

Fair Research Contracting On-Line Tool

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Project full title:	Creating and enhancing TRUST worthy, responsible and equitable partnerships in international research
Project acronym:	TRUST
Type of funding scheme:	Coordination and support action
Work programme topics addressed:	Reducing the risk of exporting non ethical practices to third countries, GARRI-6-2014
Project web-site:	www.trust-project.eu/
Deliverable number	3.2
Date	18 December 2018
GRANT AGREEMENT No:	664771
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Thanks to Jacintha Toohey, the author of the first report on the FRC, from which some parts were copied and thanks to Prof. Carel IJsselmuiden for comments on an earlier version of the report.



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Executive Summary

Engagement, communication and dissemination are key to the success of any ethics project.

The goal of the TRUST Project is to catalyse a global collaborative effort to improve adherence to high ethical standards around the world. In line with the project's strategic output is the development of three tools to counter ethics dumping:

1. A Global Code of Conduct for North-South Collaboration in research
2. A Fair Research Contracts Web tool and,
3. A Compliance and Ethics Follow-up Tool.

This report describes the second tool, a fair research contracting (FRC) online tool. It is based upon work that was initially undertaken for development of COHRED's Research Fairness Initiative RFI, initiated in 2011 and advanced by work of the TRUST project.

The online tool is fully developed, tested and operational, please access by clicking [here](#) or visiting the website at: <http://frcweb.cohred.org>. COHRED will ensure that the FRC Website Tool will remain operational for at least 3 years after the ending of TRUST. In addition, COHRED is working hard to obtain further resources to help fill such a crucial gap in global research capacity building and achieving equitable research partnerships.



 **Fair Research Contracting**
Optimising Global Health Innovation



FAIR RESEARCH CONTRACTING
FRC TOOLKIT

ABOUT THE TOOLKIT

BEFORE SIGNING A CONTRACT, MAKE SURE TO GET WELL INFORMED ON:

- ✓ NEGOTIATION STRATEGIES
- ✓ RESEARCH CONTRACTS
- ✓ RESEARCH DATA
- ✓ INTELLECTUAL PROPERTY
- ✓ RESEARCH COSTING
- ✓ CAPACITY & TECHNOLOGY
- ✓ COMMUNITY ENGAGEMENT

Background/Introduction

The benefit of, and need for, fair research contracts can best be explained with the situation in global health research. Undertaking research in low income countries can lead to significant benefits flowing into high income countries. In 2009, Glickman et al¹ undertook a systematic review to examine what led to a "dramatic shift in the location of clinical trials" and concluded that important factors are:

1. Substantial cost savings through lower labour costs.
2. Shortened timelines for clinical testing due to a larger pool of research participants.
3. Lower regulatory barriers for research in low and middle income countries.
4. International harmonization of intellectual property rights protection.

To take full advantage of these benefits of conducting medical research in low- and middle-income countries, research institutions in high income countries have invested substantially in building legal and contracting expertise to the benefit of their institutions and their own stakeholders. On the other hand, it is rare that an institution in a low- or middle-income country even has one legal adviser, let alone a legal or contracting department. As a result, the benefits of research collaborations remain heavily skewed towards the beneficiaries based in high income countries²

A basic framework was developed by COHRED³ that can assist low- and middle-income partners in making contractual demands on high income partners without requiring their own large legal teams. The framework focuses on the fair distribution of post-research benefits, intellectual property rights, data and data ownerships, specimen ownership and usage, technology transfer and institutional capacity-building as key outcomes of the FRC process. *TRUST* enabled COHRED to expand the FRC into an interactive, web-based tool that is applicable to areas beyond research for health.

Debbie Marais

[New guidance on fair contract negotiation in collaborative research partnerships.](#)

Lancet Global Health 2013.

Debbie Marais, Jacintha Toohey.

[More equitable north/south research partnership.](#)

Euroscientist, September 2013.

Andrea Rinaldi.

[Guide aims to shift research benefits in North-South collaborations.](#)

SciDev.Net 18 July 2013.

Researchers, research managers and contract administrators with little or no legal expertise and support, can now seek on-line assistance which they can use to gain a good understanding of research contracting for equitable research partnerships thus avoiding potential exploitation.

¹ Glickman SW, McHutchison, JG, Peterson, ED, Cairns CB, Harrington RA, Califf RM, Schulman KA (2009) Ethical and Scientific Implications of the Globalization of Clinical Research, *N Engl J Med*; 360:816-823, February 19, 2009 DOI: 10.1056/NEJMs0803929.

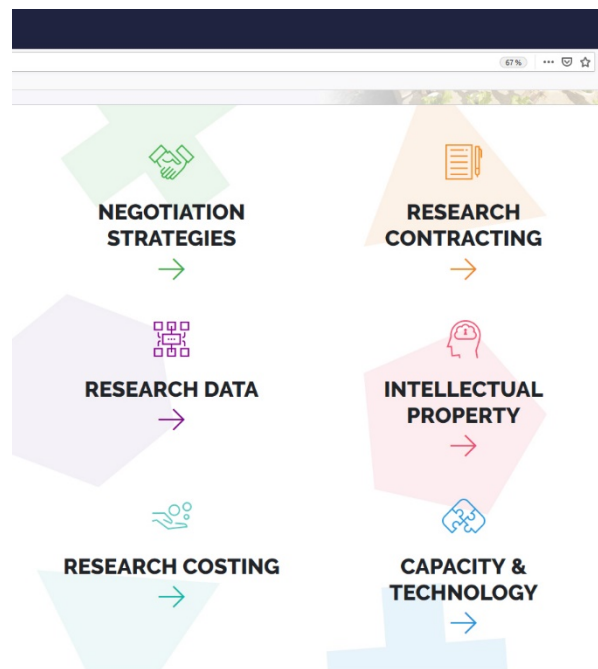
² Sack DA, Brooks V, Behan M, Cravioto A, Kennedy A, Ijsselmuiden C, Sewankambo N. Improving international research contracting. *WHO Bulletin* 2009; 87:487-488.

³ The following key partners were involved with Cohred, IDDDR,B, Univ of the Witwatersrand, Fiocruz Brazil, London School HTM, Makerere University Uganda, and WIPO.

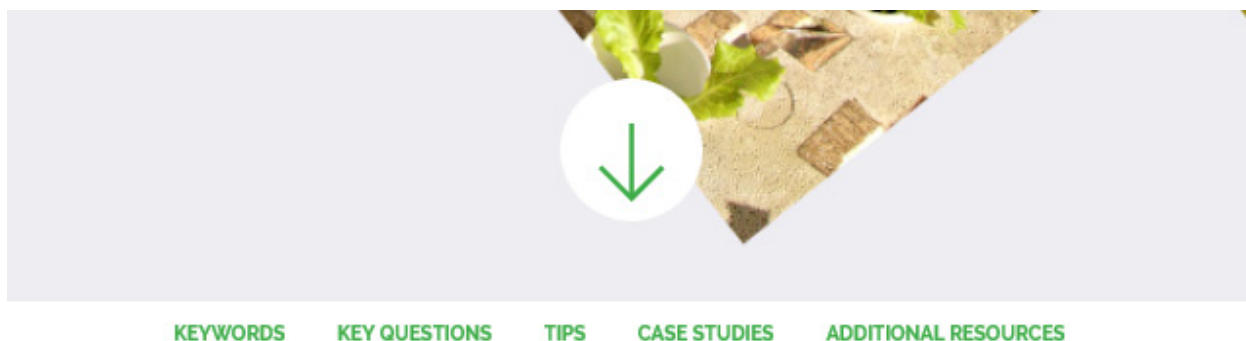
Key Features of the Online Tool

Six key features are essential to reach the above-mentioned goal and enable users to gain the basic knowledge and understanding of research contracting and its crucial elements. The six “toolboxes” are all accessible from the landing page:

- **Negotiation Strategies:** Provides key definitions to understanding the various aspects of negotiations, whether a research partner is at basic start point or an advanced level in the development of contract negotiations.
- **Research Contracting:** Provides a basic understanding of contracts and contracting for a research partner to better manage respective responsibilities, opportunities and risks that impact the research partnership.
- **Research Data:** Provides the essential principles concerning rights, responsibilities, including accountability and access to data in collaborative research.
- **Research Costing:** Provides research partners with a basic understanding of cost considerations when developing a full cost research budget proposal.
- **Intellectual Property:** Provides an introduction to some of the key general principles that require consideration before participating in research collaborative agreements.
- **Capacity & Technology:** Provides elements to understanding ways in which a research partner can maximise what works while building capacity for long-term development.

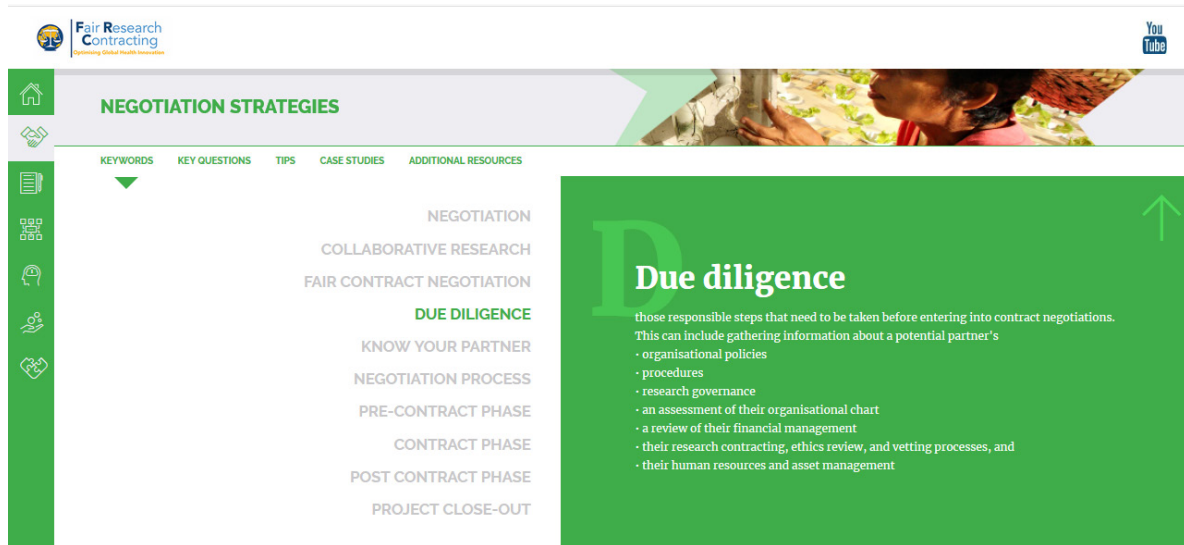


The toolboxes are structured in the same way, designed as self-explanatory and they contain a short summary inviting users to explore the following five instructive sections:



- **Keywords:** Definitions and insight in relevant terminology
- **Key Questions:** General information and basic knowledge
- **Tips:** Ideas how to make the general information applicable
- **Case Studies:** Insight in the translation of the given information into reality
- **Additional Resources:** Further reading material for in-depth research

The user-friendly navigation allows access to each toolbox with its sections from each site.



In terms of access and download capacity, the web developer made the tool accessible on mobile phones. In addition to this, the programming and choice of graphics guarantees the accessibility also by users in regions where internet access is difficult or bandwidth low.

FRC Dissemination and Impact

As the FRC tool goes hand in hand with COHRED’s [Research Fairness Initiative](#), conferences on the RFI presented an opportunity to promote the FRC. To date, we are aware of six major citations.

On July 12, 2018, the British Medical Journal (BMJ) Global Health published an open access article called ["Addressing the tensions and complexities involved in commissioning and undertaking implementation research in low- and middle-income countries"](#). In their recommendation to their research questions the authors say:

"Beyond supporting their own researchers in these negotiations, institutions from the Global South could also link together to support each other and to share strategies and modified approaches to ensure fair research contracting and commissioning"



drawing on existing initiatives such as the Council on Health Research for Development which provides guidance on fair research contracting."

On October 2, 2018, the School for Public Health at the Michigan University published an article called [“Research Abroad: Understanding local Contexts and Advocating for Change”](#). The article cites the Research Fairness Initiative (RFI) extensively (of which the FRC is a part) and mentions TRUST as an effort reach fairness and equity in abroad research.

In addition, please see the following publications.

Kate Miller

[NEWSFLASH: Developing best practise tools on Global Research Contracting – FRC Toolkit.](#)
Global Health Ethics, October 2017.

Julie Cook, Kate Chatfield, Doris Schroeder

[Promoting equity and preventing exploitation in international research: the aims, working and outputs of the TRUST project.](#)
In: Ethics and integrity in life sciences research, September 2018.

Kate Chatfield

[The ethics of research: how to end the exploitation of vulnerable communities.](#)
The Conversation, 2017, March 22.

Jim Lavery, Carel IJsselmuiden

[The Research Fairness Initiative: Filling a critical gap in global research ethics.](#)
Gates Open Research, Nov 2018.

Outlook

COHRED agreed to maintain the FRC for at least three years after the TRUST project ends, this will be until December 2021. The TRUST Co-ordinator, Prof. Schroeder, would like to express her thanks for this effort.