuable if this is grounded in a collaborative effort with LMICs to promote autonomy and ownership and to build capacity for negotiation, thereby

ensuring the sustainability of the process. Konji Sebati described how the World Intellectual Property Organization (WIPO) makes a number of resources available to build the capacity of LMICs to harness IP for innovation. WIPO also partners with BIO Ventures for Global Health (BVGH) in the WIPO Re:Search platform. BVGH was represented at the meeting by Jennifer Dent, who explained how this platform aims to stimulate partnerships that pursue both product development and capacity building in the resource-poor partner in parallel.

Table 2 presents a summary of the research contracting challenges and enabling strategies presented by participants on the first day of the meeting. Interestingly, discussions at the fair research contracting workshop held in April at Forum 2012 also became increasingly focused on capacity building and technology transfer, as well as on inadequate compensation of indirect costs. (See Appendix 2 for a summary of discussion points from the Forum 2012 FRC workshop).

Table 2

RESEARCH CONTRACTING CHALLENGES AND ENABLERS EMERGING FROM DAY 1		
	GAPS, NEEDS, CHALLENGES	ENABLING STRATEGIES & POLICIES
LEGAL, FINANCIAL & CONTRACTING MANAGEMENT CAPACITY	Variable. Recognition of need for legal expertise* (<i>INDEPTH members</i>)	
	Deficiencies in several areas symptomatic of regional (lack of) capacity (<i>IFAKARA</i>)	
	Lack of legal capacity & understanding of contracting terms & conditions* (<i>ICDDR,B regional partners</i>)	
	Significant gaps in contracting management capacity* (<i>EDCTP grantees</i>)	
	Importance of stewardship and efficiency to minimise risk and maximise return on investment (<i>Funders & primary award recipients</i>)	Focus on cooperation and capacity building for sustainable development (<i>FIOCRUZ, NRF, IDRC</i>)
	Research costing a major challenge for LMICs (<i>ESSENCE</i>)	Costing guidance document (<i>ESSENCE</i>)
TECHNOLOGY TRANSFER, OWNERSHIP OF PRODUCTS, DATA SHARING (IP)	Tech transfer arrangements impeding national innovation* (<i>Macedonia</i>)	
	Access to and protection of data a major focus (<i>INDEPTH</i>)	
	Variable requirements on data release time frame* (<i>Joint Funders Initiative</i>)	

4 Addressing the Issues

AT THE MEETING, PARTICIPANTS BEGAN TO DEVELOP POTENTIAL SOLUTIONS for addressing the challenges identified. The discussion focused on developing model contracts and checklists, and on contracting and negotiation guidance, which would both become the basis of a web-based toolkit and advisory service. Based on the form that these outputs began to take during working group sessions, plans for advocacy and dissemination were outlined on the final day of the meeting.

In an open space brainstorming session, participants highlighted key issues for consideration when formulating model contracts or checklists and contracting (negotiation) guidance. These are presented briefly in the relevant sections below. Thereafter, participants formed working groups to begin to define and describe what each solution would look like, and outline a plan for getting there. These are depicted visually in Table 3, incorporated into the web platform that would house these solutions.

4.1. Contracts / Checklists

Key considerations

There was agreement amongst participants that developing checklists or model contracts was a good first step, provided they are accompanied by support and training and do not replace longer-term capacity building and empowerment strategies. Checklists were favoured over model contracts, largely because checklists were seen to be less prescriptive or formulaic, could be kept short and simple, and could be specific enough to be meaningful but broad enough to be adapted to regional or local contexts. Checklists are also likely to be more effective than contract templates in providing step-by-step training in decision making around contracting. Using a blend of technical and non-technical terminologies, checklists could provide targeted guidance based on an individual or institution's level of expertise. Participants highlighted the value of including case studies and examples to give context to the checklists. Institutions and regional organisations could be encouraged to share model contracts and engage in collaborative learning around best negotiation practices and experiences. Similarly, networks of regional management associations (e.g. SARIMA, CABRIMA) could be utilised to provide input

and regionally appropriate examples. Although web-based checklists may increase accessibility and allow for periodic updating, it was suggested that these templates and checklists be made available offline as well, particularly in regions where internet connectivity may be limited.

4.2. Negotiation / Contracting Guidance

Key considerations

A critical first step in developing contracting guidance is to find out what is already available in terms of training, capacity building and resources. Identifying and collating best practices in contract negotiation will provide the foundation for this guidance. It is also expected that this process will involve raising awareness about the problems and possibilities of negotiation. In this regard, it will be important to unpack the perverse incentives that drive LMIC institutions and researchers to agree to contracts on any terms. Exploring and understanding what accounts for pressure – both internal and external – to sign con-

tracts was considered critical for adapting guidance to adequately address these issues. Similarly, participants were cognisant that contracting guidance cannot replace building mutually respectful relationships based on trust, which tends to require a longer term investment on the part of both partners. Guidance could include strategies for fostering such relationships – externally (between signing partners) and internally (between researchers and institutional legal advisors) – and for ensuring that national and institutional contracting is complementary. Clarifying roles and responsibilities within an institution will be key, as will building multidisciplinary teams to contribute diverse skills and expertise to the contracting process. As with checklists, this web-based negotiation guidance, while globally accessible, should be regionally concentrated in terms of information and training, and preferably available in different languages. Participants recognised the diversity of contracts and agreements for different types of institutions and partnerships. Creating a typology of contracts for different types of research partnerships may be useful for institutions to make decisions about what is applicable in a variety of situations.

4.3. Intellectual Property

Summary of discussion points

The complexity of issues around intellectual property (IP) rights, as well as conflicting views about the importance of certain aspects of IP, created a bottleneck in the discussions. This was resolved by a decision to focus, on day three, only on contracts and checklists, and contracting / negotiation guidance – with the understanding that the checklists and guidance would also address issues related to IP. A short summary of the main discussion points is presented here.

There was a suggestion that there should, as a first step, be a situation analysis of LMIC needs with respect to IP, although that may be outside the scope of what this guidance can achieve with limited time and resources. Nonetheless, and notwithstanding the complexity of the issue, it was felt that the risks and benefits for all parties in the partnership could be clarified upfront in a contract. The main conclusion emerging out of the debates around IP was that the full range of IP and all its aspects needs to be defined and clarified – and thereby demystified for scientists and researchers. Once IP is unpacked into its

parts, these can be dealt with by providing an IP ‘toolbox’ – a number of checklists dealing with the different aspects of IP, for institutions to decide which is most appropriate to their context and situation. Similarly, regional hubs could be created for locally relevant knowledge and support.

In trying to move the focus in discussions away from patents alone, participants also 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. IP can also be useful as a tool for protecting the interests of research participants and low- and middle-income institutions and countries. Awareness needs to be raised around these protections and about the TRIPS flexibilities that can be harnessed for public health benefit. Similarly, strategies could be identified for assisting institutions to deal with donor language that limits profit-making from the products of funded research. In the same way, governments and the public sector could be supported and encouraged to establish dedicated research funds for IP invention and innovation, so that the results of research can be scaled up for common public good. There is also, then, a need for policies and guidance on who owns the IP from government-funded research, as well as guidance on whose national law is applicable on jointly created knowledge and products.

4.4. Web-based Platform

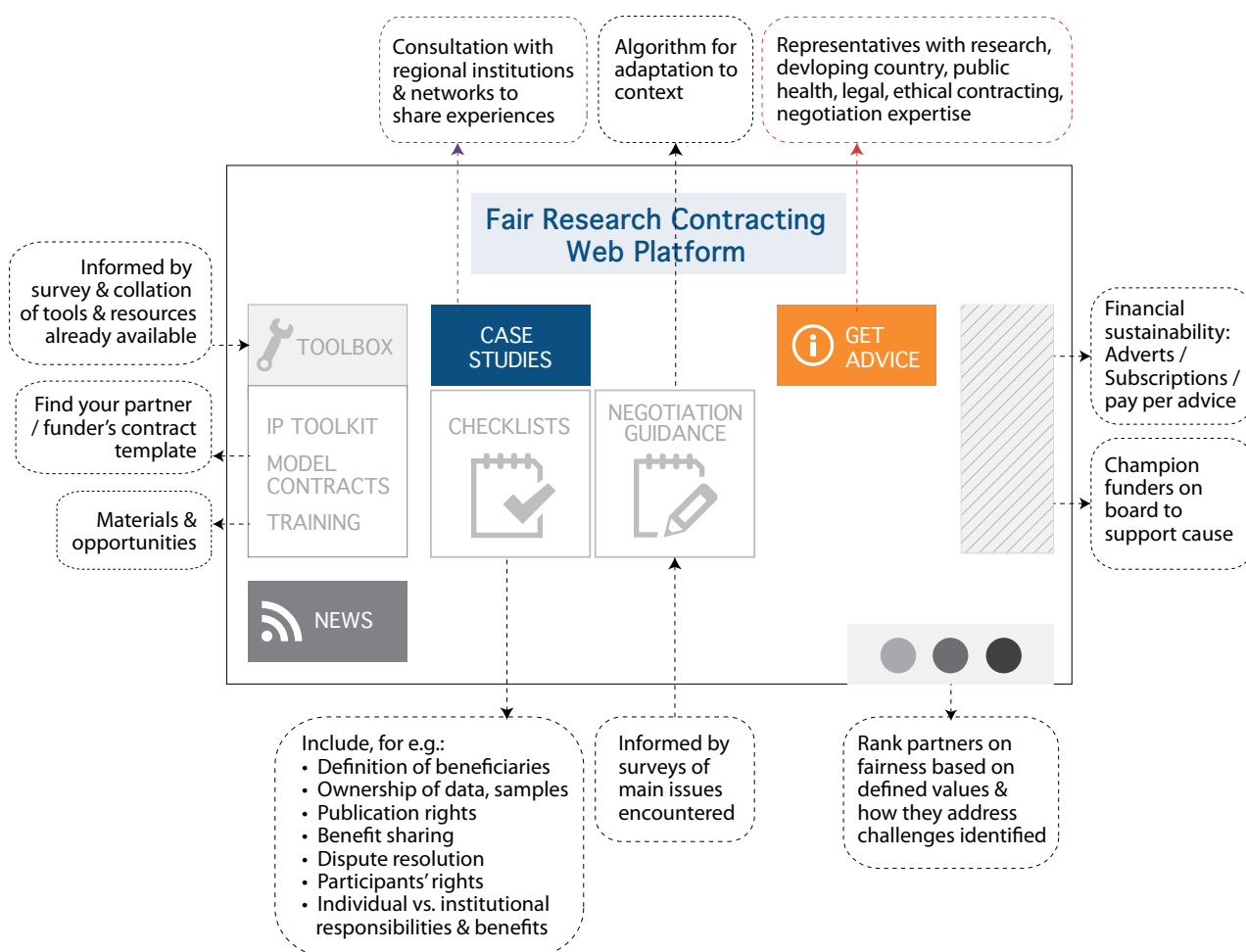
Table 3 below details what the checklist and negotiation guidance solutions will look like, with annotations regarding how these will be informed and developed. It shows a web platform incorporating a number of resources for fair research contracting. The web platform will be driven by the leading partners of the consortium being formed as a result of the Bellagio meeting. The toolbox will be populated following a process of identifying and collating tools and resources already available. The IP toolkit, as outlined above, will unpack intellectual property into its parts, and provide checklists for dealing with these aspects in different situations. The model contracts will include contracting templates from major collaborating partner and funding organisations, allowing institutions to search for the template relevant to their partnership. The toolbox will also contain training materials (related

to research contract management and negotiation) and information about training opportunities and capacity building programmes.

A consultation exercise with regional institutions and networks will generate case studies of experiences (good and bad) to demonstrate the consequences (good or bad) or contracting capacity (or lack thereof). These case studies will be made available on the web platform to stimulate learning and awareness raising. The checklists and contracting guidance developed by the consortium of partners will be made available on this platform. These, too, will be informed by surveys of the main challenges encountered in research contracting, as well as by extensive consultation with a group of experts representing different perspectives in research partnerships. The negotiation guidance is likely to include an algorithm which will assist

institutions in developing their own contract negotiation decision making processes. Ultimately, there will be a live advisory service for interactive advice on specific questions and issues arising. Networks of pro bono organisations will be tapped into to provide at least part of this service. A dashboard that ranks partners on contracting fairness based on defined values and how they work to address the challenges identified will also be included on the web platform. The site will be kept up to date with regular postings of news and latest developments in research contracting and partnerships. Strategies will be explored for making the platform financially sustainable over the long-term, including the possibility of subscriptions, payment for specialised advice, or advertising. It will also be critical to identify funders who will champion and support the cause.

Table 3 CHECKLISTS & CONTRACTING GUIDANCE ON A WEB-BASED PLATFORM



5 Taking Action

IN PREPARING FOR THE BELLAGIO MEETING, participants were asked to start thinking about how they – and their organisations – could engage with us following the meeting to ensure the most productive way forward for this work. Consequently, when we arrived at the session to discuss ‘next steps’, participants were well positioned to make informed commitments of support towards taking the fair research contracting initiative forward. Pooling of model contracts, needs assessments and surveys of institutional networks, offers of expertise and advice, collecting case studies of what has worked and what has not, and financial support were some of the commitments made by meeting participants on behalf of their organisations.

Although COHRED will take the lead in driving this initiative, a group of key partners at the meeting committed to forming a consortium to take the process forward. In Table 4 below, a tentative, detailed work plan is outlined for the next six months (for which funding has been secured), including deliverables and partner commitments.

Conclusions & Recommendations

This meeting made it clear that negotiating fair contracts which enable country ownership and capacity strengthening remains a central issue for low- and middle-income country institutions. Many organisations lack access to legal expertise, while their ability to negotiate mutually beneficial research contracts is further hampered by a lack of contract management capacity, financial know-how, managerial and administrative structures. The result is that the research partnerships that these organisations engage in frequently leave little behind in terms of capacity – perpetuating a cycle of disempowerment where negotiating power remains weak. Raising awareness around the consequences of this lack of contracting capacity is critical. If we are truly committed to moving low- and middle-income countries beyond aid, we need to place the tools for negotiating fair research contracts in the hands of LMIC institutions. For this, a commitment from all partners is required.

Challenges faced in research contracting have been identified as including benefit sharing; capacity building and technology transfer; ownership of data, samples, publications; intellectual property rights; inadequate compensation for indirect costs; lack of legislative frameworks; and lack of clarity around conflict resolution.

Individually, each of these issues have received a fair amount of attention. But available guidance on how to deal with such challenges has, on the whole, been generated in and by high income countries, focusing on how high income institutions can navigate these issues in partnership with other high income institutions, or with their lower income counterparts. The focus of the Bellagio FRC meeting was to develop a plan for the provision of guidance that takes as its starting point the perspective and needs of LMIC institutions.

The benefits of this work will be quickly felt by LMICs. Without fair research contracts, a major global opportunity is lost for relevant capacity transfer to LMICs. The total value of global health research expenditure is estimated at \$132 billion annually, of which 20% or more involves LMICs directly. The magnitude of this budget alone implies that fair contracting can make a major contribution to institution and system building for research and innovation for health, equity and development

We make the following recommendations and now call on our partners to consider how they can support the actions listed below.

Table 4

PLAN OF WORK, JANUARY - JUNE 2013					
2013	CONSORTIUM	EVIDENCE-BASE	AWARENESS-RAISING	WEBSITE	FUNDING PROPOSAL
JANUARY	Sign on by partners Define roles & responsibilities	Extension of preliminary surveys – issues & good practices	Consultation with networks for issues & experiences (case studies)	Collating existing contracts, resources, materials	Identify funding champions
Input		INDEPTH, ICDDR,B, EDCTP	NRF, FIOCRUZ, IN-DEPTH, ICDDR,B	COHRED, DDCF, EDCTP, IDRC, WOTRO & partners	COHRED & partners
FEBRUARY	Engage networks →	Analysis of stakeholder survey results	Consultation with networks for issues & experiences (case studies)	Collating existing contracts, resources, materials	
Input		COHRED	COHRED through networks	COHRED, DDCF, EDCTP, IDRC, WOTRO & partners	
MARCH	Input from partners →	Thought piece	Thought piece	IP toolkit	
Input		COHRED & partners	COHRED & partners	WIPO, PIIPA, BVGH, WITS & partners	
APRIL	Engage networks →	User acceptance testing & engagement		IP toolkit	
Input		COHRED partners		WIPO, PIIPA, BVGH, WITS & partners	
MAY	Engage networks →	User acceptance testing & engagement		Case studies & resources on website mock up	Writing funding proposal
Input		COHRED & partners		External consultant	COHRED & partners
JUNE	Input from partners →	Planning for global meeting: bringing perspectives together, raise awareness, secure buy in		Case studies & resources on website mock up	Writing funding proposal
Input		COHRED (Connect) & partners		External consultant	COHRED & partners
Deliverables	Consortium of partners	Detailed analysis of contracting challenges & experiences	Thought piece publication with case studies: consequences of lack of capacity	Web pilot ready to go live	Funding proposal & business plan

1. Move beyond an ad hoc, institution-by-institution approach

While some high income universities offer fellowships to LMIC institutions for research management skill transfer, these are one-on-one and ad hoc approaches, and are inadequate to deal with global contracting inequalities. We advocate for moving beyond an “institution by institution” approach to build capacity at institutional and national levels and aim for global support for this initiative.

2. Build LMIC capacity to negotiate on their own terms

Making the fair research contract a national, regional, or multi-national standard can prevent “shopping around” – high income country institutions simply moving to other institutions or even countries. At the global level, good practice guidelines, endorsed by funders, will also make shopping around more difficult. Maintaining a focus on building capacity in LMIC institutions and governments to define partnerships and contracts on their own terms will result in real development.

3. Build the evidence base for contracting needs and develop guidance based on this

Preliminary surveys conducted in the lead up to the Bellagio meeting confirmed that there are significant unmet needs with respect to contracting capacity in LMIC institutions. It will be important to expand on these surveys to build the evidence base of contracting needs and strategies employed to deal with these challenges, which in turn will inform the guidance that is subsequently developed.

4. Sensitise all stakeholders to the consequences of lack of contracting capacity

Sharing experiences – good and bad – will form an invaluable component in mutual learning and awareness raising around contracting issues. We issue a global call for case studies and anecdotal data on the consequences of insufficient contracting capacity in perpetuating LMIC dependence on high income partners and donor aid. Advocating for global adoption of solutions to address the challenges faced will be greatly advanced by such case studies.

5. Unpack the contrary incentives that drive LMIC institutions and researchers to agree to contracts on any terms

Exploring and understanding the pressures placed upon LMIC institutions – from both internal and external sources – to sign contracts is critical for adapting guidance to adequately address these issues.

6. Establish a consortium of partners to drive this initiative forward

A committed group of partners is needed to take the next steps in collating resources, building the evidence base and developing contracting guidance. While COHRED will take the lead in this process, the consortium needs representation and input from all affected stakeholders.

7. Develop contract checklists and negotiation guidance

Readily available, applicable tools need to be developed to assist LMIC institutions in various situations: where there is no lawyer, where there is minimal legal expertise, and where there is a lawyer who needs support. These tools could take the form of contract checklists and generic negotiation guidance, while recognising that each contract situation is unique and there is always a role for one-one guidance.

8. Make products and services accessible on an interactive web-based platform

On its own, a document is not likely to be sufficient to support LMIC institutions – particularly in the complex field of IP. Therefore, we recommend the design of an interactive e-learning and live online support mechanism for advising on specific issues related to fair research contracting. The products (checklists and negotiation guidance) and services (live advisory) developed should be globally accessible on a web-based platform. Commitments of support (skills and expertise, financial and material resources) from partners will be critical in making this sustainable.

9. Identify funders and high income partners to champion this cause

The reality is that, for these goals to take shape, initial resource mobilisation is essential. A longer term strategy to ensure that the tools and platforms which result are sustainable must be built into any plans.

10. Involve the private sector and pharmaceutical industry: Support LMIC institutions to engage in partnerships that foster social entrepreneurship

Fostering social entrepreneurship is key to moving beyond aid. Developing contracting guidance products and services is supportive of social entrepreneurship because it enables institutions to become better contract negotiators in general – not just with high income donors. Engaging the private sector and pharmaceutical industries to contribute to the solutions will be a key step in this process.

Appendices

Appendix 1: List of participants

Prof Pamela Andanda

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Pamela Andanda, Ph.D., is an associate professor at the School of Law, University of the Witwatersrand, Johannesburg (South Africa). She is an Executive member of Ethics, Law and Human Rights Working Group (ELH) of the African AIDS Vaccine Programme (AAVP) and a strategic advisory committee member of UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR). She was a member of the European Commission's Expert Group on Global Governance of Science and regularly acts as an expert and evaluator in the Ethics Review procedure of the European Commission's Seventh Framework Programme for Research and Technological Development. Her research interests are in the areas of intellectual property, biotechnology, health law, bioethics, policy analysis, commercial law and regulation of biomedical research.

Dr Bakari Bakari

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Bakari Bakari is Director of Research Operations for the Ifakara Health Institute with the responsibilities for overseeing the Institute's branches and stations, managing regional operations as well as the Institute's international funding. Prior to joining IHI Bakari was Director of Operations for the Global Development Program at the Bill and Melinda Gates Foundation where he led efforts to ensure the right organizational structure, processes, and systems are in place to support the program's mission of reducing global poverty. Prior to his work at the Gates Foundation, Bakari was Program Director at the University of Washington where he led the implementation efforts of the largest clinical trial on HIV discordant couples which was conducted in various countries in Africa. Bakari also worked at the University of Alabama at Birmingham in increasingly leadership roles from the Central Administration to program implementation. In addition, Bakari spent time in the private sector in both USA and Tanzania. He received a bachelor of commerce and management from the University of Dar es Salaam, and his MBA from the University of Alabama at Birmingham where he also took graduate courses in public health.

Dr Mary Bassett

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Mary T. Bassett is a Program Director for the Doris Duke Charitable Foundation, leading its African Health Initiative, an effort that focuses on strengthening health systems in projects underway in Ghana, Mozambique, Rwanda, Tanzania and Zambia. In late 2011, she additionally assumed leadership for the Child Abuse Prevention Program, which for 10-years has made grants aimed at preventing child maltreatment.

Prof Jie Chen

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Director of Key Lab of Health Technology Assessment and Advisor of National Institute of Hospital Management, Ministry of Health, China. Professor of Department of Hospital Management, School of Public Health, Fudan University. Foundation Council member and STRATEC member of Global Forum for Health Research. International Health Technology Assessment Magazine Editor Committee member. Dr. Chen graduated from Shanghai Medical University in 1966. She obtained a Master degree of Medicine in the area of Public Health in Shanghai Medical University in 1981. She also studied at Harvard University, School of Public Health in the Master program of Health Policy and Management during 1985-1986. Dr. Chen worked as a physician and paediatrician for ten years. Afterwards, she founded the Department of Hospital Management, School of Public Health, Shanghai Medical University. In 1993, she was appointed as Vice-President of Shanghai Medical University. She was also the member of the National Expert Committee of the Ministry of Health in China in the past 20 years. In 1998, Dr. Chen joined the headquarter of World Health Organization, and was appointed as Executive Director of Non-Communicable Diseases Cluster (1998~2000), Special Representative of the Director General, WHO (2000~2003.10). As a professor in Social Medicine, Health Administration, Clinical Epidemiology, Hospital Management and Health Economics, she wrote more than sixty articles and books on these topics. Furthermore, she has been a tutor for more than thirty students on their Masters or PhD program.

Dr Michael Clarke

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Michael Clarke is Director, Global Health Policy at the IDRC. He was former Director, Information and Communication Technologies for Development and Director, Research for Health Equity. Previously he served as Director, eCurriculum, Faculty of Medicine, and Professor, Department of Biochemistry, Microbiology and Immunology at the University of Ottawa, as well as Assistant Dean, Information Technology, Faculty of Medicine and Dentistry, and Professor, Department of Microbiology and Immunology at the University of Western Ontario. His medical research and international development career has taken him to Africa and China. He holds a PhD in microbiology from the University of Guelph.

Ms Renata Curi

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Ms Curi is responsible for the coordination of business and contracts at CDTs / FIOCRUZ. She is a qualified advocate, responsible for the legal department of the Center for Technological Development in Health FIOCRUZ, especially the formalization of partnerships with private companies, public sector and academia, in the national and international levels to develop healthcare solutions. She is part of the Integra Group on Technology Assessment in Health National Institute of Technology in Neglected Diseases, which participates in the Working Group's Rebrats Meth. Renata concluded her Masters in Law and New Technologies in UNESA and MBA in Business Law at FGV / RIO, and is currently a doctoral student at the Institute of Economics of UFRJ, which is dedicated to the theme Risk Sharing Agreements.

Dr Judith de Kroon

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Dr de Kroon has an educational background in bio-medical sciences, with a PhD in Medicine and post-doctoral training in medical ethics and public administration. She has 8 years of experience as a researcher, in West-Africa (GTZ, subject: epidemiology of HIV/Aids) and in the Netherlands (LUMC, subject: immunotherapy). Dr de Kroon has worked as a policymaker for a private Foundation (Aids Fonds), for the Dutch government (Dutch Ministry of Health) and is currently employed by the Dutch research council (the Netherlands Organisation for Scientific Research, NWO) where her main task is to develop foresights and provide strategic advise (including but not limited to the development of new research programmes and the organisational IPR policy).

Ms Jennifer Dent

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Jennifer Dent joined BIO Ventures for Global Health in September 2011 with primary responsibility for commercialization and alliance management programs, including WIPO Re:Search. She has 20 years of broad-based pharmaceutical and biotechnology experience, including negotiation and structuring of deals and management of multi-partner, global discovery and commercial alliances. Prior to joining BIO Ventures for Global Health, Jennifer held various senior management positions in sales, marketing, global product strategy, business development and alliance management. She has global experience working in the HIV/AIDS field with Roche in Switzerland and also worked for Genentech and Roche in Canada, New Jersey, and California. Jennifer served as Vice President, Business Development, Marketing and Sales at CombiMatrix, a biotechnology company in Washington State. She received her M.B.A. at the University of Western Ontario in Canada.

Mr Danny Edwards

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Danny joined COHRED in 2011 as a policy analyst. Danny's post graduate background is bioethics, and his professional experience has been in the development and implementation of health policy. He has held several senior policy roles in the United Kingdom: first leading on a review of the genetic testing of human embryos at the Human Fertilisation and Embryology Agency, and later leading on international policy for the UK concerning the relationships between intellectual property, innovation, trade, development and public health. While at COHRED he has focused first on delivering FORUM 2012, and providing intellectual input to matters of intellectual property, innovation and public health.

Mr Jens Hinricher

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Jens Hinricher is an international lawyer working in public health research. He has experience in legal and compliance issues, as well as overseeing and managing a busy contracts office. Jens is well versed in contract drafting, reviewing and negotiating and familiar with major international donors and their respective requirements (e.g. NIH, USAID, DFID, EU, UN, Global Fund, Gates etc.). He is qualified and experienced in IP and publication issues and is currently employed as General Counsel at ICDDR,B (International Centre for Diarrhoeal Disease Research, Bangladesh) - being inter alia responsible for:

- Advising the Executive Director and senior management on legal issues, in particular those relating to the status, privileges, immunities and exemptions of ICDDR,B, its Board of Trustees, Directors and Officers
- Ensuring compliance of the organization's by-laws and activities with the respective host country Ordinance as well as other host country agreements and arrangements
- Managing the smooth and continued operation of ICDDR,B's contracts and grants office with responsibility for research funding in excess of 60 million US Dollars per annum
- Drafting, reviewing, negotiating and approving the organization's agreements with bi-lateral and multi-lateral donors, including other international organizations, governments, foundations, NGOs and the private sector, related to national, regional and international activities, collaboration and cooperation

Prof Carel IJsselmuiden

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Carel is a public health physician and epidemiologist. He has worked in rural medicine, peri-urban and urban health care and environmental health services, as well as in academic public health education and research ethics training. He has also published in various areas in applied research and public health. Carel was the founding Director of the University of Pretoria's School of Health Systems and Public Health until his appointment as COHRED Director in January 2004. Prof. IJsselmuiden, as COHRED Director, is ex-officio member of the Board.

Ms Florine Jobin

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Florine Jobin joined COHRED in October 2011 as the personal assistant of COHRED's Director, Carel IJsselmuiden. She is responsible for the day-to-day management of the Director's office and provides him with administrative support. She also conducts background research for the office. Florine holds a Diploma and a Masters degree in Anthropology from the Universities of Geneva and Neuchatel respectively. She has also pursued a postgraduate course in 'African societies and development' in Spain. She has experience in social sciences research and events management and organisation, with particular focus on the health sector.

Dr Gerald Keusch

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Dr. Keusch is a professor of Medicine and International Health at the Schools of Medicine and Public Health, Boston University. He is also the Associate Director of the National Emerging Infectious Diseases Laboratory. Prior to this appointment at BU, Dr. Keusch served as Director of the Fogarty International Center at the National Institutes of Health and Associate Director for International Research in the office of the NIH Director. A graduate of Columbia College and Harvard Medical School, he is Board Certified in Internal Medicine and Infectious Diseases. He has been involved in clinical medicine, teaching and research for his entire career, most recently as Professor of Medicine at Tufts University School of Medicine and Senior Attending Physician and Chief of the Division of Geographic Medicine and Infectious Diseases, at the New England Medical Center in Boston, MA. His research has ranged from the molecular pathogenesis of tropical infectious diseases to field research in nutrition, immunology, host susceptibility, and the treatment of tropical infectious diseases and HIV/AIDS. He was a Faculty Associate at Harvard Institute for International Development in the Health Office. Dr. Keusch has delivered numerous named lectures on topics of science and global health at leading institutions around the world. He is presently involved in international health research and policy with the NIH, the U.S. National Academy of Sciences' Institute of Medicine, the United Nations, and the World Health Organisation.

Prof Adel Mahmoud

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Adel A. F. Mahmoud, M.D., Ph.D, is a Professor at The Woodrow Wilson School of Public and International Affairs and The Department of Molecular Biology at Princeton University. He has recently retired as President of Merck Vaccines and member of Management Committee of Merck & Company, Inc. His prior academic services at Case Western Reserve University and University Hospitals of Cleveland spanned 25 years concluding as Chairman of Medicine and Physician-in-Chief from 1987 to 1998. Dr. Mahmoud's academic pursuits focused on investigations of the determinants of infection and disease in human schistosomiasis and other infectious agents. In laboratory and field studies in several endemic areas, he developed the scientific bases of strategies to control helminthic infections which have been adopted globally. At Merck, Dr. Mahmoud led the effort to develop four new vaccines which have been launched in 2005-2006, including: combination of Measles, Mumps, Rubella and Varicella; Rota Virus; Shingles and Human Papillomavirus. Dr. Mahmoud's leadership in setting strategies for Global Health shaped the agenda of the Forum on Microbial Threats of the Institute of Medicine in recent years by tackling topical issues such as biological threats and bioterrorism; SARS; Pandemic Flu and others. He is an active contributor to scientific literature and authored and edited several textbooks and reports. Dr. Mahmoud received his M.D. degree from the University of Cairo in 1963 and Ph.D from the University of London, School of Hygiene and Tropical Medicine in 1971. He was elected to membership of the American Society for Clinical Investigation in 1978, the Association of American Physicians in 1980 and the Institute of Medicine of the National Academy of Sciences in 1987. He received the Bailey K. Ashford Award of the American Society of Tropical Medicine and Hygiene in 1983, and the Squibb Award of the Infectious Diseases Society of America in 1984. Dr. Mahmoud is a fellow of the American College of Physicians and a member of the Expert Advisory Panel on Parasitic Diseases of the World Health Organization. He served on the National Advisory Allergy and Infectious Diseases Council and is a past president of the Central Society for Clinical Research and the International Society for Infectious Diseases. He is currently serving as a member of the National Science Advisory Board for Biosecurity and Committee on Scientific Communications and National Security (CSCANS) of the National Academy of Sciences.

Ms Debbie Marais

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Debbie joined the Research and Development (R&D) group at COHRED in 2010. The two major objectives of COHRED's R&D work include increasing understandings of how research for health can and does contribute to improving health, equity and development, and, secondly, how we can translate such understandings into practical tools, approaches and methods that low- and middle-income countries can use to optimise the health and economic benefits of research for health. Debbie's professional interests also focus on mental health research and policy, which forms part of her PhD research. Debbie holds a Masters degree by dissertation in psychology and a second Masters degree and qualification in counselling psychology. She has extensive experience in research project management and coordination and has further experience working on various research and academic programmes in the School of Psychology at the University of KwaZulu-Natal. Debbie continues to work as a psychologist in the mental health field in South Africa, and is currently honing her skills in open space facilitation.

Prof Charles Mgone

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Prof. Charles Mgone is the Executive Director of the European and Developing Countries Clinical Trials Partnership (EDCTP) since February 2007. Born in Tanzania, Charles Mgone has considerable experience in research and research administration. He initially trained as a clinician in Tanzania and the United Kingdom, practising and teaching Paediatrics as well as conducting research. While in the UK he took a PhD in Medical and Molecular Genetics, a discipline which he continued to pursue in studying various aspects of infectious diseases including measles, malaria, HIV/AIDS, Chlamydia and other sexually transmitted infectious. During this period he worked as the Deputy Director of the Papua New Guinea Institute of Medical Research. Prof. Mgone has served as advisor at international and national levels on various matters, especially on malaria and HIV/AIDS but also on child health and public health issues. He has written many papers in peer-reviewed journals and has served as the chief editor of the Papua New Guinea Medical Journal. He is the current Chief Editor of the Tanzania Paediatric Journal. Before joining EDCTP, Prof. Mgone was Network Director of the African Malaria Network Trust (AMANET) where he was responsible for coordinating the African response to the malaria burden through accelerating the development of malaria vaccines and other interventions. In this role, he was responsible for developing and overseeing capacity development of African institutions and scientists conducting clinical trials. This included networking of the African scientific community, creating of an enabling environment through training, enhancing of ethics review and regulatory framework and the provision and management of grants. His first appointment at EDCTP was as the Head of Africa Office in Cape Town where he was responsible for fostering of African ownership and commitment to the EDCTP programme by engaging with policy makers, scientific community, networks of excellence, NEPAD and African Union. Prof. Mgone has considerable experience in health research administration and health research capacity strengthening in developing countries. He has an unwavering commitment to accelerating clinical trials and enabling strong input of the scientific community from developing countries to genuine partnerships with researchers from the north, working on the poverty related and neglected diseases.

Mrs Jeanette Quarcoopome

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Jeanette Quarcoopome is both a trained journalist and a lawyer by profession and practice. She possesses a solid background in communication skills and has rich experience in information dissemination for strategic impact. She has applied her strong academic qualifications in diverse capacities such as at the United States Embassy in Ghana, where she served as Information Specialist in the Public Affairs section of the Embassy and also at the Ghana office of the PANOS Institute of West Africa (a Dakar-based media advocacy organization) where she was Coordinator with overall responsibility for the Institute's programmes in all Anglophone West Africa and some Francophone countries. Subsequently, as Director of Programmes at the Media Foundation for West Africa (MFWA), Jeanette co-ordinated a wide range of programmes at the sub-regional level including activities of the MFWA's Network of lawyers for the defence of journalists, a media law reform programme, a media rights monitoring programme under which she supervised a team to produce daily reports highlighting violations of press freedom and freedom of expression generally across sixteen countries in West Africa. During that time she was also instrumental in coordinating the MFWA's involvement in the design and implementation of a robust advocacy strategy for the passage of a proposed Right to Information law for Ghana. She has been associated with several continental workshops and conferences both as a participant and as a resource person. Jeanette Quarcoopome serves on a number of Boards and Steering Committees

including the Board of Directors of the New Times Corporation (publishers of one of Ghana's widest circulating dailies), the Steering Committee of the African Freedom of Information Centre (Kampala, Uganda) and the Programme Management Team of the Ghana Research and Advocacy Programme (G-rap). She joined the INDEPTH Network Secretariat as Communications and External Relations Manager to share with the team her capacity, knowledge and experience in managing NGO and civil society advocacy programmes.

Ms Liesl Schoonwinkel

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Liesl has spent her entire career addressing an audience in some form or another. She has twenty one years experience in teaching, training, public speaking, keynote addresses, facilitating workshops, presentations at conferences and acting as MC at diverse functions. Currently she specializes in creativity, thinking preferences and whole-brain management. She is an experienced trainer and facilitator in the corporate, public and educational sector for organisations such as Sanlam, Amplats, Volkswagen, WOW Factors India, World Health Organisation, Elleries, Geen and Richards, SA Department of Education and Falkirk College, Scotland. She is the co-author and developer of one of the first global internet based corporate training programmes which carries the accreditation of the Business School of The University of Potchefstroom, South Africa. In partnership with Karen Hodges, she is the co-author and presenter of a corporate social investment Education Development Programme that focuses on using creativity and thinking preferences in the everyday classroom, every day. It is presented at various schools, colleges and universities across South Africa and internationally. She regularly appears as motivational / guest speaker at various events such as graduation ceremonies, featured speaker for Toastmasters, the SA Hospitality Association and Sanlam. She is often invited as keynote or workshop presenter at numerous conferences, most recently ACRE (International Creativity Conference in Africa), UK Creativity Jamboree, Mindcamp Canada, Creativity Costa Rica, International Society for Co-operative Education and Business Creativity above the Japanese Garden at Tswane University SA. Her talent for captivating diverse audiences is clear in the range of MC work she has performed, ranging from numerous international conferences to graduation ceremonies with 1300 guests. She serves as director on the board of the not-for-profit Redzebra Youth Development Foundation and is a collaborator of the not-for-profit Facilitators Without Borders Canadian initiative. People who have experienced her presentations have had this to say: "enthusiastic, energizing, accurate information without boredom, brilliant, if we applied this, we could change the entire organization, inspiring, the best speech I've ever had the privilege of listening to."

Dr Konji Sebati

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Dr Konji Sebati, born in South Africa, is a Director in the Global Issues Sector at the World Intellectual Property Organisation (WIPO), heading two Divisions; the Traditional Knowledge, Cultural Expressions and Genetic Resources Division and the Global Challenges Division. She is a former Ambassador of the Republic of South Africa to Switzerland, The Vatican and Liechtenstein; and most recently to France/UNESCO and OECD. She is a Medical Practitioner by training, a degree conferred in Kenya during her years away from apartheid South Africa. She also obtained a Diploma in Child Health, and a Diploma in Public Health Planning and Health Services Management. She also studied Hospital Management on Haifa Technion, Israel. She practiced as a medical practitioner in Kenya and South Africa. She was appointed Regional Director for Health in charge of 21 Public Health clinics spread around the peri-urban and rural areas of Odi District in Pretoria, South Africa. She was later promoted to be a Hospital Administrator of Odi Hospital, Pretoria, and was part of the planning and commissioning team of the hospital. Konji later joined the pharmaceutical industry; first with Roche Pharmaceuticals, South Africa as a Medical Advisor, then moved on to Pfizer Pharmaceuticals in South Africa, where her started as the Medical Director in charge of Clinical Research, Product registration, Safety and Pharmacovigilance, Quality Assurance, and Sales force training. The portfolio of Corporate Affairs Director was later added to her span of control. She was later moved to Pfizer Headquarters in New York as Public Affairs Director for Africa and Middle East, and then transferred to the Corporate Affairs Division, Philanthropy Department, to be in charge of Pfizer's HIV/AIDS Philanthropy programs worldwide. Konji launched Pfizer's flagship program, the Diflucan Partnership Program; donating free medicines, Diflucan, for the treatment of HIV/AIDS associated opportunistic infections to governments and non-governmental organizations worldwide, with an emphasis on Africa and other developing countries. Amongst some of her prestigious awards, Konji Sebati received a recognition award in 2004 from the Elizabeth Glaser Paediatric Foundation as "The Most Outstanding Woman in the fight against HIV/AIDS. Later that year she was awarded the recognition of "Africa Businesswoman of the Year 2004" by Africa Investor, in recognition of her role in the Corporate world, at Pfizer, as an advocate for better health care and management in Africa.

Dr Bratislav Stankovic

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Dr. Bratislav Stankovic is a registered US Patent Attorney. He holds a Ph.D. degree in Biological Sciences from the University of Nebraska-Lincoln, a J.D. degree from the University of Wisconsin-Madison, and a M.Sc. degree from the University of Novi Sad. Dr. Stankovic is admitted to practice law in Illinois and in Wisconsin, teaches Patent Law at Loyola University Chicago, and has practiced at one of the largest IP law firms in the USA, Brinks Hofer Gilson & Lione in Chicago. He serves as a Science and Technology Advisor to the President of Macedonia Dr. Gjorge Ivanov, and is a Principal Investigator at the Center for Intellectual Property and Technology Transfer (CIPTT). His experience includes intellectual asset management, innovation management and strategy, patent prosecution, and counseling in the fields of biotechnology, biochemistry, bioengineering, nanobiology, and pharmaceuticals. His papers are available for download on Academia and on the Social Science Research Network. He is a recipient of two U.S. Fulbright Scholarships for IP Law. Dr. Stankovic is a Lecturer in the joint University of Strasbourg-University Ss. Cyril & Methodius LLM program in Intellectual Property Law. He writes and teaches on patent law and policy, biotechnology, research ethics and bioethics, law and medicine, molecular, plant, and space biology. He has over 20 years of experience as a scientist, including 5 years as a Chief Scientist at the NASA-funded Wisconsin Center for Space Automation and Robotics, University of Wisconsin-Madison, where he was the principal investigator for experiments on the Space Shuttle and the International Space Station.

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Dr van Jaarsveld is Chief Executive Officer of the National Research Foundation. His career in research, teaching and leadership include academic and management positions at the Universities of Pretoria and Stellenbosch, as Dean of Science, Adjunct Professor: Environmental Studies Programme at Dartmouth College, USA, Vice President and more recently, CEO of the National Research Foundation. He obtained his PhD in Zoology from the University of Pretoria. Pursued post-doctoral studies and research in Conservation Biology and Global security in Australia and the UK and has published in excess of 100 primary papers, including highly cited works in Science and Nature. Dr van Jaarsveld is recipient of 16 Professional Awards, including awards for the most outstanding young scientist; Outstanding Academic Achiever award; and the Chancellor's award for Excellence in Tuition and Learning from the University of Pretoria; University of Stellenbosch Vice-Chancellors award for Research Excellence; and the Centenary Medal for distinguished career in research, teaching and leadership from the "SA Akademie vir Wetenskap en Kuns". He is co-recipient of the International Zayed prize for the Environment, a member of several professional and academic organisations and associations, including being a Fellow of the Royal Society of South Africa and an elected member of the South African Academy of Sciences. On the international front, Dr van Jaarsveld has served as co-chair of the Millennium Ecosystem Assessment follow-up: Sub-global assessments; member of the IUCN nominations committee; IPBES science focal point; Chair: G8 science ministers Group of Senior Officials on Global Research Infrastructure and Co-Chair of the Belmont Forum.

Appendix 2: Summary of discussion points from FRC workshop at Forum 2012

Participants at this workshop engaged in open space, facilitated discussions to come up with a list of do's and don'ts in relation to the challenges identified as facing LMIC institutions in research contracting.

CAPACITY BUILDING & TECHNOLOGY TRANSFER	INTELLECTUAL PROPERTY
<p>Do's:</p> <ul style="list-style-type: none"> • Agree on definition • Mapping exercise to identify existing capacity & resources • LMICs should create their own templates • Map existing tech transfer organisations developing countries • Develop specialised training / courses • No research without leaving capacity behind • To be fair, must have third world capacity building • No prior templates – each contract is unique and should be negotiated • Inclusion of technology transfer platforms in initial basic research • Structure contracts to provide genuine partnerships, not master: servant • Ensure researchers in LMICs are not just used as fieldworkers but are trained in all aspects so as to become authors • Train researchers on how to do fair research contracting – e.g. on the basics...what is MoU, MoA, NDA? When do you use what, when? How can you get help? 	<p>Do's:</p> <ul style="list-style-type: none"> • WIPO should provide workshops on IP management – demystify IP within the scientific community • Establishment of technological innovation centres (TICS – WIPO) • WIPO's arbitration to mediation division for conflict resolution • Capacity building • Recognise that IP goes beyond WIPO • Guidelines should include how to protect against exploitation • Institutions should include provisions for researchers' rights • Author on IP (inventor) should have some benefits – e.g. royalties – to stimulate further innovation • Public funds should lead to public goods <p>Restrictions:</p> <ul style="list-style-type: none"> • Patenting has a huge cost to be carefully considered • National laws should not be too restrictive
OWNERSHIP OF DATA, SAMPLES	BENEFIT SHARING
<p>Do's:</p> <ul style="list-style-type: none"> • Offer training to scientists about their rights • Provision of financial support beyond the end of the contract for maintenance of generated products (results, data, IP etc) • More exposure on material transfer agreements (MTAs) • Make these explicit in ethics reviews – i.e. should be addressed in research proposals • Provision on confidentiality and private information (e.g. data from clinical trials) <p>Restrictions:</p> <ul style="list-style-type: none"> • No safari research! Don't extract without contributing • Ensure that funders cannot be authors on the studies they fund • Ownership means rights and obligations: cost of maintaining biobanks and databases beyond the end of a contract is an issue • Ownership and access rights are often mixed up • Ethical standards & obligations behind these databases and biobanks not always met 	<p>Do's:</p> <ul style="list-style-type: none"> • Create a broad legislative framework or international treaty to add national guidelines to enable individual projects / programmes to leverage this to get a fair contract • Use constitutional law principles to apply international treaties • Choose a contract law that regulates the contract – example – English law. International law allows this • If no legislation, can be institutional policy (standardisation) <p>Restrictions:</p> <ul style="list-style-type: none"> • Contracts and legislation are not the whole solution – just part of it

INADEQUATE COMPENSATION OF INDIRECT COSTS

Do's:

- Consult available guidance documents (ESSENCE)
- Assess ability of researchers to accurately define and allocate costs
- Develop a costing culture (recognise full costs)
- Real cost calculations when budgeting
- Standard policy in research institutions in a country
- Establish minimum standards
- Equal system for calculation of overheads regardless of north or south
- Support the development of research culture

Restrictions:

- Don't subsidise pharmaceutical costs & northern research institutions & donors
- Don't create divisions / competitions between national institutions
- Don't recreate research hierarchies – e.g. northern funder – national institution (contracted) – local institutions (sub-contracted)
- Differential costs for different funders

CONFLICT RESOLUTION

Do's:

- Include a definition of conflict resolution insurance and a mechanism for resolution
- Select a neutral court for conflict resolution, if necessary
- Instead of including court selection in contracts, rather include lawyers or other bodies that can be solicited for assistance in case of a conflict
- At national level, all contracts should have a standard, especially for publically financed research, so that contracts do not differ from one another
- Include independent arbitration for smaller contracts (e.g. WIPO)
- Agree on some common standard for arbitration
- Using a standard contract, provide training for key issues to increase fairness
- Establish a "double court" rule according to where the damage happens – determine, besides the place/ court of resolution, the law language and principles applied

Restrictions:

- International contracting to avoid imposing court of one of the contractors' home countries as the jurisdiction

LACK OF NATIONAL LEGISLATIVE FRAMEWORKS

Do's:

- Create a broad legislative framework or international treaty to add national guidelines to enable individual projects / programmes to leverage this to get a fair contract
- Use constitutional law principles to apply international treaties
- Choose a contract law that regulates the contract – example – English law. International law allows this
- If no legislation, can be institutional policy (standardisation)

Restrictions:

- Contracts and legislation are not the whole solution – just part of it

Participants were then asked to choose one of the seven issues and as a group discuss what values underpin the issue, what is needed in terms of investment, and how to go about achieving this (essential outcomes). Participants gravitated to two key issues: 1) capacity building and technology transfer and 2) compensation of indirect costs.

	VALUES	INVESTMENT	ESSENTIAL OUTCOMES
CAPACITY BUILDING & TECHNOLOGY TRANSFER	<ul style="list-style-type: none"> • Beneficence • Autonomy • Persistence (long-term) • Respect • Sustainability of resources and expertise • Equity / equitable treatment of all partners • Political power • Country ownership & benefit • Mutual benefit • Capable of defending its own interests • Fairness / honesty • Capacity building / empowerment 	<p>Unfortunately, no notes were recorded during the capacity building / tech transfer group discussion on investment</p>	<p>Short-term:</p> <ul style="list-style-type: none"> • Definition of what needs to be mapped – e.g. technology transfer and contracting resources • Mapping exercise on existing technology transfer resources & capacities in LMICs (e.g. existing networks such as SARIMA) • Identification of success stories and case studies of successful innovation & technology transfer <p>Medium-term:</p> <ul style="list-style-type: none"> • To set up a network of technology transfer offices in LMICs • Defining good technology transfer practices and guidelines for institutions and countries in need – also, templates, checklists etc <p>Long-term:</p> <ul style="list-style-type: none"> • Training new / next generation of technology transfer officers • Fair contracting guaranteed
INADEQUATE COMPENSATION OF INDIRECT COSTS	<ul style="list-style-type: none"> • Equity • Common understanding • Accountability • Capacity building & tech transfer • Market (local) fairness • Accountability • Transparency • Good financial management • Wellbeing • Integrity • Standard recovery based on costing models of the institution 	<ul style="list-style-type: none"> • Increased awareness: implications of accepting research funding; implications of not knowing real / indirect costs • Definitions of direct costs and indirect costs • Development of research management and administration capacities • Funders' change of paradigm 	<p>Short-term:</p> <ul style="list-style-type: none"> • Distribution / access to ESSENCE guidance document on costing through networks / partners' websites <p>Medium-term:</p> <ul style="list-style-type: none"> • Engaging with research managers & finance people through workshops • Engaging with funders to raise awareness <p>Long-term:</p> <ul style="list-style-type: none"> • Change of financial practice at country level • Number of institutions who use ESSENCE document as basis for negotiating costs • Increased funds to cover indirect costs

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