



Draft Fair Research Contracting Webtool



TRUST

Equitable Research Partnerships

Fair Research Contracting On-Line Tool

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Executive summary

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 our work to date and the current status of our development of the second tool, a fair research contracting (FRC) online tool. The final tool will be based upon work that was initially undertaken for development of COHRED's Fair Research Contracting Initiative and advanced by work of the TRUST project.

Whilst the final interactive version of the tool is yet to be developed and tested, the groundwork for development has now been completed and a mock-up of the webpages is available.

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

¹ Seth W. Glickman, M.D., M.B.A., John G. McHutchison, M.D., Eric D. Peterson, M.D., M.P.H., Charles B. Cairns, M.D., Robert A. Harrington, M.D., Robert M. Califf, M.D., and Kevin A. Schulman, M.D. (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.

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* will expand the tool into areas other than medical research and, importantly, create an interactive online tool.

The development of this tool will mean that vulnerable groups, such as researchers without legal support, can seek on-line assistance which they can use to gain a good understanding of research contracting for equitable research partnerships and avoid exploitation. The FRC on-line tool aims to give power to vulnerable populations under non-ideal conditions.

Achievements to date

The following list summarises our key achievements so far:

Jan – Mar 2016

Held planning meetings with internal COHRED team

Held Meetings with web developer

Identification, background review and collation of materials for the FRC online tool, including familiarization with other online web toolkits

Coordinate an internal team in COHRED

Develop a conceptual outline

Apr – Jun 2016

Develop web mock-up for review at the Nairobi plenary meeting May 2016

Present a draft mock-up to TRUST Partners at plenary meeting in Nairobi

Secure feedback from TRUST partner review and integrate feedback into mock-up

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.

Jul-Sept 2016

Preparation of draft outline of content based on FRC resources

Summarize FRC content materials/resources including components on Strategies for Negotiation, Capacity Building, Data ownership, Intellectual Property, Indirect costs and Contracting (in legislative context)

Oct-Dec 2016

Present second version of mock-up at TRUST team meeting in Paris in October 2016

Integrate feedback and amend second version of mock-up in preparation for internal circulation and review

Develop draft a third version of the mock-up of online tool for TRUST team review

- ∞ Circulate third version of mock-up and collect and collate feedback

Jan-Feb 2017

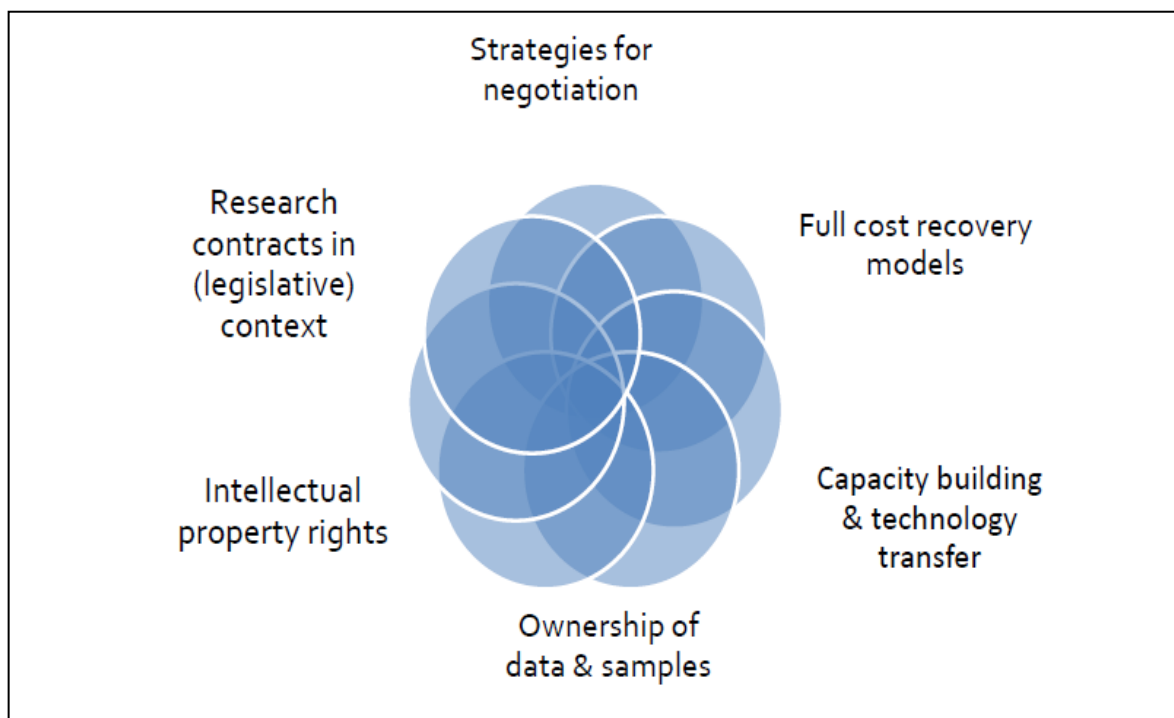
- ∞ Integrate feedback and develop final full draft FRC version with web developer

- ∞ Finalise and prepare FINAL DRAFT web tool

- ∞ Present Fair Research Contract Draft at TRUST plenary meeting in Cape Town in February 2017.

Key Features of the Online Tool

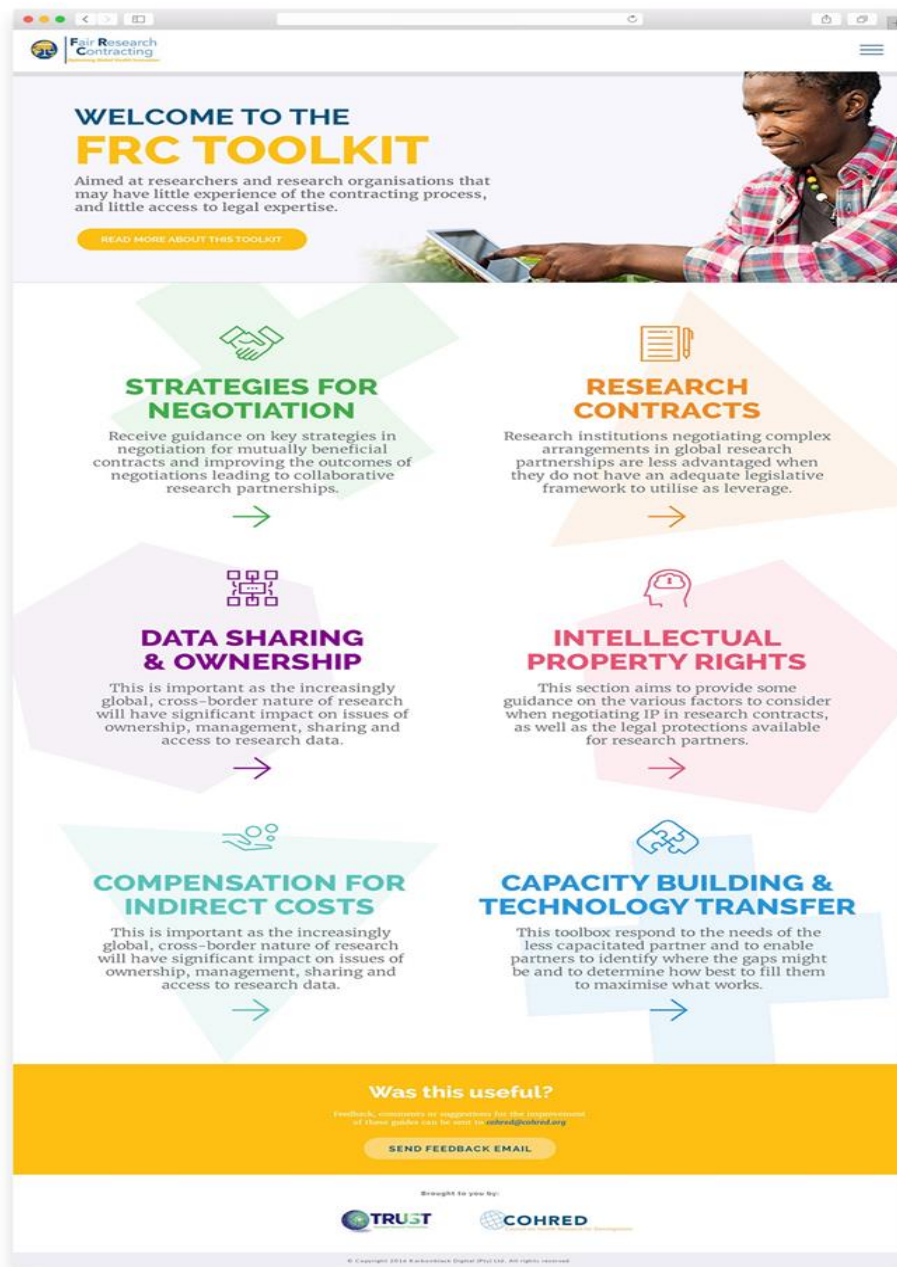
The key features of the online tool emerged from the culmination of work for the Fair Research Contracting Initiative. This initiative highlighted six key features that are essential for fair research contracting as shown in the diagram below. Each of these features will be represented in the TRUST online tool.



What will the Fair Research Contracting Tool look like?

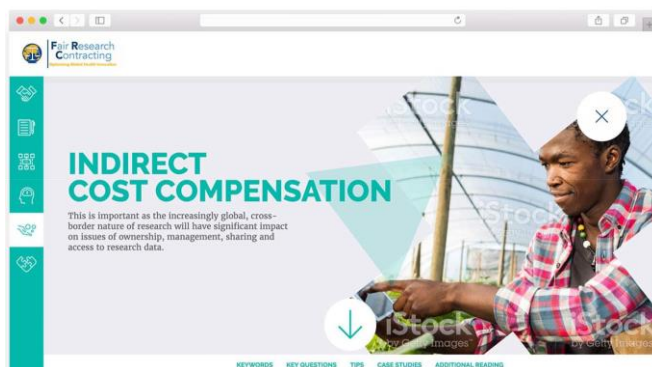
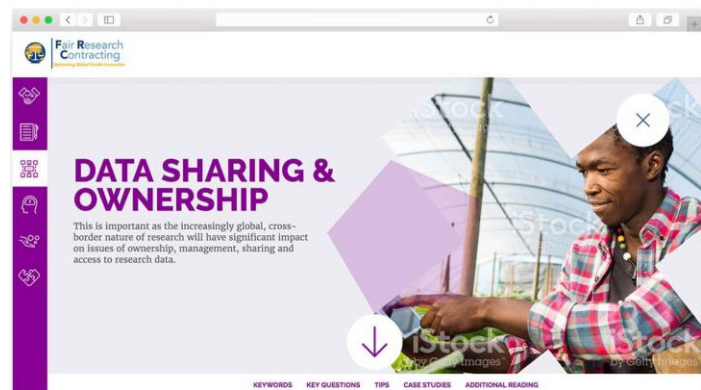
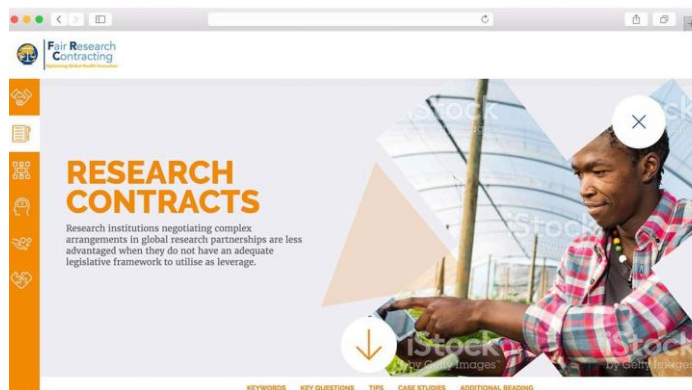
The front page

The FRC toolkit front page shows the six key features described above. From the front page, users can select one of the six features, which will then lead the user to a toolbox for that feature.



Landing pages

Each of the six features will have their own landing page – something like the following:



Inside the toolboxes

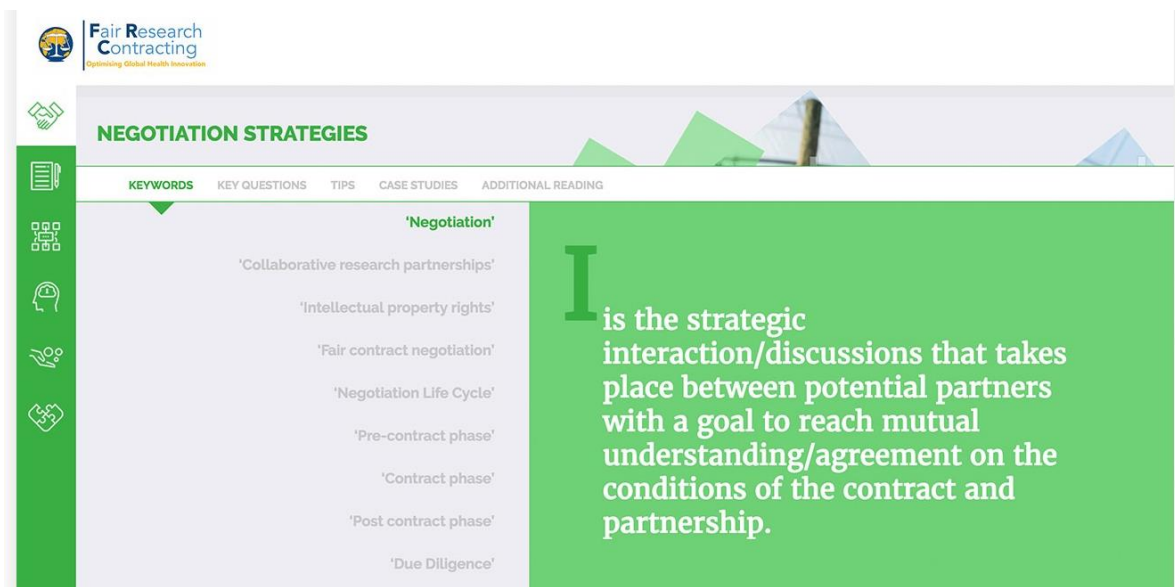
Within each of the six tool boxes there are five generic access points that can be seen at the bottom of the page. These lead to information on:

- Keywords
- Key questions
- Tips
- Case Studies
- Additional Reading

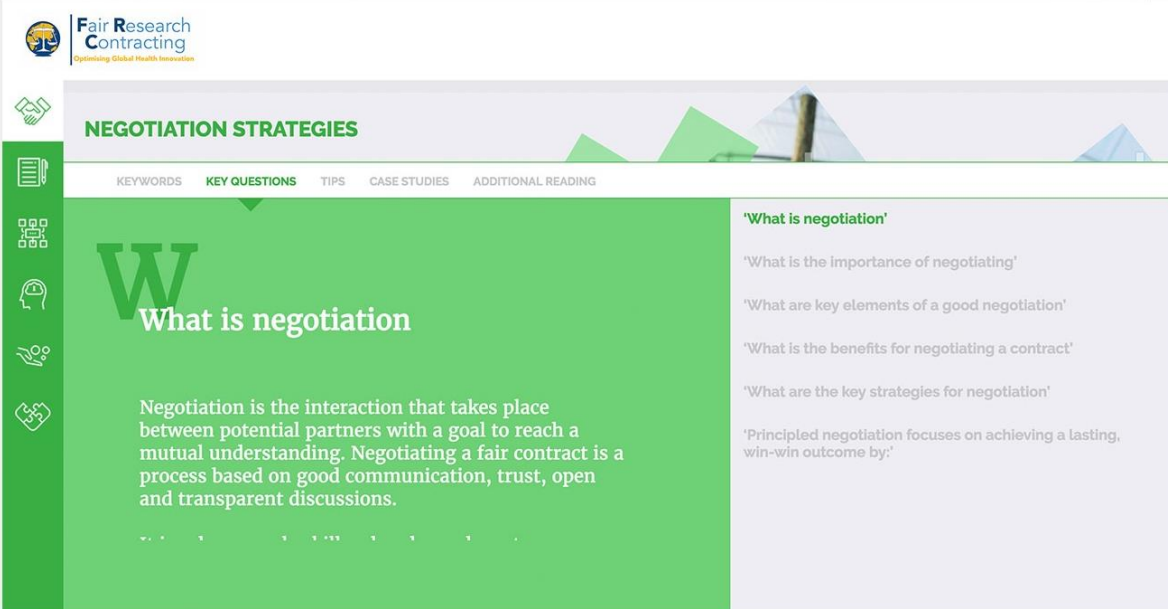


If we click on one of these access points, it will lead us to further information. For example:

Sample of the 'KEYWORDS' in Strategies for Negotiations



Sample of the 'KEY QUESTIONS' in Strategies for Negotiations



Fair Research Contracting
Optimizing Global Health Innovation

NEGOTIATION STRATEGIES

KEYWORDS **KEY QUESTIONS** TIPS CASE STUDIES ADDITIONAL READING

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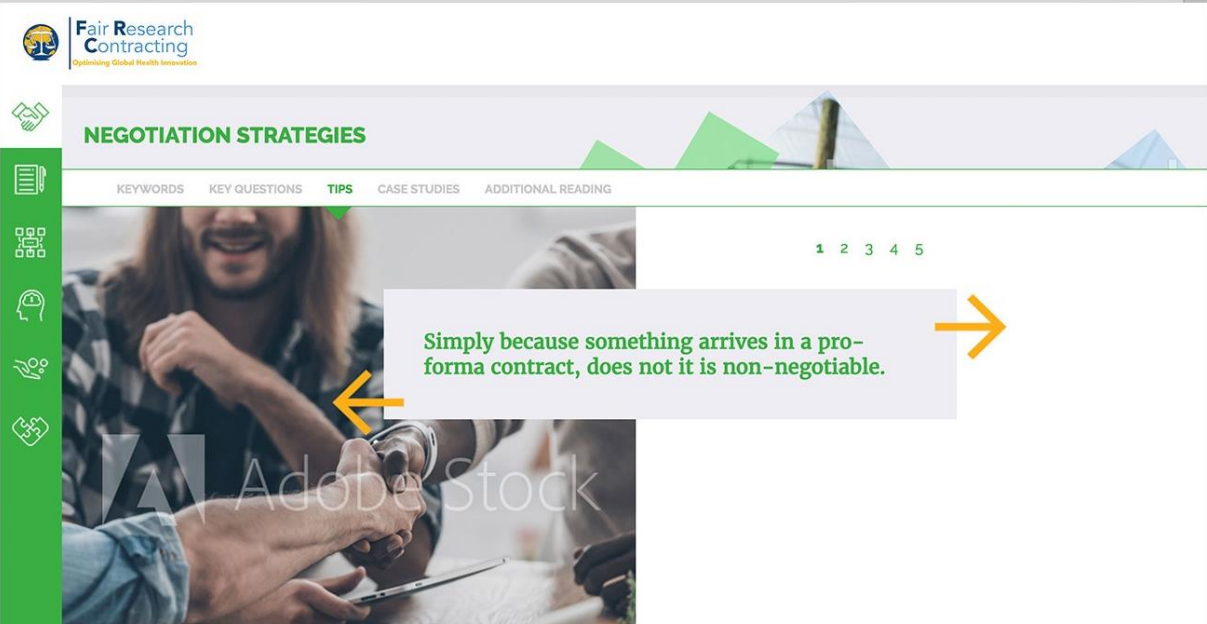
What is negotiation

Negotiation is the interaction that takes place between potential partners with a goal to reach a mutual understanding. Negotiating a fair contract is a process based on good communication, trust, open and transparent discussions.

'What is negotiation'

- 'What is the importance of negotiating'
- 'What are key elements of a good negotiation'
- 'What is the benefits for negotiating a contract'
- 'What are the key strategies for negotiation'
- 'Principled negotiation focuses on achieving a lasting, win-win outcome by:'

Sample of 'TIPS' in Strategies for Negotiations



Fair Research Contracting
Optimizing Global Health Innovation

NEGOTIATION STRATEGIES

KEYWORDS KEY QUESTIONS **TIPS** CASE STUDIES ADDITIONAL READING

1 2 3 4 5

Simply because something arrives in a pro-forma contract, does not it is non-negotiable.

Adobe Stock

The next steps

The draft FRC tool has a complete framework. The next phase of the development of the FRC online tool is to ensure that the tool is fully functional. The TRUST consortium will provide input to the development and refinement of the tool content. Further internal review and external review with TRUST advisors and partners will be conducted. Thereafter the tool will be translated into French, Spanish and Hindi.

Date	Activity
Feb-Mar'17	Present draft of prototype with visuals, layout at Plenary meeting, Cape Town Secure commitment from partners on content development Collect final comments/suggestions for changes to design frame
Apr '17	Integrate Feb meeting feedback/changes to design frame for web-support tool based on engagement of partner partners Send out to TRUST consortium & industry partners for pilot test functionality and content
May-Jun'17	Conduct internal consultation on content relevance with relevant consortium experts on each toolbox Finalise web tool content
Aug-Oct'17	Review and test web tool with consortium Send back to web developer for changes/edits
Nov-Jan'17	Conduct internal review of web tool final changes Make final design changes to frame for web-support system as per internal review Conduct a final usability test of web tool & finalise web tool for full functionality
Feb-Jun '18	Translate web tool to 3 languages: French, Spanish and Hindi Review and finalise language settings and test functionality
Jul-Aug '18	Send out for confirmation of full implementation, conduct pilot with as agreed for final technical and functional specification with internal project partners
Sept'18	Produce FINAL FRC web tool



In terms of access and download capacity, we have discussed with the web developer the requirements for the tool to be accessible on mobile phones. In addition to this has been careful attention to ensure that the on-line tool can be accessed by users in regions where internet access/bandwidth is difficult. Therefore, it is envisaged that the graphics and text are to be carefully balanced to cater for slow internet access.