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1. **Background and Involvement of COHRED with TRUST**

COHRED is an international organization committed to the improvement and development of health-related research in low- and middle-income countries, as well as to the on-going capacity building within the research communities and institutions in these countries. The special interest of our organization is the establishment of research partnerships based on fairness and equity, guaranteeing the collaboration of institutions from high-income countries with LMIC institutions as equals. A signed research contract marks the official beginning of such a partnership.

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 al. 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 time lines 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 countries.

Any project that aims at improving the adherence to highest ethical standards in scientific work and research is of interest for COHRED. At the core of COHRED's work is the development of fairness and equity in research partnerships and collaboration. COHRED had already identified the problems related to fair research contracting as far back as 2010-2011. In a situation where there are no trained legal staff or consultants, it is hard to imagine that research institutions and researchers in low and middle income countries can ever get a fair deal - benefitting at least proportionately to their own investments in research collaborations. The “Fair Research Contracting” (FRC) effort was formalised during a meeting at the Rockefeller Foundation's Bellagio Center in Italy in 2012. Our alignment with the TRUST partners and our commitment to this truly important EU project resulting among others in three tools to counter Ethic Dumping was logical.

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A basic framework was developed by COHRED⁴ 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.

Based on this framework, the creation of an interactive online tool will enable researchers, research managers and contract administrators with little or no legal expertise and support, to seek on-line assistance which they can use to gain a good understanding of research contracting for equitable research partnerships thus avoiding potential exploitation.⁵

1.1. "Africa does not need charity, it needs true and fair partnerships.”

These were the words of the President of the European Union spoken during his State of the Union speech 2018⁶ that he introduced by saying “Africa is the future”.

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⁴ The following key partners were involved with Cohred, IDDDR,B, Univ of the Witwatersrand, Fiocruz Brazil, London School HTM, Makerere University Uganda, and WIPO
⁵ see also the original proposal with amendment (available on demand)
The EU President focused in the Africa related part of his speech on economics and future investments, promoting in agreement with the Chairperson of the African Union reciprocal commitments as the way forward. True and fair partnerships should help to make African-European trade more significant. The President made also very clear, that “Europe needs this partnership just as much”.

The Fair Research Contracting project sees itself confirmed and supported on highest level, as we understand economical and investment efforts within Africa strongly linked to research and academic work. New investment activities will start with research, and these new or expanded efforts will certainly include the health sector.

In addition to that, the EU President stated explicitly that “we want to focus our investment where it matters most”, referring to the support of African students and researches with the Erasmus program. By 2027 their number should rise from 35,000 to 105,000.

The goal of the EU is, according to this speech, an economic partnership between equals – the goal of the TRUST project and the FRC especially are research partnerships between equals.

### 1.2. Fair Research Contracting and the Research Fairness Initiative

The FRC is linked to COHRED’s Research Fairness Initiative (RFI) and goes hand in hand with the latter. The RFI is a service to improve the fairness, efficiency and impact of research collaborations globally and was created with the aim of improving global health, equity and development. The RFI has been designed, firstly, as a reporting system that is used by all research stakeholders and can be validated by the RFI Secretariat, and secondly, as a learning platform to increase understanding and sharing of innovations and best practices. The RFI is divided into three main domains, which are each further divided into five subtopics. Each topic is then further subdivided into three indicators. For each indicator, COHRED asks organizations to describe their current organizational practices, reference relevant standard operating procedures, policy directives or other written guidelines through an attachment or link, and report on future steps to improve that particular indicator within the next one to two years.

Answering all questions results in a report that makes the nature of the organization’s partnership transparent and ideally documents the way, in which a collaboration based on fairness and equity has been established before, during and after the research project.

One major objective of the RFI is to develop research and innovation system capacities in low- and middle-income country (LMIC) institutions through their research partnerships with high-income country (HIC) institutions. LMIC institutions using the FRC online tool will be better prepared to engage in research partnerships and to fully understand and evaluate existing RFI reports in order to set the fair bases for their own collaborations.

The RFI project was finalized in 2017 and is under constant review for improvement. The reporting system has been successfully promoted, and the first reports have been published in 2018.

Consequently, publications and other dissemination activities for either of these two projects are used to promote the other whenever possible and appropriate.
2. COHRED’s Main and Secondary Roles

COHRED’s main role as a participant in the TRUST project was to lead and oversee the development and implementation of the FRC online tool (Work Package 3 Standards and Fair Research Contracting). The main responsible team members for the FRC project were Prof Carel IJsselmuiden, Jacintha Toohey and Holger Postulart; other coworkers were involved in research, text editing and website programming (see details in the next section).

Our secondary role consisted in contributions to the other TRUST deliverables, notably the Global Code of Conduct and the Compliance Tools, based on COHRED’s expertise in the development of services and tools that improve the work of researchers and ethic committees in the health sector. In addition to that, COHRED was of course committed to contribute to TRUST’s overall coordinating and supporting activities. Carel IJsselmuiden has to be seen as the main contributor, but all COHRED team members involved in the FRC project contributed to brainstorming, conceptual development and improvement of the TRUST deliverables through E-mail exchange, active participation in TRUST meetings and conferences, and they all undertook dissemination/promotion activities (see details in the next section).

2.1. FRC

In order to fulfil our main role, COHRED created and coordinated an internal team that would work and concentrate on the FRC development. Its main goal was to identify, review and collate materials and resources for the FRC tool. Equally important was the development of a conceptual outline for the FRC online tool. The team members including the web programmer and designer familiarized therefore with existing online toolkits in order to come up with a visually attractive, technically high-end and easy to use website.

Six key features have been identified to enable users to gain the basic knowledge and understanding of research contracting and its crucial elements:

- **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.

- **Intellectual Property**: Provides an introduction to some of the key general principles that require consideration before participating in research collaborative agreements.

- **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.

- **Capacity & Technology**: Provides elements to understanding ways in which a research partner can maximise what works while building capacity for long-term development.
The team summarized the FRC content materials/resources regarding these key features that would be presented as “toolboxes”. Their programming and web layout were discussed and decided in meetings with the web developer. Interim drafts and the final draft of the FRC versions were presented to the TRUST consortium and modified according to their input.

2.2. FRC and RFI

The Research Fairness Initiative is designed to fill in a gap: Various methods exist to evaluate the quality of research and its results, and scientific work in general. Until 2017 there was no instrument that would allow to evaluate or describe the quality of the research partnership(s), especially regarding fairness and equity.

Another gap that needs to be filled is the absence of legal expertise and knowledge in LMICs in terms of research contracting; this need is now addressed with the Fair Research Contracting web tool.

There is a strong link between the FRC and the RFI that has been considered by the internal COHRED team right from the start of the TRUST project. Accordingly, the COHRED staff working on the RFI has been constantly updated on the FRC progress whereas the FRC team familiarized with the RFI. The link and completing aspects of both projects were and are highlighted in relevant meetings, conferences and publications, as well as shared with the institutions that uses the RFI and have published their first reports, notably:

- Special Programme for Training and Research in Tropical Diseases (TDR), World Health Organisation, Geneva, Switzerland
- Instituto de Higiene e Medicina Tropical, Universidade NOVA de Lisboa, Lisbon, Portugal
- Université Alioune Diop de Bambey, Bambey, Diourbel, Senegal

RFI reports are currently worked on at:

- Swiss Tropical and Public Health Institute (Swiss TPH), Switzerland - internal report is ready and waiting for approval by the TPH Director
- IRESSEF, Senegal
- CEA-SAMEF, Senegal
- Univ of Cape Town, South Africa
- Medical Research Council, South Africa
- Institute for Development Research (IRD), France
- CAPRISA (Centre for the AIDS Programme Research in South Africa)

Nine more institutions in Africa, Asia, Europe and the USA have expressed their interest.
3. The Global Code of Conduct and the Compliance and Follow-Up Tool

Whilst clinical trials in low and middle income countries are likely to stay the most ethically sensitive area in global research ethics, a sensitivity which the TRUST consortium composition reflects, the TRUST projects aim at overcoming a restricted mentality which hampers global research ethics from taking the next step: agreeing generic risks of “ethics dumping”, developing a global code of conduct and providing tools that can be used by LMIC populations and institutions to avoid exploitation.

Two relevant TRUST deliverables are:

- Develop a global code of conduct that can be used by the European Commission and funders world wide to foster ethical research and equitable partnerships.
- Develop a compliance and ethics follow-up tool for research conditions in resource-poor settings

COHRED contributed especially to the development and improvement of these two deliverables throughout the whole period of the TRUST project. It goes without saying that we also contributed to other deliverables whenever possible.

COHRED delivered its active support to TRUST project activities beyond the development and improvement of these two deliverables, such as:

- Organization and realization of internal TRUST meetings; active participation in these meetings
- Organization and realization of Conferences; active participation in these meetings
- Communication, dissemination and promotion of the TRUST project and its deliverables
- Support in reviewing/commenting the progress of other TRUST deliverables and activities
4. Detailed Description of COHRED’s Core Contribution – the FRC Toolkit

The COHRED internal team’s collaboration with the web developer results in a fully operational web page that is programmed and designed as a toolkit to gather and apprehend the basic and most relevant information on Research Contracting. It was crucial to develop the online tool in consideration of limited access to the internet in LMICs, therefore accessible via cell phones. Graphics and text have been carefully balanced to cater for slow internet access.

Equally important for us was its user friendliness, to be achieved by a self explaining navigation and rather intuitive handling of the website’s content.

Whilst not replacing the advice of a contract lawyer or expert this online tool enables the user to better understand the various aspects of negotiations; the management of respective responsibilities, opportunities and risks that impact the research partnership; the principles concerning rights, responsibilities, including accountability and access to data in collaborative research; the key general principles that require consideration before participating in research collaborative agreements; the cost considerations when developing a full cost research budget proposal; and the ways in which a research partner can maximise what works while building capacity for long-term development. The case studies and the additional resources allow the user to more in-depth research and preparation for upcoming contracting negotiations.

4.1. Development of the Online Tool

The process of developing the final FRC online tool took three years of intense work, starting after the TRUST kick-off meeting (October 2015) in 2016 with:

- Planning and scheduling meetings with internal COHRED team and web developer
- Identification, background review and collation of materials for the FRC online tool, including familiarization with other online web toolkits
- Coordinating an internal team in COHRED
- Developing a conceptual outline
- Developing web mock-up for review at the Nairobi plenary meeting May 2016 by the TRUST partners; integrating feedback into mock-up
- Preparation of draft outline of content based on FRC resources
- Summarizing FRC content materials/resources including components on Strategies for Negotiation, Capacity Building, Data ownership, Intellectual Property, Indirect costs and Contracting (in legislative context)
- Presenting second version of mock-up at TRUST team meeting in Paris in October 2016; Integrating feedback
- Developing draft of a third version of the mock-up of online tool for TRUST team review; collecting and integrating feedback
- Circulating the third version of mock-up, collecting and collating feedback
In the beginning of the year 2017 we presented the first prototype with visuals and layout at the Plenary meeting in Cape Town to the TRUST partners and collected final comments/suggestions for changes to the design frame.

During the following months we undertook the time-consuming task of constantly improving the tool, completing the material and editing the text used on the web site.

The prototype consisted in six toolboxes based on the six key features mentioned above, each of which had to be worked on in the same manner, according to the work-plan for 2017 (see also the report “Fair Research Contracting On-Line Tool”7):

- Integrating meeting feedbacks/changes to design frame; send results to TRUST consortium and industry partners for functionality and content testing
- Conducting internal consultation on content relevance with relevant consortium experts on each toolbox
- Finalising web tool content
- Conduct a final usability test of web tool & finalise web tool for full functionality

The web tool was indeed fully functional by the end of 2017, its final version was ready in September 2018, accessible on www.frcweb.cohred.org.

Fig. 4: Landing page (top) of the FRC toolkit, final version 2018

The landing page gives access to a section informing about the tool and its functioning as well as to the six toolboxes “Negotiation Strategies”, “Research Contracting”, “Intellectual Property”, “Research Data”, “Research Costing” and “Capacity & Technology”. The user can select the feature of his choice and was led to the relevant toolbox for that feature.

Fig. 5: Toolbox “Research Contracting” (top), navigation to each other toolbox (sidebar left)

All toolboxes are structured in the same way, designed as self-explanatory and containing a short summary inviting users to explore the following five instructive sections. The content of these sections is based on the material/resources identified and finally selected by the COHRED team:

- **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 TRUST Partners and industrial partners confirmed the excellence of structure, layout and functionality of the web tool; these remain in the final version. However, there was still room for improvement, notably regarding the written parts and the quantity of resources and case studies for each toolbox. Accordingly, our activities in 2018 were:

- Collecting final comments and suggestions to improve the text; finalizing editing
- Research for further additional resources; sending out to TRUST partners for approval; adding to web content
- Collecting further case studies for each toolbox; sending out to TRUST partners for approval; adding to web content
- Conduct pilot as agreed for final technical and functional specification with internal project partners
- Produce FINAL FRC web tool
- Dissemination and promotion activities

4.2. The Team

The core team working on this project had a high staff turnover; its main members were Najia Musolino (2015/16), Jacintha Tooley (2016/18) and Holger Postulart (2018). Their work was supervised by Carel IJsselmuiden who remained available for discussion and consultation throughout the whole project. The team collaborated with IT providers and programmers in Brazil and South Africa, notably Rafael Sahb.

The progress and finalization of the FRC are documented in two reports⁸; two versions of a FRC flyer⁹ are used for information and promotion.

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4.3. Communication, Promotion and Publication

Beyond the successful production of the deliverable, it is worth noting that a first workshop on FRC was held at the invitation of the South African Medical Research Council, in November 2016. This workshop included legal and innovation office staff concerned with contracting.\textsuperscript{10}

Holger Postulart initiated the collaboration with the WHO country office in Kigali, Rwanda, and the RBC, Rwanda Biomedical Center. The goal of this collaboration is the dissemination of the FRC on national level and beyond as well as the organization of relevant workshops and seminars that will also include the RFI. The first workshop is planned for 2019 in Kigali, co-organized with the RBC.

Due to the strong link with COHRED’s Research Fairness Initiative, COHRED used conferences or meetings where the RFI as main topic to also promote the FRC. Such promoting activities resulted for example in an invitation to hold a workshop on the FRC (Globethics.net International Conference, see below). Important events with a tangible positive outcome for both projects, RFI and FRC, took place especially in 2018:

- CUGH 2018 Annual conference in New York, USA, 15-18 March 2018
  Session on “Improving the Fairness and Impact of Global Health Research Partnerships” (Prof. Carel IJsselmuiden)
- COHRED Colloquium 5 on the RFI, in collaboration with sc³nat, Geneva, Switzerland, 12 April 2018
  Workshop on “COHRED’s Fair Research Contracting (FRC)” (Holger Postulart)
- Globethics.net International Conference, Colley-Bossy, Switzerland, 4-6 June 2018
  Workshop on “COHRED’s perspective and work on the Fairness Initiative for research partnerships” (Carel IJsselmuiden)
- U.S. National Academies of Sciences, Engineering, and Medicine, workshop, Washington D.C., USA, 13-15 June 2018, “COHRED’s perspective and work on the Fairness Initiative for research partnerships” (Carel IJsselmuiden)
- EuroScience Open Forum 2018, Toulouse, France, 9-14 July 2018,
  “Research integrity & ethics - are we getting it right?” (Carel IJsselmuiden)
- INSERM Meeting, Paris, France, 6-7 September 2018
  RFI Presentation (Carel IJsselmuiden)
- SNSF and SDC workshop, Thun, Switzerland, 12-14 September 2018
  Session on the RFI (Carel IJsselmuiden)
- Ninth EDCTP Forum, Lisbon, Portugal, 17-20 September 2018
  Scientific Symposium: “Optimizing the Impact of Research Partnerships for all Partners – the Research Fairness Initiative (RFI)” (Carel IJsselmuiden)

Publications on the RFI are susceptible to equally concern the FRC or mention it directly. 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”\textsuperscript{11}. In their recommendation to their research questions the authors say:

\textsuperscript{10} The workshop report is available on demand

\textsuperscript{11} https://gh.bmj.com/content/3/4/e000741
“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”\textsuperscript{12}. 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

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.

\subsection*{4.4. FRC – A Sustainable Project}

The FRC – now together with the RFI – is at the core of COHRED’s objectives and activities. Therefore, the organization is committed to the project’s sustainability. COHRED agreed to maintain the FRC for at least three years after the TRUST project ends, this will be until December 2021. During this period, COHRED will undertake fundraising in order to further improve the toolkit.

It is foreseen to add a communication platform for users, enabling them to connect and network, to share their experiences, to provide ideas for improvement and, to access a forum where they can ask specific questions to (legal) experts in terms of research contracting. Consequently, COHRED plans the creation of a network of legal experts who are willing to support this project (ideally pro bono). With the help of these experts, specific trainings and seminars on Research Contracting will be organized and held in the future as means to complete and improve the knowledge that users have gained through the FRC toolkit.

\textsuperscript{12} https://sph.umich.edu/news/2018posts/hpp-supplement-102118.html
Ideally, lawyers interested in the topic can be trained in order to become experts themselves and make legal expertise locally available where there is no lawyer at present.

In the first half of 2019 we will identify a first pool of African research institutions that need the FRC and are willing to use it. This in combination with the other above-mentioned will make the FRC well known, if not indispensable for the concerned communities.

The goal is to maintain the FRC beyond the period of three years – that is as long as necessary.
5. COHRED Contributions to the Global Code of Conduct and the Compliance and Follow-Up Tool

5.1. The Global Code of Conduct

Ideally, the FRC would make research participants knowledgeable and prepared in terms of fairness and equity prior to the start of research. The same applies to the Global Code of Conduct in Resource-Poor Settings as an instrument for researchers from high-income countries. The Code This Global Code of Conduct for Research counters ethics dumping by:

- providing guidance across all research disciplines
- presenting clear, short statements in simple language to achieve the highest possible accessibility
- focusing on research collaborations that entail considerable imbalances of power, resources and knowledge
- using a new framework based on the values of fairness, respect, care and honesty
- offering a wide range of learning materials and affiliated information to support the code

Those applying the code will be researchers and research funders who oppose double standards in research and support long-term equitable research relationships between partners in lower-income and high-income settings based on fairness, respect, care and honesty.

The Global Code of Conduct is available through the TRUST project website\(^\text{13}\) and on the website created for the Code: http://www.globalcodeofconduct.org/

This website gives detailed information about the Code and its development, the underlying values, relevant resources and learning material.

\(^{13}\) http://trust-project.eu/deliverables/deliverables-and-tools/
5.2. The Compliance and Follow-Up Tool

While the FRC and the Global Code of Conduct help lay the bases for fair research partnerships and collaborations, it is also important to provide tools for use during and after research, especially in areas of compliance gaps. Here it is important to remember that risks and compliance issues are two different things just as compliance issues and compliance gaps are two different things. For instance, the risk for “ethics dumping” is higher with unequal power relations. A multinational pharmaceutical company with a drug ready to enter clinical trials on the one hand and a low-income country population with a relevant pandemic on the other hand present a potential risk of “ethics dumping”.

However, unequal power relations in themselves are not a compliance issue. One can only talk about compliance issues when “ethics dumping” has already occurred. For instance, many low-and middle-income countries have legal instruments, which forbid the transfer of biological samples across national borders without material transfer agreements (MTA). If samples are nevertheless taken abroad without an MTA, one can speak of a compliance issue.

The legislation is in place and it has been ignored (out of ignorance, in which case training and awareness raising measures are required, or on purpose, in which case compliance tools are required). The TRUST project’s results in the Compliance Tool Report.14

Fig. 9: Cover of the Publication about the Compliance and Follow-up Tools

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5.3. COHRED’s Contributions

As already pointed out, COHRED contributed especially to the development of these two deliverables, e.g. through brainstorming, participation in the conceptual work, counseling during the process of further improvement, assisting in text editing and active participation in the relevant meetings and conferences.

Besides our personal input in meetings and discussions, a major contribution to the Compliance Tool has been done through COHRED’s work on the FRC and the RFI. Valuable elements for follow-up strategies and compliance could be taken/modified from the RFI reporting system that serves these two goals. Once the necessary material for the content of the FRC was identified and selected, it was also used as a pool of information in the development process of the Compliance Tool.

The TRUST consortium counts as a major achievement the acceptance of the Global Code of Conduct by the European Union, decided and communicated at the conference at the European Parliament on 28 June 2018. The Deputy Director General of DG Research, European Commission, declared the code as “reference document to be consulted and applied by all relevant research projects applying for H2020 funding”. As from that date, the Code is listed on the EU webpage for funding applicants as a reference document.\textsuperscript{15}

In their announcement of the Global Code of Conduct, the EU Commission also refers to the FRC\textsuperscript{16}:

“Implementation of the code of conduct in research practice is supported by a Fair Research Contract toolkit developed by members of the TRUST consortium. This toolkit helps administrators, researchers and legal advisors in low- and middle-income settings to achieve equitable research contracts in collaboration with research teams from high-income settings. Freely accessible online tools provide up-to-date information, links and references to help users understand the factors underpinning an equitable and transparent research partnership.”

\textsuperscript{15} http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/coc_research-resource-poor-settings_en.pdf
\textsuperscript{16} http://ec.europa.eu/research/infocentre/article_en.cfm?artid=49377
6. **COHRED Contributions to Coordinating and Supporting Activities**

The work of the TRUST consortium including COHRED’s contributions results in the successful production of all required deliverables and, due to the outstanding motivation and commitment of the group, in deliverables beyond the project setting. Relevant articles and reports have been published, websites have gone on line and besides numerous virtual meetings 15 face-to-face meetings and workshops took place.

The overall successes can be listed as follows:

- Successfully engaged key stakeholders within the following target audiences: Ethics committees, Policy-makers and advisors, Vulnerable populations, Academia, Industry representatives and researchers, NGOs and the general public,
- Established a multichannel dissemination platform for a continuous and up-to-date flow of information to the wider public,
- Delivered six project reports, including a Case Studies Deliverable on “Ethics Dumping”, a major fact-finding mission on Generic Risks of Exporting Non-ethical Practices, and a detailed report on National and International Compliance Tools,
- Successfully involved vulnerable populations in the debate around global, inclusive and fair research without double standards, providing them with opportunities and means to voice their requests and concerns,
- Organised seven international meetings and workshops,
- Produced two short films, the first introducing the project consortium and its aims, and the second presenting the plea by members of different San communities from South Africa for a San Code of Ethics,
- Launched an international Case Study competition.
- Successfully promoted TRUST and its deliverables, resulting in
  - numerous invited papers on TRUST given in Europe, Asia, the Americas and Africa;
  - use of TRUST outputs by Aljazeera stream in a 30 minutes program on protecting indigenous people;
  - being awarded as a funder success story, once by Sis Net, once by DG Research;
  - massive international media attention for the launch of the Sun Code of Research Ethics;
  - the download of the first TRUST book over 50,000 times;
  - the adoption of the Global Code of Conduct by the European Commission and the EDCPT
- The necessary coordinating and supporting activities happened in team work, executed by all members of the consortium according to their expertise and skills set.
- COHRED contributed to the following activities that were crucial for the successful realization of the TRUST project as a whole:
6.1. Organization of TRUST Meetings/Workshops

COHRED’s representatives actively helped organizing these events and attended those marked with *:

<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
<th>Host</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015, October 04-05*</td>
<td>TRUST kick off meeting</td>
<td>UNESCO</td>
<td>Paris, France</td>
</tr>
<tr>
<td>2016, March 11-12</td>
<td>Case studies meeting</td>
<td>FERCI</td>
<td>Mumbai, India</td>
</tr>
<tr>
<td>2016, March 21-22</td>
<td>1st Kimberley meeting</td>
<td>SASI</td>
<td>Kimberley, South Africa</td>
</tr>
<tr>
<td>2016, May 23-25*</td>
<td>Case studies meeting</td>
<td>PHDA</td>
<td>Nairobi, Kenya</td>
</tr>
<tr>
<td>2016, May 31-June 1</td>
<td>2nd Kimberley meeting</td>
<td>SASI</td>
<td>Kimberley, South Africa</td>
</tr>
<tr>
<td>2016, October 19-20*</td>
<td>European partners meeting</td>
<td>INSERM</td>
<td>Paris, France</td>
</tr>
<tr>
<td>2016, November 15-16</td>
<td>3rd Kimberley meeting</td>
<td>SASI</td>
<td>Kimberley, South Africa</td>
</tr>
<tr>
<td>2017, February 24-25*</td>
<td>4th Kimberley meeting</td>
<td>SASI</td>
<td>Kimberley, South Africa</td>
</tr>
<tr>
<td>2017, Feb 28-Mar 2</td>
<td>Kalk Bay plenary meeting</td>
<td>UCT</td>
<td>Kalk Bay, South Africa</td>
</tr>
<tr>
<td>2017, June 12-14*</td>
<td>Funder workshop</td>
<td>EDCTP</td>
<td>London, UK</td>
</tr>
<tr>
<td>2017, October 17-18</td>
<td>The San Code of Research Ethics</td>
<td>SASI</td>
<td>Upington, South Africa</td>
</tr>
<tr>
<td>2018, February 12-13</td>
<td>Oberwinter plenary meeting</td>
<td>UCLAN</td>
<td>Bonn, Germany</td>
</tr>
<tr>
<td>2018, June 28*</td>
<td>Brussels consortium meeting</td>
<td>UCLAN</td>
<td>Brussels, Belgium</td>
</tr>
<tr>
<td>2018, June 29*</td>
<td>Final dissemination meeting</td>
<td>UCLAN</td>
<td>Brussels, Belgium</td>
</tr>
<tr>
<td>2018, June 30*</td>
<td>Brussels management meeting</td>
<td>UCLAN</td>
<td>Brussels, Belgium</td>
</tr>
</tbody>
</table>

For a detailed description of the content and outcome, please see the TRUST Engagement Reports (available on http://trust-project.eu/deliverables/deliverables-and-tools/).

6.2. Funding platform and Industry platform

As it is stated in THRUST’s first Engagement Report, “research funders hold a critical position directly linking to policy-making processes and therefore regulation and assurance of adherence to research governance and ethical standards”. Based on the funder database created by EDCTP, a funder platform has been developed aiming at raising interest, promoting collaboration and obtaining input on TRUST’s deliverables, especially the Compliance and Follow-Up Tool.

Industry plays a crucial role as a motor for and beneficiary of research. TRUST therefore considered the participation of industrial companies a necessity and created the Industry
Platform. The main objective is to motivate the concerned industry to an engagement for highest possible ethical standards, not only to help protect “vulnerable populations” subjects to research but also as the opportunity for the companies to create reputational capital.

6.3. Communication and Dissemination Strategies

The TRUST consortium developed communication and dissemination strategies aiming at

- supporting the project’s mission to catalyse a global collaborative effort to improve adherence to high ethical standards around the world,
- providing a voice to marginalized and / or over-researched populations,
- engaging funders into the network and
- engaging industry into the network.

The means that TRUST uses to successfully communicate and disseminate the projects to the largest possible audience are mainly the project website, social media, Brochures, eNewsletters and meetings/conferences. In addition to these, TRUST produced films and gave interviews to specialized media.

Relevant stakeholders are addressed with a two-way-flow of information where their feedback is received and integrated into the project production, whilst outcomes of the project are extensively shared and disseminated. The quality of project outcome and related communication is externally controled by the TRUST Advisory Board, consisting of internationally renowned experts. The TRUST Engagement Panel ensures an increasing project outreach and the impact of the dissemination activities. The panel has 13 members, one representative of each partner organization. Finally, the Stakeholder Inventory is a collection of contacts of key and relevant institutions or individuals that might be potentially impacted by, or interested in, the TRUST project’s work and outcomes. The inventory is the bases for our well targeted audience and lists:

- Ethics Committees
- Academia
- Vulnerable Populations
- The general public and CSOs
- Policy-makers (e.g. Funders) and advisors
- Industry representatives and researchers

TRUST’s communication and dissemination strategies were successful: upon invitation, TRUST representatives attended more than 40 conferences in Europe, Asia, the Americas and Africa as speakers and presented the TRUST project and its deliverables (see detailed information in the second Engagement Report).
6.4. Publications

During the project period, the TRUST Consortium published numerous articles, reports and – following a contract with the Springer Verlag – books. The following gives a short description of important publications:

Ethics Dumping – Springer Book
The Report on Paradigmatic Case Studies which was informed by a competition to collect case studies, was one of TRUST’s first deliverables. The case studies were refined and reordered for a book publication by Springer in 2018. The full reference is: Schroeder D, Cook Lucas J, Hirsch F, Fenet S, Muthuswamy V (2018): Ethics Dumping – Case Studies from North-South Research Collaborations. SpringerBriefs in Research and Innovation Governance, Springer International Publishing.

Relatedly, on December 12 2017, an article by Prof. Doris Schroeder called “Ethics dumping’ – the dark side of international research” was published online by The Conversation UK. On December 26 2018, the same article was published by The Independent.

Book Series: Advances in Research Ethics and Integrity
Volume 4 of the book series “Advances in Research Ethics and Integrity” featured a commissioned book chapter about TRUST. Promoting Equity and Preventing Exploitation in International Research: The Aims, Work, and Output of the TRUST Project authored by Julie Cook, Kate Chatfield and Doris Schroeder. The chapter presents the three TRUST achievements: Global Code of Conduct, Fair Research Contract tool and the Compliance follow-up tool.

Evidence-Based Complementary and Alternative Medicine
On September 19 2018, a Review Article was published in Evidence-Based Complementary and Alternative Medicine, Volume 2018. Lead author Dr Kate Chatfield collaborated with colleagues from Iran using the four TRUST values in a completely different field. Care, respect, honesty and fairness were used as an ethical framework for Herbal Medicine.

Springer Handbook of Research Ethics and Scientific Integrity
An entry on benefit sharing for this Springer handbook edited by Ron Iphofen was commissioned from Prof. Doris Schroeder. After review and minor revisions, the article (just under 8,000 words): Benefit Sharing – Looking for global justice was accepted for publication in October 2018.

Central European Journal of Medicine
Dr Michael Makanga and Dr Michelle Singh (EDCTP) published a paper in the Central European Journal of Medicine about the history of medicine and ethics. TRUST work was highlighted in this article.
Confirmed publications for 2019 are :

**Equitable Research Partnerships – Springer book**
The 2nd gold open access Springer book to be published from TRUST will appear in 2019. The book reports the story of how the Global Code of Conduct for Research in Resource-Poor Settings was built to counter the practice of Ethics Dumping.

**Special Symposium CQHE – Three papers and one editorial**
Three TRUST papers and one editorial are due to be published gold open access in a special symposium of the Cambridge Quarterly of Healthcare Ethics in January 2019.

**The San Code of Research Ethics - Its Origins and History**

Publications in preparation with status

2. Laird, S and Wynberg R. Ethical Research Partnerships on the Genomics Frontier: Rethinking the framing of access and benefit sharing.
7. Conclusion

In the light of TRUST achievements and COHRED’s FRC online tool it is justified to declare this as a worthwhile project with impact well beyond normal. The foundation is laid for fundamental changes in research partnerships and collaboration towards fairness and equity in the relationship between research institutions from high-income countries and LMICs.

SERI played a major role: its funding was essential to make this happen – without it, there would not have been the FRC nor inputs from COHRED that helped realize the other deliverables and outcomes of the TRUST project.

The project’s impact is as yet difficult to measure, but there is no doubt that it will be useful in the future to achieve fair research partnerships, to protect “vulnerable populations” in the process of research and to prevent ethics dumping, or even more to establish the highest possible ethical standards in research collaboration and conducting.

Even though the FRC toolkit is on-line and fully operational, it is important to understand the FRC as a project in development. The website certainly is a corner stone of the project, but the potential of the FRC goes far beyond the impartment of good basic knowledge about research contracting and its related issues. Therefore, COHRED is committed to maintain the online toolkit for three years – but also to raise funds for further improvement and the development of the FRC as an exhaustive approach to research development on the bases of fairness and equity – wherever it is needed. Clearly, this requires long-term work and we are committed to do it.

After all, before we teamed up with TRUST, we had noted that there were possibly only 2 qualified research contracting lawyers in sub-Sahara Africa, at least in the public sector. Clearly, one project and one website are not sufficient to resolve this capacity crisis – but it was a good start. We are grateful to SERI for having made this start possible.