

Sustainability Roadmap



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Sustainability Roadmap compiled by the University of Cape Town for the TRUST Project

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Acronyms and Abbreviations

ACF	<i>Action Contre la Faim</i>
ACHS	Association of Critical Heritage Studies
COHRED	Council on Health Research for Development
EDCTP	European and Developing Countries Clinical Trials Partnership
FERCI	Forum for Ethics Review Committees in India
FGVA	Foundation Global Values Alliance
FRC	Fair Research Contracting Tool
GCC	Global Code of Conduct for Research in Resource-Poor Settings
H3Africa	Human Heredity and Health in Africa
IBC	International Bioethics Committee (UNESCO)
IPR	Intellectual Property Right
LIAZ	Local Infrastructure from A to Z
LMIC	Low- and Middle- Income Country
RFI	Research Fairness Initiative
SASC	South African San Council
SASI	South African San Institute
UCLan	University of Central Lancashire
UCT	University of Cape Town
UNESCO	United Nations Educational, Scientific and Cultural Organization
WIPO	World Intellectual Property Organization
WITS	University of the Witwatersrand
WTO	World Trade Organization

1. Setting up a Sustainability Roadmap for the TRUST Project

The goal of the TRUST Project is to catalyse a global collaborative effort to improve adherence to high ethical standards when conducting research around the world. Commencing in Paris in October 2015, TRUST is a 39-month project funded by the European Community's Horizon 2020 Programme.

The TRUST Project consists of a global consortium of members, all of whom participated in developing a range of outputs, including a [Global Code of Conduct](#) (GCC) for Research in Resource-Poor Settings, an [online tool](#) which assists institutions and individuals with limited access to legal advice to achieve fair research contracts, and a [compliance and ethics follow-up tool](#) designed for use in conditions with high levels of vulnerability.

Involvement in the TRUST Project generated much interest and energy, resulting in a number of outputs - not originally envisioned in the contract – being developed. For example, the [San Code of Research Ethics](#), a code affiliated to the GCC, was developed in addition to the contract and generated significant interest within the global research community (see for example, Kekulawala and Johnson 2018; Maxmen 2018; Merson et al 2018).

Officially coming to a close in December 2018 (following a 3-month extension), the TRUST Project will nonetheless persist as many of its outputs have long-term usability. It is believed that through activities which go beyond TRUST, adherence to high ethical standards around the world can continue to be improved.

This report outlines the activities and resources needed for certain elements of each of the TRUST deliverables or tools to persist beyond the lifetime of the project. It also includes outputs related to TRUST but not envisioned at the start of the project. These are outlined in what we call a 'Sustainability Roadmap'.

In this report, each deliverable or tool's sustainability roadmap is presented according to the following structure:

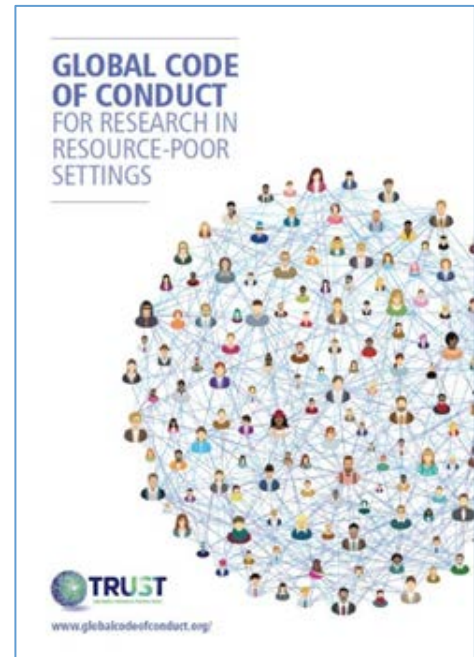
- A. A description of the product.
- B. A brief description of the target audience.
- C. The institution(s) responsible for the roadmap's execution.
- D. A summary of the accessibility of the tool or product, including languages it will be made available in and websites where it can be downloaded or where more information about it can be accessed.
- E. The estimated longevity of the deliverable or tool. This includes sustainability measures aimed at enhancing its longevity, including classification of the sustainability tasks into: outstanding work on tools; capacity-building; awareness raising; education; and networking.
- F. Any financial, technical, human or other capacity-related resources needed for the execution of the roadmap.

2. TRUST Products: Deliverables and Tools

2.1. THE GLOBAL CODE OF CONDUCT

A. Description

One of the TRUST Project's most important products is the Global Code of Conduct for Research in Resource-Poor Settings ([GCC](#)). This code counters ethics dumping - the export of research practices that would not be acceptable in high-income settings but which are instead implemented in resource-poor settings. Based on a four values framework consisting of **fairness**, **respect**, **care** and **honesty**, the GCC was developed collaboratively by the University of Central Lancashire (UCLan) together with all TRUST partners. The GCC was formally launched on 15 May 2018 in Stockholm where it was presented to the Leadership Council of the Sustainable Development Solutions Network. Following the TRUST Project's closing event at the European Parliament in Brussels in June 2018, the GCC was adopted as a [reference document for Horizon 2020](#),



meaning that it is now endorsed by one of the [biggest research funders in the world](#), the European Commission. In July 2018 the GCC was also adopted by the European and Developing Countries Clinical Trials Partnership ([EDCTP](#)). Discussions are ongoing in multiple institutions in South Africa to promote the Code as formal institutional policy. These include the University of Cape Town (UCT), Wits University, and the Medical Research Council. We anticipate a 'snowball' effect once it is adopted by a few Southern institutions.

B. Target audience

It is expected that the GCC will be applied by a global audience consisting of ethics committees, research funders, and researchers working in resource-poor settings.

C. Responsible institution(s)

Dissemination of the GCC is primarily the responsibility of UCLan, but all TRUST partners are involved in ongoing initiatives to spread awareness about the code and promote its adoption within their networks.

D. Accessibility

The GCC has its own standalone website (www.globalcodeofconduct.org/) where it can be downloaded in English as well as in each of the languages it has thus far been translated

into, namely, Russian, French, German, Spanish, Portuguese, Chinese, Japanese, and Hindi. Translation into Arabic is in process. This website ensures that the code and learning materials associated with it, will be available after the end of the TRUST Project cycle.

Those seeking more information about the code can do so by contacting globalcodeofconduct@uclan.ac.uk.

E. Longevity and sustainability measures

Hosting of the GCC website is independently funded and the website will remain functional for as long as the GCC is a mandatory reference document or as long as it is deemed to be useful for others. The website contents will be updated and maintained by the team from UCLan.

The GCC will be promoted via capacity building; education; awareness raising; networking; policy impact, as well as influencing ethics committees.

A Springer Briefs book about the development of the code will be released in the Northern spring in 2019. The book will be freely available upon publication as it will be published via the gold open access route.

Whilst there are no immediate plans to update the code, discussions with the funder on the possibility to do so have been planned.

F. Resources needed

As long as the GCC remains endorsed by the European Commission it will not need considerable financial and human capital to promote it.

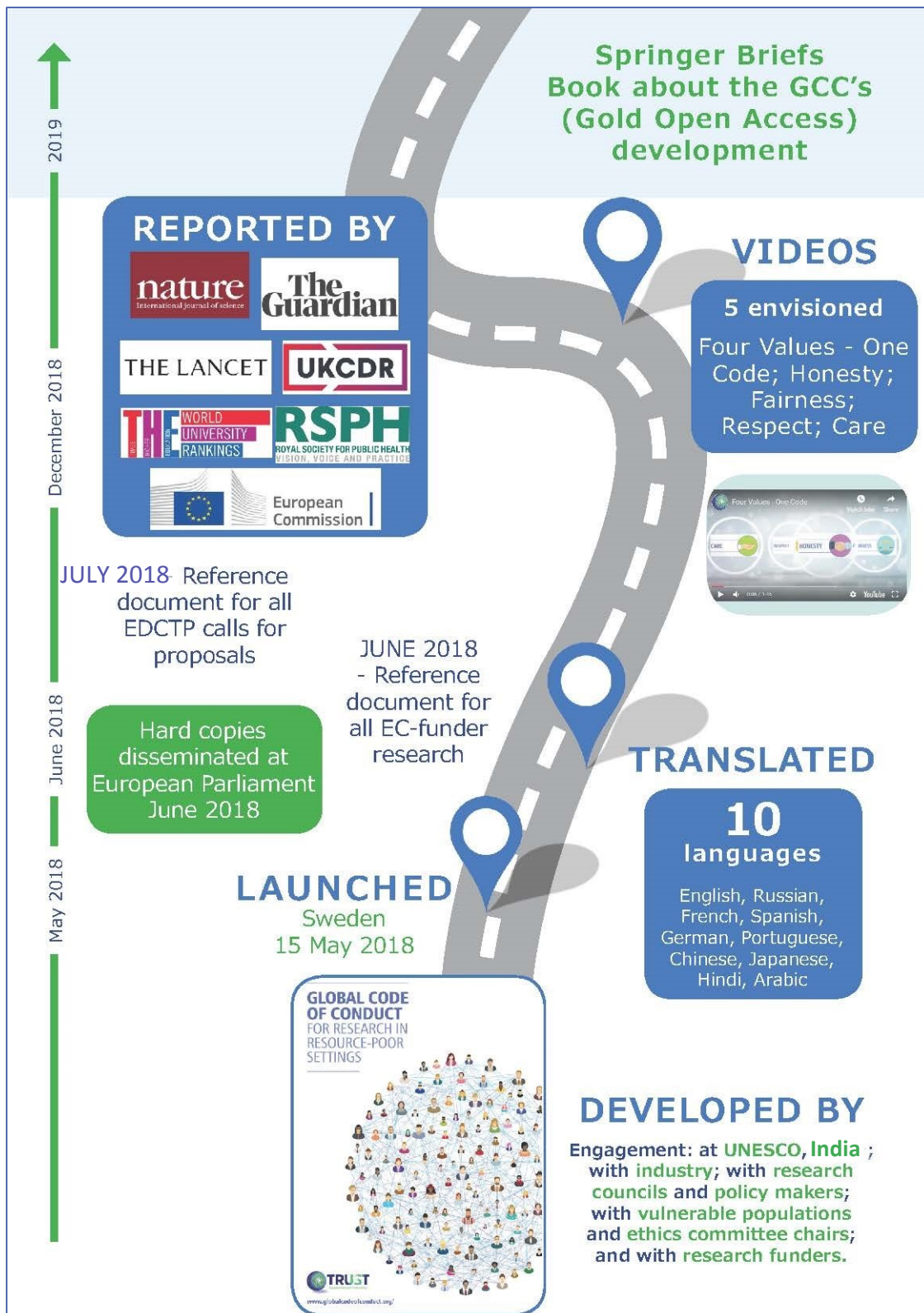


FIGURE 1. A graphic depiction of the GCC Sustainability Roadmap

2.2. THE FAIR RESEARCH CONTRACTING TOOL

A. Description

The Fair Research Contracting (FRC) online toolkit was designed as a tool to bring equity and fairness into research contracting between partners from high-income countries on the one side and low- and middle- income countries (LMICs) on the other. The tool empowers parties from LMICs to conclude contracts whereby they are not disadvantaged in terms of intellectual property, data ownership and use, capacity building, sharing of benefits, and financial outcomes.

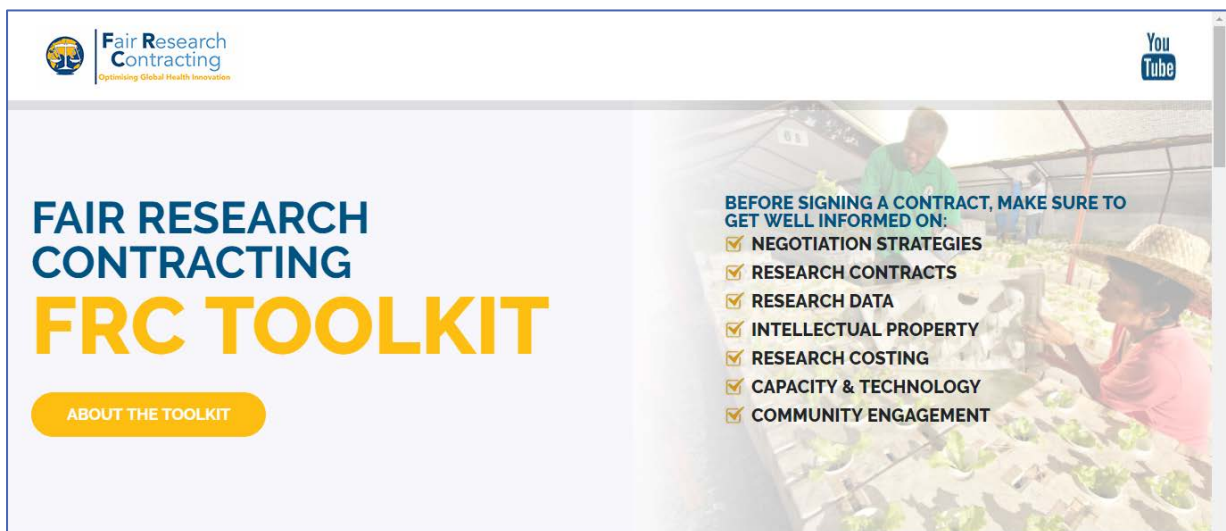


FIGURE 2. The FRC home page (<http://frcweb.cohred.org/>)

The FRC online toolkit provides basic information on **six key issues** regarding research contracting:

- Negotiation strategies
- Research contracting
- Research data
- Intellectual property
- Research costing
- Capacity and technology

The use of the online tool alone will not replace the advice of a contracting lawyer or expert, but it enables the user to better understand the various aspects of negotiations. The case studies and additional resources available on the FRC website allow the user to undertake more in-depth research and preparation for upcoming contracting negotiations.

The approach of this online tool suggests steps to improve negotiations in research collaborations with emphasis on practical action, rather than technical advice.

B. Target audience

The FRC toolkit is aimed at any individual or organisation intending to engage in a research partnership (for example, researchers, investigators, research organisations, research managers, legal services, technology transfer offices, ethics committee members and community stakeholders) with little or no access to legal expertise or support.

C. Responsible institution(s)

The FRC was developed by the Council on Health Research for Development ([COHRED](#)) with input from other TRUST consortium members. The maintenance of the FRC into the foreseeable future will be COHRED's responsibility.

D. Accessibility

The FRC online tool is available at <http://frcweb.cohred.org/>. There is also a link to the FRC on the GCC website under Resource Hub – Learning Materials.

The toolkit is easy to access and use from anywhere in the world, the website being programmed and tagged in a way that makes it easily available for anybody who is searching on the internet for sites related to research contracting.

E. Longevity and sustainability measures

The team at COHRED has guaranteed that the FRC will remain operational for three years beyond the end of the TRUST Project. COHRED are also seeking funds to extend its use beyond this period.

COHRED considers the FRC toolkit as an instrument that works hand in hand with the COHRED Research Fairness Initiative ([RFI](#)), meaning that organisations, institutions or individuals involved in the RFI, such as the World Health Organization, for example, are aware of the FRC toolkit.

Another dissemination channel is through the users of [RHInno Ethics](#), a COHRED-developed administration and management tool for ethics committees. More than 1 400 users in 12 African countries function as 'multiplicators', disseminating information about the FRC within their networks.

For the near future, COHRED foresees the dissemination of the FRC toolkit within UN bodies, especially the UN Economic and Social Council and the Human Rights Council. Discussions are underway with the International Labour Organization which plans to integrate the FRC into the organisation's Decent Work programme.

Other plans for the future include the translation of the toolkit into other (still to be determined) languages as well as the development of additional features.

F. Resources needed

The future development of the FRC toolkit and its additional features requires further funding, and fundraising activities are foreseen. The bases for the fundraising will be the

results of systematic research regarding the question about legal knowledge and access to legal expertise in LMICs.

The website needs additional programming to realise some of the planned features such as a communication platform for registered users where they can exchange experiences, knowledge or good practices, and have access to a (still to be developed) network of experts willing to provide advice and counsel in terms of research contracting. The online toolkit will be made more interactive - for example, the user will get automated feedback on his or her progress in studying the six sections.

Another planned feature is the introduction of training sessions for research. The network of experts will be used to find the appropriate trainers and collaborators for the development of the learning tools.

2.3. COMPLIANCE FOLLOW-UP SELF-APPRAISAL TOOL

A. Description

The Compliance and Follow-up Self-Appraisal Tool works in synergy with the GCC and the FRC without unnecessary duplication. The Compliance and Follow-up Self-Appraisal Tool is used as part of a three-pronged approach to improve ethical standards in collaborative research in resource-poor settings.

The aim of the compliance self-appraisal tool is three-fold:

- (i) To raise awareness about the need for ongoing attention to ethical concerns throughout the research, beyond the initial stage of ethics approval.
- (ii) To ensure that researchers have measures in place to enhance and demonstrate compliance and keep to those measures.
- (iii) To provide funders with evidence of compliance.

The tool provides an opportunity to shine for reflective researchers with integrity: an opportunity to provide evidence of good practice to the funder, which is not time-consuming to supply.

B. Target audience

The Compliance Follow-up Self-Appraisal Tool is aimed at researchers from high-income countries undertaking research in LMICs who are mid-way through their projects. It is foreseen that the tool will also be used by ethics committees, funders, research institutions, community members and community advisory boards.

C. Responsible institution(s)

The development of the tool was led by Wits, with all of the TRUST consortium members providing input.

D. Accessibility

The tool is embedded in a report, which is available [online](#). There are no plans to translate the tool into other languages. A pamphlet describing the tool has been developed and disseminated.

E. Longevity and sustainability measures

The three deliverables which led to the Self-Appraisal Tool were shared with the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) during the WIPO-WTO Colloquium for Intellectual Property Teachers and Researchers in Africa, which was held in Pretoria in April 2018. The presentation given at this Colloquium focused on supporting policy making at the micro level (where intellectual property rights (IPRs) tend to be embedded in the business models). It emphasised the need to include IPRs in the ethical and legal governance of research and then mentioned how the TRUST Project members have dealt with these issues through the three tools. There are prospects of continued collaboration with these two United Nations bodies as a trainer and resource person.

As a member of the UNESCO International Bioethics Committee (IBC), the Wits Professor who led the work on the compliance tool, Prof Pamela Andanda, shared the report on National and International Compliance Tools with the other IBC members and it has been cited in the report of the IBC on Big Data and Health, which has been disseminated to all member states and is available [online](#).

The report has been shared with a number of ethics committees in Kenya, Uganda, the Gambia and South Africa as well as countries that are represented in the Human Heredity and Health in Africa (H3Africa) Consortium.

Future collaboration includes working with WIPO, the WTO, UNESCO's IBC, as well as the African Academy of Sciences, which has established the Data and Biospecimen Access Committee of the H3Africa Consortium. The academy co-hosted the 12th H3Africa Consortium Meeting in Rwanda where the TRUST project's GCC and Compliance and Follow-up Self-Appraisal Tool were shared with researchers in September 2018.

Dissemination will continue through training in research methods at Wits University, as well as through the efforts of the staff of the Wits Enterprise and the Wits School of Law's external relations and strategic partnerships manager.

F. Resources needed

There is a possibility to establish a research integrity and governance centre at Wits to focus on compliance and governance issues. This can be done through a South African research chair that focuses on this theme, but would depend on getting competitive funding from the National Research Foundation.

2.4. SPRINGER BRIEFS BOOK ON ETHICS DUMPING

A. Description

The Springer Briefs book [Ethics Dumping: Case Studies from North-South Research Collaborations](#) contains a wealth of resources through its presentation of contemporary, real-life case studies on ethics dumping.

B. Target audience

The book has proven to be a useful tool for teaching about research ethics; thus students, research staff, and ethics committee members are its main readers.

C. Responsible institution(s)

The development of the book was primarily the responsibility of UCLan with additional editorship from [Inserm](#) and the Forum for Ethics Review Committees in India ([FERCI](#)).

D. Accessibility

The book has been widely disseminated to the research community through the marketing channels of its publisher, Springer, and the TRUST team. It is available gold open access. To date, it has over 50 000 downloads.

E. Longevity and sustainability measures

Possibilities for dissemination of the case study summaries through interest groups and social media (for example Facebook) will be investigated and encouraged.

3. Work Completed in Addition to the TRUST Contract

A number of products were not specifically mentioned in the TRUST Project's contract, but were deemed desirable to complement existing work. This includes the San Code of Research Ethics, a guide for ethical community engagement in research, and a complaints procedure for collaborative research in resource-poor settings, these are described below.

3.1. THE SAN CODE OF RESEARCH ETHICS

A. Description

The San Code of Research Ethics was developed by the South African San Institute ([SASI](#)) and the South African San Council (SASC) with the input from members of the !Xun, Khwe, and #Khomani San communities.

The San Code is based on five values – honesty, care, justice and fairness, respect, and the fifth value being 'process'. This means that the San value a meaningful involvement in any project from start until finish. Practically, this means that the researcher or media person has to contact the SASC before approaching communities and introducing their project. They are expected to keep the SASC updated on the progress of the project and are required to share research results before publication. SASI and the SASC are currently in the process of developing a detailed procedure that will facilitate the implementation of these values. This includes an ethics application before commencement of the project and a research/media contract signed with the SASC. This process will be known as 'LIAZ' - Local Infrastructure from A to Z. The process of developing the San Code has been written up as a specific report, which will be available in January 2019 [here](#).

B. Target audience

The San Code of Research Ethics is aimed at researchers and media people who want to conduct research or work with any of the San communities in South Africa.

C. Responsible institution(s)

SASI and the SASC will oversee the implementation of the code. The San Council is in charge of reviewing research applications and making sure that researchers adhere to the code.

D. Accessibility

At the moment the San Code of Research Ethics is available for download on both the [TRUST Project](#) and [GCC](#) websites. In the near future the code will also be available from the standalone LIAZ website.

To date the San Code is available on the GCC website in English, Afrikaans, French, German, Portuguese, Chinese, Japanese and Spanish. Translations into Arabic and isiXhosa are in

process. The translations were independently funded, mostly by the TRUST Project coordinator's university.

Community members have proposed a number of ideas to promote the code and increase its accessibility amongst their own communities. A first step towards this was the rap/video competition about the code which was initiated and funded by the Foundation Global Values Alliance ([FGVA](#)). The three winning videos can be watched [here](#).

E. Longevity and sustainability measures

In terms of longevity, there is no 'end of project' associated with the San Code of Research Ethics, it will remain an ongoing project. For example, the annual Kalahari Desert Festival will be utilised as a regular opportunity to further train communities on implementing the code.

The San Code will be promoted through awareness raising; education; and influencing ethics committees. As a sister code to the GCC, the San Code will be highlighted at GCC dissemination events.

In the future, SASI intends to contact universities to inform them about the code and the LIAZ process. There are also plans underfoot to spread awareness of the code via XK FM, the local radio station for the !Xun and Khwe communities based in Kimberley.

UCLan, the coordinator, has already submitted small grants to assist the San in implementing their code. The outcomes will only be known in 2019.

F. Resources needed

Once LIAZ is operational additional staff will be appointed to review applications and facilitate all research projects. So far the domain for the LIAZ website has been purchased, but it still needs to be set up, its maintenance arranged and the information it will contain (such as academic articles) still needs to be sourced.

If needed in future, further fundraising will be undertaken to support the promotion of the code.



FIGURE 3. A graphic depiction of the San Code’s Sustainability Roadmap

3.2. GUIDE FOR ETHICAL COMMUNITY ENGAGEMENT IN RESEARCH

A. Description

Community engagement is an ethical imperative for collaborations between vulnerable communities in LMICs and research partners from high-income countries. Research participants, their local communities and research partners in international locations should be equal stakeholders in the pursuit of research-related gains. There are many existing guidebooks for effective community engagement, however, uniquely, this report ([Research With, Not About, Communities](#)) provides guidance on ethical community engagement in research from the perspective of the four TRUST values: fairness, respect, care and honesty.

During the development of the guide the team drew upon a number of sources, including the real-world experiences of communities that have engaged with international researchers over a number of years.

B. Target audience

The target audiences envisioned are researchers, civil society organisations, and research ethics committees.

C. Responsible institution(s)

This document was developed by UCLan together with *Action Contre la Faim* (ACF), the United Nations Education, Scientific and Cultural Organization (UNESCO), SASI and UCT.

D. Accessibility

The Guide is available in PDF format (free to download) from the GCC stand-alone [website](#) in the 'Learning Materials' section. It is also promoted via cross-reference linking within other TRUST publications.

3.3. COMPLAINTS PROCEDURES FOR COLLABORATIVE RESEARCH IN RESOURCE-POOR SETTINGS

A. Description

This document was founded on the idea that complaints procedures play an important role in research, helping to ensure that experience and practice are aligned with expectations. Complaints procedures can contribute to the safeguarding of participants and communities in an ongoing manner, beyond the ethical approval process. Significantly, complaints mechanisms offer a means of revealing lapses and failures in ethical conduct, thereby providing opportunities for enhancing ethical compliance in research.

TRUST proposes that an appropriate complaints mechanism is vital for ensuring ethical compliance throughout a study, and suggests that this should be compulsory for collaborative research in resource-poor settings.

This document offers guidance for:

- Establishing a tailored complaints mechanism that is designed to meet the needs of the individual participants, local partners and the local community.
- Using a range of methods to address different types of complaints.
- Applying the four TRUST values of fairness, respect, care and honesty to help design an effective and trustworthy complaints mechanism.
- Ensuring genuine access for all research participants, local partners and the wider local community.

B. Target audience

This document is aimed at researchers; research Institutions; funders; and research ethics committees.

C. Responsible institution(s)

This document was jointly developed by UCLan and SASI.

D. Accessibility

[The Guide](#) is available in PDF format (free to download) from the GCC stand-alone [website](#) in the ‘Learning materials’ section. It is also promoted via cross-reference linking within other TRUST publications.



4. Ongoing Dissemination Efforts Undertaken by TRUST Partners

Dissemination efforts aligned with specific TRUST products have already been listed, e.g. coordinator efforts on behalf of the GCC. The following describes efforts by particular partners rather than by product.

4.1. UNESCO

Past and current dissemination efforts

Throughout the TRUST Project’s lifetime, UNESCO has undertaken extensive stakeholder engagement in order to create awareness of the TRUST products and tools. Through its stakeholder engagement UNESCO has reached out to the following target groups: ethics committees; vulnerable populations; policy makers; academia representatives; community-based organisations; and industry representatives.

Through its internal network, UNESCO has shared information about the TRUST project via the UNESCO GEObs network and to all the members of the International Bioethics Committees; the World Commission on the Ethics of Scientific Knowledge and Technology; the UN Inter-Agency Committee on Bioethics; the International Council for Science; and the UNESCO Chairs in Bioethics.

Future dissemination efforts

Beyond the project activities, UNESCO is able to provide a place for the GCC and the San Code of Ethics on the UNESCO GEOBs database - www.unesco.org/shs/ethics/geobs .

4.2. FGVA

Past and current dissemination efforts

Throughout the TRUST Project lifecycle FGVA has been closely involved in developing project outputs. This has been achieved through several interviews with industry representatives and attendance of the International Federation of Pharmaceutical Manufacturers (Geneva) and European Federation of Pharmaceutical Industries and Associations (Brussels) meetings to obtain input, allay fears and lay the foundation for developing an industry platform.

In terms of dissemination, the FGVA team has been presenting both the San Code of Research Ethics as well as the GCC as best practices in conferences that deal with ethical issues. For more on this, see the engagement report deliverable.

FGVA was instrumental in initiating and funding the rap/video completion among San youth. This resulted in music videos which have been widely shared and viewed.

Future dissemination efforts

Future dissemination will be undertaken via capacity building; education; awareness raising; networking; making policy impact; and influencing ethics committees.

Dissemination efforts will be aimed at industry representatives, academics and UN bodies, through management seminars, lectures and publications.

4.3. FERCI

Past and current dissemination efforts

The FERCI team participates in local training programmes all over India, and has been instrumental in disseminating TRUST outputs to various ethics committees in India.

Dissemination has happened through conducting workshops and distributing reading materials.

Future dissemination efforts

In the future, TRUST outputs will be shared with the Indian Council of Medical Research, the Clinical Development Services Agency, and the Forum for Ethics Review Committees in Asia Pacific. Soft copies will be made available through ethics networks and during workshops and training programmes, and pamphlets and policy briefs will be prepared.

The FERCI team plans to interact with government agencies to make the outputs from TRUST mandatory for all international collaborations.

Some international groups have indicated their interest to collaborate with FERCI.

Seeing as FERCI is an NGO, additional funds will be needed for sustained dissemination efforts.

4.4. UCT

Past and current dissemination efforts

Since October 2018, the team at UCT has been developing an online course on research ethics for the university's Science Faculty. The course is aimed at all students in the faculty who intend to undertake research with human participants. Completing the course successfully will become mandatory in order to obtain ethics clearance.

Future dissemination efforts

In 2019 the course material will be reviewed by the Office of Research Integrity, and an interactive web-based platform will be developed to host the learning material and accompanying quizzes. It is hoped that the course will be updated and adapted in future so that it can be rolled out across all of the university's faculties.

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