







A Self-Assessment Tool For Institutions

This guide is meant for use by academic and research institutions – public, private or non-profit-especially for those operating in low- and middle-income countries – and for persons responsible for providing contracting advice to researchers.

Its objective is to encourage institutions to assess their structure, policies and contracting approaches to research and innovation agreements and, subsequently, to develop a roadmap to strengthen these.

Our ultimate aim is to help improve fairness in research and innovation for global health, equity and development.

In Collaboration With







A Self-Assessment

Toolkit for Institutions

A step-wise process for self-assessment and improvement of research contracting in academic and research institutions in low- and middle-income countries

This is a collaborative effort of the Council on Health Research for Development (COHRED) and the Swiss Commission for Research Partnerships with Developing Countries (KFPE) aimed at levelling the playing field in global science collaborations

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This booklet is introductory. More detailed and regularly updated information is available from the matching website at freebook.cohred.org

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www.cohred.org www.kfpe.ch



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Contracting

- = the process of reaching an agreement with specific terms between two or more persons or entities
- = can be done in writing or verbally
- = includes both formal contracts and less complex partnership arrangements like memoranda of agreement (MOA), memoranda of understanding (MOU), or agreement templates

Contracting as an Institutional Competency

- » Researchers work in institutions that provide them with infrastructure, finances, salaries, laboratories, classrooms, communication departments and more. While some institutions allow their staff to sign contracts in their individual capacities, this is the exception and is usually the result of an absence of legal support or a research office. In these cases, should the researcher not follow through on the agreement, it is likely that her/his home institution will be affected even if only in reputation.
- » Therefore, research contracting should be an essential competence in any institution, business or organisation engaging in collaborations to conduct research, obtain funding, get access to expertise or equipment, access new populations or problems, or to scale up solutions.
- » This self-assessment starts from the point of view that ANY such organisation needs a formally identified 'research contracting' office or function. It can be small and its main function is to access external expertise, or it can be large and be self-sufficient. Institutions may also jointly set up a research contracting office that serves more than one institution. In any case, all institutions need to understand what competence they have or have access to, and where they should improve in order to make the most of research and innovation collaborations.

Contracting and Types of Research

- » While we have heard senior scientists and even research funders say that contracting does not apply to social science or as co-investigators, we are good friends and do not need a contract or our research never leads to intellectual property rights so we do not need a contract or contracts are only used in the science environment in another country – in reality, all research and innovation collaborations are governed by some institutional agreement or framework.
- » Yet, in spite of the statements above, everyone seems to agree that when a transfer of funds between partners is concerned, then it is logical to have a signed agreement or contract
- » For purposes of this publication, all types of research collaborations do better if institutional agreements are in place. This does not just apply to funds, but also to data ownership, access and use, the allocation of costs, and many more aspects.

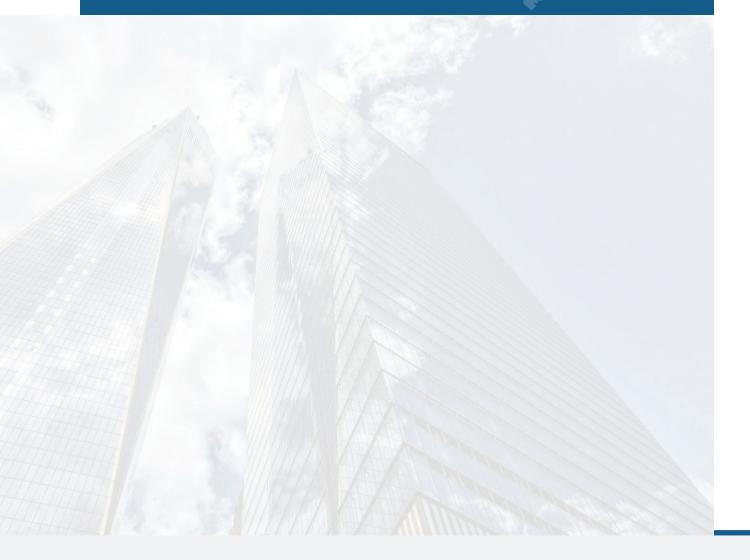


Research Office(r) / Function / Capability

- » To be or become proficient in negotiating and concluding fair and equitable contracts, institutions should allocate this responsibility to a person, or locate it in an office, or establish a dedicated research office. The larger the institution and the more contracts are managed, the more likely it is that a fully staffed office is required.
- » For purposes of this publication, we use the terms "Research Office(r)" to indicate this variability in size of such an 'office' or 'function' or 'capability'.

CASE STUDY - Example: **UK Government's Lambert Toolkit**:

https://www.gov.uk/guidance/university-and-business-collaboration-agreements-lambert-toolkit Contracting between universities and business can be a highly unequal affair, in terms of access to expertise to negotiate and conclude fair contracts, even in the UK. For this reason, the UK government has set up an extensive website with agreement and contracting templates that universities can use when developing agreements and contracts with industry.





Abbreviations Self Assessment Tool



Council on Health Research for Development.

(http://www.cohred.org)

FRC

Fair Research Contracting

(http://frcweb.cohred.org)

HIC

High-Income Countries

ICDDR,B

International Diarrheal Disease Research Center, Bangladesh

(https://www.icddrb.org)

IP / IPR

Intellectual Property / Intellectual Property Rights

KFPE

Commission for Research Partnerships with Developing Countries

LMIC

Low- and Middle-Income Countries

RFI

Research Fairness Initiative

(https://rfi.cohred.org)

SCNAT

Swiss Academy of Sciences

(https://naturalsciences.ch/organisations/scnat)

UNITECTRA

Unitectra is the technology transfer organization of the Universities of Basel, Bern and Zurich

(https://www.unitectra.ch/en)

WHO

World Health Organization

(https://www.who.int)

WIPO

World Intellectual Property Organization

(https://www.wipo.int)





Self Assessment Tool

Using This Guide

1. We recommend <u>two institutional features</u> that are essential for the implementation of research contracting and for improving this capability over time.

These are described in - Chapter 2 - UNDERSTANDING INSTITUTIONAL RESEARCH CONTRACTING

2. We provide a <u>10-Step Approach</u> for assessing your institution's capability to negotiate and conclude fair and equitable research agreements and contracts.

This is dealt with in - Chapter 3 - CONTRACTING

3. We summarize all this into a <u>1-page SELF-ASSESSMENT TOOL</u> that can be applied to understand current strengths and weaknesses of your institution's research contracting capability.

This is presented in - Chapter 4 - SELF-ASSESSMENT TOOL

4. The result of a 'Self-Assessment' is a ROADMAP TOWARDS IMPROVEMENT.

Use the same pages - Chapter 4 - SELF-ASSESSMENT TOOL - and begin changing.

Conclude what makes sense for you to do as an institution, as a group of institutions (see example of UNITECTRA), through national support or even through regional or international offices. This is meant to emphasize that finding a gap in your contracting capability does not automatically mean that the best solution is institutional ... it can also be done jointly!

Example: UniTecTra (https://www.unitectra.ch/en)

is a non-profit company owned by the Universities of Basel, Bern and Zürich in Switzerland to "support scientists in their collaborations with industry involving commercialization of research results and contractual matters". Unitectra demonstrates that matters related to contracting and technology transfer can be too complex or too fast changing for most institutions to attempt to develop their own, in-house expertise. Collaboration between institutions or at national level may provide suitable solutions.



Using This Guide Self Assessment Tool

5. Consult our <u>Fair Research Contracting website</u>, where we post regularly updated information – and, if resources allow, make available even more tools to support fair and equitable research contracting.

This is presented on https://frcweb.cohred.org

6. Share your experience with us – "the good, the bad, and the ugly". We are not trying to 'name and shame' (we will never do that), but we do want to understand what is happening in the world of research contracting, so that we can continuously improve our support, and add resources to the website.

Email us at: frc@cohred.org

Of course – if you are a HIC partner or funder – you may wish to encourage the use of this self-assessment guide so that you can support your partners in low- and middle-income countries to negotiate and conclude fair and equitable research contracting.





Comment

Global coalition to accelerate COVID-19 clinical research in resource-limited settings



There is no available vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) announced the launch of the SOLIDARITY trial, an April 2, 2020 infections and no drug with proven clinical efficacy, international study of potential treatments for COVID-19 so140-6736(20)30798-4 although there are several candidates that might be to be conducted in Asia, South Africa, Europe, and the effective in prevention or treatment. Encouragingly,

On March 18, 2020, the Director-General of WHO Published Online Americas.5 WHO has an important convening role in

Collaboration Is at the Heart of Research and Innovation

Almost all research of any importance is done collaboratively between researchers in more than one organisation, often in more than one country. Innovation is, almost by definition, a multi-partner activity. Networks of collaborations are replacing simple partnerships to deal with even larger challenges and opportunities and reach innovation even faster. Whether networks or simple partnerships, all are based on agreements.

Contracts are agreements that are negotiated. For there to be an agreement, the parties must come to a 'meeting of the minds' - but many factors, internal or external, can either facilitate or hinder arriving at this 'meeting of the minds', including:

- The reasons for wanting to conclude the agreement, in other words, what both parties want from the research collaboration which may vary greatly between various partners
- The nature of laws and policies that may govern the agreement which may vary greatly between institutions and the countries in which they are based
- Access to external or internal specialist legal advice often not available at all in low- and middleincome countries
- Gender/race/poverty/socio-economic factors/prior education and training may impact the power balance between the persons entering into the agreement on behalf of their institutions
- Projects may rely on commitment of resources by each partner which is another reason for having the mutual expectations set out in a contract.

Clear agreements and contracts facilitate collaboration, reduce conflicts, and make partnerships more equitable by ensuring that all parties contribute and benefit fairly. Excellence in research contracting is as essential for institutional growth and sustainability as excellence in science is for innovation and development. The two are intimately tied together. This Self-Assessment Guide deals with contracting to encourage more equitable research partnerships involving low- and middle-income countries.



"Contract negotiation" is an essential competence for any research institution. More often than not, the institutional ability to negotiate and conclude equitable and fair research agreements differs greatly between partners. Some organisations have fully staffed legal sections focusing almost exclusively on contracting, others have access to external experts who may or may not have specific knowledge about contracting in research and innovation, and yet others may not even have a guideline, template or protocol to follow and leave it to individual researchers to sign off on their contracts.

The ability to negotiate and conclude fair and equitable contracts depends on three major areas of institutional competence:

- 1. **Institutional support for contracting** providing an 'office' or 'function' with expertise of laws and policies that must be complied with.
- 2. **National legislation, regulations and policies** that set certain norms and provide domestic protections.
- 3. And negotiation skills of institutional staff.

Use this Self-Assessment of Research Contracting Capability to:

- » Assess your institution's capability to support its researchers in negotiating, concluding and managing contracts
- » Provide your institution with a roadmap to improve its own contracting capabilities or its ability to access external expertise
- » Convince your partners and research funders to provide support for the improvement of your institution's contracting competencies
- » Identify areas where <u>national</u> support would be more effective than or complementary of <u>institutional research contracting capacity</u> to encourage fair and equitable research and innovation partnerships

There is more and regularly updated information on the FRC website: http://frcweb.cohred.org





2.1. Institutional Research Office or Capability

Fair Research Contracting is best achieved if it is embedded in an institutional structure. Ideally, every institution should have a research office or 'function' or 'officer' who has the responsibility for overseeing research contracts. Developing the institutional framework for fair contracting is the first step in working towards developing fair contracting capacity and expertise in the institution.

Make it obligatory that all research contracts are reviewed by the research office(r). Make final approval and signature of contracts an institutional responsibility – it should not be left to individual researchers. Of course, make sure the review and approval process is 'lean', efficient, low on cost and administration – but do it!

There are many reasons for this recommendation for institutionalizing contracting – including:

- » it is crucial that you have one unit/function/officer within your institution who takes responsibility for this task. This helps to develop expertise and ensures that your research office(r) becomes proficient in understanding contracts and the legal and financial implications which stem from contracting;
- » it enhances institutional contract negotiation competence even in the face of great power differentials with investigators, institutions or research funders that provide the funding;
- » it enables the identification of training needs for administrative and research staff; in grant-writing and grant-management so your institution can act, and external partners and research funders may choose to help;
- » it promotes learning across many contracts which improves design and implementation of your own institutional policies and best practices (such as implementing the Research Fairness Initiative (RFI) (https://rfi.cohred.org)). This will result in better monitoring & evaluation and more transparency all of which will make your organisation a more competitive research and innovation partner.

- » Research Office(r) signing off on all contracts
- » Experienced / Trained contract negotiators
- » Knowledge of legal obligations
- » Knowledge of internal policies



2.2. Begin with a Project Specification

Research proposals tend to be written for scientists and funders – not for institutional research managers, research support staff, legal and financial advisors. Therefore, design a template that allows a researcher to quickly summarize the issues that are most relevant to competent research contacting, in a manner that is understandable to the Research Office(r) who may not be scientists. Ask researchers to complete a simple template you should develop, that could include:

Scope and Objectives

- » Outputs (data, publications, conferences,)
- » Outcomes (technologies, innovations, products, services, patents, IPR, spin-off business, ...)
- » Future impact (on the institution and host country, changes in policy, practice, status of a disease, understanding of problems, encouraging new solutions, ...)

Key Considerations

Information on important areas for which the research institution – rather than the researcher - will be or may be responsible – now and in the future.

- 1. **Required resources** staff with appropriate training, materials, facilities, IT connections and equipment;
- 2. **Project budgeting and cost-recovery** for these resources; explain whether or not the institution is expected to contribute and how it be fully reimbursed for all costs incurred;
- 3. Clarify how or **who will manage this project** on behalf of the institution, their responsibilities and possible gaps in their expertise;
- 4. Outline actions, if any, that will **optimize research and research management capacity** at the institution or nationally;
- 5. Specify how **patents, technology transfer or IPR** will be shared with your institution, or how partners will use this for mutual benefit.
- 6. Describe the relevance of the research to local, community, national or global development goals;
- 7. Give details on aspects that your institution cares about:
 - 7.1. Promoting participation and seniority of women scientists;
 - 7.2. Minimizing environmental impact of research;
 - 7.3. Minimizing risk that research impacts negatively on other societal structures and services;
 - 7.4. Promoting a high standard of research integrity.



Competencies Required

- » Standardized Project Specification Template
- » Routine use of Template by Researchers, Content Experts, Principal Investigators

The extent to which these considerations can be realized through an informal or formal research collaboration agreement will ultimately depend on the nature and scope of an individual project.

Research outcomes, outputs and the impact of the project should therefore be determined at the outset so that the legal and financial consequences flowing from the project may be factored in when negotiating and drafting contracts.

The PROJECT SPECIFICATION is the foundation of the contract between the parties and the starting point of the negotiation process.

3. Contracting In 10 Steps

Getting from an idea to collaborate to agreeing on the terms of a formal partnership is a dynamic process which involves negotiating the respective rights and obligations of the parties, often in the context of complex legal and financial consequences produced by the partnership or network. For example, should a dispute arise between the parties during the course of the collaboration, which dispute resolution mechanism would be most appropriate in the circumstances? Or, in which legal jurisdiction would the matter be determined? Or, who is responsible for damages during and, especially, after research?

Legal and financial expertise is often required, as may be ethical expertise, to advise the parties as to their respective rights and obligations. Depending on the complexity of an agreement, simple templates or 'memoranda of agreement' may be used, or, when situations are more complex or carry more risks, more specialist advice may have to be sought.

Very particular to research agreements are issues relating to ownership of intellectual property rights, technologies, use of data and restrictions on the publication of the results of a research project.

Intellectual property law is a specialized and complex area of the law which requires specialist expertise.

The most important considerations for formal and informal research collaborations are listed in this section.



3.1. Scope of the project

For the purposes of the contract, the nature and scope of the project must be clearly and meticulously defined so that each party's respective rights and obligations in relation to the implementation of the project may be easily identifiable.

The implementation of the project may take place in stages or be subject to certain suspensive conditions. The way in which funding is to be received may also be linked to the completion of certain tasks or project milestones. Make these issues clear in the description of the project scope.

Key considerations

- 1. Identification of research deliverables, outputs, and outcomes
- 2. Identification of roles and contributions of respective parties
- 3. Agreements on decision-making powers, project management and on-going monitoring & evaluation
- 4. Agreement regarding ethics review of research
- 5. Will funding be provided by way of a single grant or will be it transferred in instalments?
- 6. What is the duration of the project?
- 7. Where will the project be located?
- 8. Which party will be responsible for obtaining and maintaining regulatory and ethical licences, consents and approvals etc.?
- 9. Are there any health and safety and/or security and/or ethical policies and procedures which must be complied with?
- 10. How will changes to research outputs be accommodated and agreed?

- » Understanding research / research projects
- » Legal knowledge national law, licensing, regulatory, health, safety
- » Financial expertise costing, full cost accounting



3.2. Funding / Financial

This is one of the key factors to be considered. Therefore, the way funding will be received and for what it can be used must be set out in exact detail to ensure that the project does not experience interruptions on account of the withholding of funds. The way funding is to be received may also be conditional upon the completion of certain tasks or project milestones in which event the probability of meeting such suspensive conditions timeously must be considered carefully before signing a contract.

"Making promises that are not kept" is a major source of reputational risk for research organisations and institutions – another reason why contracting cannot simply be left to individual researchers: the institution is also at risk in case of non-performance.

Key Considerations

- 1. Is the party providing the funding subject to any funding conditions?
- 2. When and how will funding be received?
- 3. Which party will be responsible for which project costs?
- 4. Which party will be responsible for overhead and transaction costs?
- 5. If the funding originates in a foreign country, is the transfer of funds subject to any exchange control regulations? Who carries the risk for 'exchange losses'?
- 6. Is the research institution required to keep accounts of its expenditure on the project and if so, what accounting standards are required?
- 7. What are the consequences for the late payment of funds? Consider charging interest on outstanding amounts.
- 8. Which party has the right to interest received on grant funds?
- 9. Which party will be responsible for additional/unforeseen project expenses?
- 10. Which party will be responsible for any taxes levied on project expenses?
- 11. Which party will own equipment purchased or constructed using the financial contribution?

- » Finance expertise accounting, audit, tax advisory
- » Legal knowledge contract law



3.3. Publication, Data Ownership, Data Use and Access Rights, Data Sharing Obligations and Confidentiality Restrictions

Publications are 'academic currency'. The right of researchers to publish the results of research seems so 'logical' that it is often implied rather than stated explicitly in agreements or contracts. The same applies to institutions - publications improve reputation, attract highly qualified staff, impress funders and demonstrate relevance to national development goals. For both, increased requirements to share data is a reality but needs to be specified in agreements. Personal data protection laws that place restrictions on the transfer of personal data to third parties outside the country are increasingly being adopted in Africa as elsewhere around the globe. See for example

(https://www2.deloitte.com/za/en/pages/risk/articles/personal-data-protection-in-africa.htm

Contracting requires understanding of national and regional legislation to deal adequately with data sharing and transfer.

The contracting process and final contracts must balance the rights of the various parties in relation to the right of data access and use, publication of academic papers, decision on who can access data and for what purposes. The researcher and the host institution should ensure that the results produced by the research are not prohibited from publication by virtue of publication rights or intellectual property rights afforded to the other collaborating party/parties in the partnership.

Key Considerations

Ideally, a general agreement is reached before contracting even starts – that attribute publication rights, patents, credits and data ownership fairly to all partners.

Beyond this - there are considerations including:

- 1. What are the academic rights and responsibilities of the researcher in relation to publishing results of the research? What about future use? What about authorship credits immediate and in future?
- 2. Are there any clauses in the contract especially those dealing with publication rights and intellectual property rights of the other party/s in the collaboration that reduce the researcher's ability to access, use or publish research results in an inequitable manner?
- 3. Is the researcher limited or prohibited from disclosing or publishing any confidential information relating to the other party/s? Does the same apply to all other party/s in a similar manner?
- 4. What international treaties and data protection laws need to be considered for this specific contract?
- 5. Do we know and understand whether there are personal data transfer restrictions?
- 6. Are cross-border operations legally compliant?

- » Editorial expertise
- » Legal knowledge specific areas of publication rights, data ownership and use, intellectual property rights, personal data protection laws



3.4. Intellectual Property Rights / Technology Transfer / MTAs

Innovations resulting from the research process may be used for revenue generation including through commercial means or by convincing research funders for grant renewals, for example. The ability to use and exploit the intellectual property is therefore a potentially very valuable asset to both researchers and research institutions (*Example Stanford & Google*). No surprise that IP related issues may end in court (CRISPR / Harvard / UCSF; see for example: https://www.technologyreview.com/2016/08/17/158261/incrispr-fight-co-inventor-says-broad-institute-misled-patent-office/). A good contract will definitely help any party in such cases.

Intellectual property law is complex, changes rapidly and continuously, and requires a careful understanding of what each party's rights are in relation to the innovation. For example, different rights are acquired depending on whether a party owns the intellectual property or merely has a right of access and use. It is also important to note that the enforcement of intellectual property rights differs depending on which national law applies to such agreements.

Important tools that your institution should have available to include in contracts deal with Technology Transfer and Material Transfer Agreements (MTAs) for biological materials.

Key Considerations

- 1. Are you able to identify any potential IP which may arise from the project?
- 2. Are there existing rights in relation to "background IP" which may contribute to the discovery of the innovation? What are the rights of the party/s in relation to background IP?
- 3. Which national law (which relevant legislative framework) is governing the use and protection of the IP arising from the project?
- 4. Which party/s will own the IP especially in publicly-funded research?
- 5. Which party/s will have access and use of the IP; what are the duties of disclosure between partners?
- 6. Which party will have the right to register patents or any other protection over the IP? The Lambert Toolkit models are a good reference point for fair rights allocation according to the balance of funding. See reference section below.
- 7. Which party will be responsible for expenses or fees relating to registering and/or maintaining protection over the IP?
- 8. Are there privacy and confidentiality restrictions which may prohibit the publication of the discovery of the IP?
- 9. Will there be an obligation on the party discovering the IP to disclose the finding to the other party/s?
- 10. Are there any public benefit considerations which require that the findings of the research project be made public?

- » Legal expertise intellectual property rights, publication rights, data ownership and use
- » Financial expertise estimating financial benefits
- » Ethics



3.5. Application of International Treaties

There are an increasing number of international treaties – that may impact on how research collaborations result in the sharing of ownership of data, IP, and other benefits with countries and populations. The most recent of these is the Nagoya Protocol (https://www.cbd.int/abs/) – an international agreement which aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way between and within nations. It is influential, but only applies to countries that have signed on and it requires substantial and specialized legal expertise to implement. Even many research institutions in high-income countries do not have the legal expertise to deal with this adequately. This is a good example of a contracting situation in which a national or even regional support structure would be key support to have or to develop.

Key Considerations

- 1. Which international treaties need to be considered for this specific contract?
- 2. How will this influence the contract how can it support the interests of each party and the countries where they are located?

Competencies Required

» Legal knowledge – intellectual property rights, international law, specific areas such as biodiversity.



3.6. Applicable Law / Legal Framework Governing The Contract

Contracts often stipulate that "the terms of this contract will be governed by the laws of country..." The country where the main research partner of the main funder resides is usually designated as the country whose laws apply. This is sometimes negotiable, and the laws of a third country could be decided upon if this can increase fairness of the agreement. Ideally, your institution should have access to legal expertise familiar with the laws of the designated country – if you want to be able to realistically assert your rights under a contract in case of a conflict.

Key Considerations

- 1. Which jurisdiction is applicable to the interpretation of the contract or regulating any dispute in relation to the contract?
- 2. Do we understand the implications of applying the national law of a foreign country to the contract?
- 3. Do we have access to legal expertise equipped to interpret such law should it become necessary in circumstances where a dispute arises or compliance with a regulation is required to carry out the research?

Competencies Required

» Legal knowledge – country specific contract law, dispute resolution



3.7. Limitation of liability

Liability in relation to a research project may arise in the form of, inter alia, a claim for indirect damages or losses by a third party or even one of the collaborating party/s. Closely linked to this are the undertakings and warranties given by a party in the process of concluding an agreement. A party may be held liable for any such undertakings or warranties given that it had given even before the research started.

Other potential areas for liability for which the research institution rather than the individual researcher may be held responsible include negligence of the researcher, negative impact of research on communities or environment, side-effects of clinical trials, and more.

It is therefore prudent to expressly exclude or limit liability in relation to any such undertakings and warranties, and complications of research.

Key Considerations

- 1. What undertakings and warranties have already been given or are required to be given in terms of the agreement?
- 2. Is it necessary to exclude liability for such undertakings and warranties, and how can this best be done?
- 3. Is it necessary to take out insurances as part of the research project and budget?
- 4. Is it important to identify appropriate measures to isolate the institution from negative impact, negligence, unethical research or lack of research integrity in any of the other party/s? If it is important, how can it best be done through this contract?

- » Legal knowledge contract law. country-specific law. insurance law
- » Specific expertise clinical trials



3.8. Dispute resolution

It may happen that after a research collaboration has started, a dispute arises between the party/s in relation to the interpretation, implementation or cancellation of the contract. An appropriate (and affordable) dispute resolution mechanism should be identified from the outset. In the absence of a dispute resolution agreement between the parties, the default position will be for a dispute to be adjudicated in Court which can be a costly exercise and such costs are usually not provided for in research budgets.

This option may be problematic for other reasons as well. For example, where the parties do not agree to resolve a dispute in a specific jurisdiction, the matter may be prosecuted in the country where the defendant party resides, the consequence of which may be difficulties that arise in litigating in a foreign country or in enforcing a judgement/award in a foreign jurisdiction.

Disputes may, therefore, remain unresolved – leading to lack of trust, unwillingness to share data, or engage in future collaboration. All around, these are poor outcomes of disputes. A mutually acceptable and implementable dispute resolution mechanism is therefore one key to any successful, long-term partnerships.

Contracts should make provision for alternative dispute resolution mechanisms, i.e. not involving a Court process where possible. The benefit of doing this at the time of contracting is that the parties may determine the best option for their particular circumstances; for example, an academic institution with little or no legal resources may prefer a mediation process over a more expensive arbitration or litigation process. The choice of jurisdiction is, again, an important consideration because conducting an arbitration in a foreign jurisdiction may be costly. The parties may also agree to a 'hybrid mechanism' - referring all disputes first to mediation and failing resolution the dispute will be referred to arbitration. There are many options, and your Research Office(r) should be able to select and negotiate for those that suit your institution best.

Key Considerations

- 1. Do we understand the different dispute resolution mechanisms that are available to us (mediation, litigation, arbitration)?
- 2. Where is the other party/s domiciled / resident?
- 3. Which country or forum will have jurisdiction to adjudicate a dispute between the parties?
- 4. Do we have access to legal expertise in a foreign jurisdiction should it be required?
- 5. What persons or organizations can be approached to lead on the dispute resolution?

- » Legal knowledge litigation, arbitration, country-specific law
- » Alternative dispute resolution mediation



3.9. Termination and Breach

A party that is in breach of any of its obligations under a contract should be afforded an opportunity to remedy such breach upon receipt of notice of such breach. In the event that the defaulting party is unable to remedy the breach, the innocent party should be entitled to cancel the contract or demand compensation or other relevant actions to save a collaboration or reduce damages resulting from the breach.

Good research contracts should make provision for early termination of the contract and set out how and in what circumstances this can be done.

Key Considerations

- 1. Are the notice periods within which to remedy a breach sufficient and fair?
- 2. What are the consequences of cancellation on the rights and licences granted by one party to another, including the right to publish?
- 3. Will the party providing the funding to the project be reimbursed for funds contributed?
- 4. If the party providing the funding is the defaulting party, should it still be reimbursed for funds contributed?
- 5. Will the academic institution be entitled to recover monies for work done prior to the breach?
- 6. What other costs will an academic institution be entitled to recover from the other party/s on account of their breach and subsequent termination of the contract?
- 7. Which party will be liable for damages resulting from such breach?
- 8. Which party will be liable for costs associated with the early termination of the employment of the personnel working on the project?

- » Legal knowledge contract law, country-specific law
- » Understanding research / research project
- » Financial expertise finance administration, costing





3.10. Code of Practice, Guidelines, Research Fairness Initiative

A final consideration - contracts are made to prevent conflicts and, should these arise, to provide a roadmap how to resolve them.

It is, of course, better to prevent conflicts altogether. No matter how much expertise is invested in writing contracts and contract clauses like those above, it is the spirit of collaboration between the researchers and between the research institutions that matter most to minimize the need to have to turn to the contracts to solve problems.

Both researchers and research institutions are key to productive research and innovation relationships – it is not just the friendships and professional respect of the Principal Investigators that matter. This booklet is concerned with the role of the research institutions and how these institutions can support excellent, relevant and ethical research and can synergize with the professional relationships between researchers to produce long-term, productive collaborations.

Besides writing good contracts, therefore, we want to recommend two other, complementary, approaches that your institutions and its research office should consider using from now:

- 1. "Guide for Transboundary Research Partnerships 11 Principles and 7 Questions", an excellent guideline developed by the Commission on Research Partnerships with Developing Countries (KFPE) of the Swiss Academy of Sciences. By asking partners to accept this Guide, there is a much better chance to create lasting partnerships without having to resort to enforcing contracts. You can simply add one clause to your contract that states that "the KFPE Guide for Transboundary Research Partnerships 11 Principles and 7 Questions is accepted by all partners in this contract as basis for collaboration". (click here for the guidelines and click here for the Commission's website)
- 2. Research Fairness Initiative (RFI) is the only tool specifically designed to create transparency in research collaborations, to stimulate continuous quality improvement, fairness and equitability in research and innovation partnerships. It can and should be used by all stakeholders to level the playing field between research institutions globally. (https://rfi.cohred.org)

- » Active Research Office(r)
- » Top Management Interest and Support



4. Self-Assessment Tool

Self Assessment Tool

SELF-ASSESSMENT TOOL & ROADMAP

to Improve Institutional Research Contracting

| INSTITUTION NAME: 1. RESEARCH OFFICE(R) Yes =1 No =0 1. Does your institution have a dedicated Research Office or Research Officer (RO)? 2. Is the RO mandated to review and sign off on all research agreements and contracts? 3. Does the RO require the use of a standard template for Project Specification? 4. Does the RO require the use of standard research contract templates? 5. Is the RO trained & experienced in law or contract negotiation? 2. LEGAL EXPERTISE 0 = no access 1 = access to paralegal staff 2 = access to legal staff 1. Contracting Law 2. National Law, Licensing, Regulatory, Health, Safety 3. Dispute resolution, Alternative dispute resolution (mediation, arbitration) 4. Intellectual Property Rights, Technology Transfer, Material Transfer Agreements |
|--|
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| 5. Is the RO trained & experienced in law or contract negotiation? Subtotal (max=5) 0 = no access 1 = access to paralegal staff 2 = access to legal staff 2 = access to legal staff 2. National Law, Licensing, Regulatory, Health, Safety 3. Dispute resolution, Alternative dispute resolution (mediation, arbitration) |
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| 3. Dispute resolution, Alternative dispute resolution (mediation, arbitration) |
| |
| 4. Intellectual Property Rights, Technology Transfer, Material Transfer Agreements |
| |
| 5. Applicable law - access to lawyers in foreign jurisdictions whose law governs the contract |
| 6. Access to other legal expertise - health, biodiversity, technology, other |
| Subtotal (max=18) |
| 3. OTHER EXPERTISE 0 = no access 1 = some access 2 = high access |
| Access by Research Office(r) to Finance Office, Ethics Review Committee, Researchers, Principal Investigators |
| Subtotal (max=2) |
| SUMMARY OF READINESS FOR LEGAL CONTRACTING Score |
| Established and Experienced Research Office |
| 2. Access to Legal Expertise needed for research contracting |
| |
| 3. Access to other Expertise needed for research contracting |



Self Assessment Tool 4. Self-Assessment Tool

Notes

1. The scores and rankings provided in this table are meant to help academic and research institutions conduct a self-assessment of research contracting competence, and to repeat this over time to view progress. It may also help to prioritize where to start improving. The values are not based on any scientific evidence or order of importance. Instead, we agreed on these in the large group of reviewers to provide a metric to facilitate improving negotiating and concluding contracts in a step-wise fashion.

- 2. We request you to share results with COHRED. We will never publish data from shared results in a recognizable manner but we need such feedback to continue to improve our support for research and innovation systems in low and middle income countries. If we publish, we will publish aggregate information only to make sure that lessons are learned globally as well.
 - 2.1. You can contact us on: frc@cohred.org or via the FRC website: http://frcweb.cohred.



FRC video "Kofi the mouse"

https://www.youtube.com/watch?v=Y37UtNMNTU4

FRC publications:

Marais, D., Toohey, J., Edwards, D., IJsselmuiden, C. (2013). Where there is no lawyer – Guidance for fairer contract negotiation in collaborative research partnerships. Geneva & Pietermaritzburg: COHRED

http://www.cohred.org/wp-content/uploads/2012/04/COHRED-guidancebookletv-web-ISBN.pdf

Edwards, D., Toohey, J., IJsselmuiden, C. (2014). Negotiating Research Contracts. Geneva: COHRED

http://www.cohred.org/wp-content/uploads/2014/06/COHRED-negotiation bookletv-web.pdf

Technical guidance Notes - Fair Research Contracting

http://www.cohred.org/wp-content/uploads/2014/06/COHRED-FRC-FairResearchContracting1_WEB_EN.pdf

Technical Guidance Notes - Intellectual Property

http://www.cohred.org/wp-content/uploads/2014/06/COHRED-FRC-FairResearchContracting1_WEB_EN.pdf

Technical Guidance Notes - Data Ownership

http://www.cohred.org/wp-content/uploads/2014/06/COHRED-FRC-DataOwnership3_WEB_EN.pdf

Technical Guidance Notes – Technology Transfer and System Optimisation

http://www.cohred.org/wp-content/uploads/2014/06/COHRED-FRC-CapacityBuilding4_WEB_EN.pdf

Technical Guidance Notes – Indirect Costs

 $http://www.cohred.org/wp-content/uploads/2014/06/COHRED-FRC-IndirectCosts5_WEB_EN.pdf$

KFPE (3rd ed, 2018). A guide for transboundary research partnerships: 11 principles. Bern: KFPE.

https://naturalsciences.ch/organisations/kfpe/11_principles_7_questions

KFPE. Guidelines to conflict sensitive research

https://naturwissenschaften.ch/organisations/kfpe/csresearch

KFPE YouTube channel

https://www.youtube.com/channel/UCHz2FuJ41APGc09yV3P9fEA/featured

Recommended Readings:

Larkan, F., Uduma, O., Lawal, S. A., van Bavel, B. (2016). Developing a framework for successful research partnerships in global health. Globalization and Health 12:17.

https://globalizationandhealth.biomedcentral.com/track/pdf/10.1186/s12992-016-0152-1?site=globalizationandhealth.biomedcentral.com

WIPO (2016). Catalyzing Partnerships for Global Health. Annual BVGH Partnership Hub Report.

https://www.wipo.int/export/sites/www/research/en/docs/2016_bvgh_hub_report.pdf



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

https://www.gov.uk/guidance/university-and-business-collaboration-agreements-lambert-toolkit

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

http://www.ip-unilink.net/public_documents/A%20Brochure%20on%20Intellectual%20Property%20Rights%20For%20Universities%20and%20R&D%20Institutions%20in%20African%20Countries.pdf

Ananda, P. (2012). Managing intellectual property rights over clinical trial data to promote access and benefit sharing in public health. SECO / WTI Academic Cooperation Project, Working Paper Series 4 https://www.wti.org/media/filer_public/15/de/15de5e72-ebff-4076-b51b-37cc0db8f6b8/wti_seco_wp_04_2012.pdf

Dave A Chokshi, D. A., Parker, M., Kwiatkowski, D. P. (2006). Data sharing and intellectual property in a genomic epidemiology network: policies for large-scale research collaboration. Bulletin of the World Health Organization, 84 (5), 382-387

https://www.who.int/bulletin/volumes/84/5/382.pdf

Elsevier and CWTS. Open Data Report: The researcher perspective https://www.elsevier.com/about/open-science/research-data

Atkins, S., Marsden, S., Diwan, V., Zwarenstein, M. for the ARCADE consortium. (2016). North–south collaboration and capacity development in global health research in low- and middle-income countries – the ARCADE projects. Glob Health Action. 9: 10.3402/gha.v9.30524

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5057000/

IJsselmuiden, C., Marais, D. L., Becerra-Posada, F., Ghannem, H. (2012). Africa's neglected area of human resources for health research – the way forward. S Afr Med;102:236-241

You find many more links, readings and resources here: https:/frcweb.cohred.org

http://frcweb.cohred.org/wp-content/uploads/HR4HR-SAMJ-AFRICA.pdf





"We always try to ensure balanced contractual provisions also based on ethical <u>considerations</u>"

André Lederer, Legal Counsel, Swiss Tropical and Public Health Institute (Swiss TPH), 2020

COHRED

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