Creating and enhancing **TRUST**worthy responsible and equitable partnerships in international research

**eNewsletter 2017, Issue 3**

**Governance and Ethics: Maintaining the Distinction**

**Dr. Ron Iphofen**

Governance is a broad term for processes and systems, which are used to guide institutions, companies, or even countries towards desired outcomes.

I have long been concerned to differentiate between the governance of a research project and the review of its adherence to ethical obligations. It is relatively easy to establish regulations governing how researchers should behave; the difficulty is in ensuring their compliance. Not that we assume researchers behave badly – most don’t. The problem is how we can know what they are actually doing. Monitoring researchers’ behaviour is a problem for the funding agency, the regulators and the research-managing institution; it is a problem of research governance.

When examining the ethics of a research proposal it is no help if we get caught up in ensuring regulations are followed, or seeking to protect the reputations of funders and corporate bodies such as universities. Instead, we need to distance ourselves from corporate concerns and think about how researchers can get their jobs done safely and with the highest concern for the interests of their research participants.

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**San Code of Research Ethics launched!**

The 2<sup>nd</sup> of March 2017 was a historical day for the South African San Communities. They launched their own San Code of Research Ethics.

After decades of bad experience with researchers, TRUST supported the communities in drafting their own Code to avoid further ethics dumping.


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**The TRUST project**

The TRUST Project is an EU funded project which aims to catalyse a global collaborative effort to improve adherence to high ethical standards around the world.

In an interdisciplinary collaboration between multi-level ethics bodies, policy advisors, policy makers, civil society organisations, funding organisations, industry, and academic scholars from a range of disciplines, this project combines long-standing, highly respected efforts to build international governance structures with new exciting network opportunities in Europe, India, Sub-Saharan Africa, China and Russia.

Read more at [www.trust-project.eu](http://www.trust-project.eu/)
TRUST MEETINGS

TRUST in Kimberley again
On February 24-25, 2017, SASI hosted the fourth TRUST workshop in Kimberley. This meeting was of a very special nature as for the first time San delegates met with Sex Workers from Nairobi, Kenya to share and exchange experiences. The discussions focused on their perception of vulnerability as participants in research projects.

Furthermore, the participants talked about Respect, Honesty, Justice & Fairness, Care, and Process, the ethical principles identified in a joint effort by the TRUST members. The principles were substantiated with and related to personal experiences.

The results of these discussions were recorded and will soon be available in another TRUST video.

The San Code of Research Ethics launched!
On March 2, 2017, following the TRUST meeting in Kalk Bay (see article on page 3), TRUST partner SASI, together with the San Council of South Africa, launched their very own San Code of Research Ethics.

The Code is the result of a long process. The San have been of great academic research interest for the past decades. And photographers and filmmakers are very interested in the culture of the San. However, the San have unfortunately perceived the work with the researchers to be inequitable and even exploitative. With the help of the TRUST project, they were able to establish their very own San Code of Research Ethics.

It is important to the San that their cultural specifics are being respected and taken into consideration. But besides that, the San’s focus is on being involved equitably: The ethical value Process requires that the San leadership is consulted before any publication of research.

After this long process, the launch has been a historical day for the San communities of South Africa and TRUST is proud to be part of this successful empowerment.

The full Code and the received media coverage can be accessed on the TRUST website.

TRUST Funder workshop in London
On June 12-14, 2017, TRUST held a two-day workshop to which numerous funders were invited. As TRUST considers funders to play a major role in the policy–making process of North/South research collaboration, TRUST seeks to not only receive their input and expertise, but also to promote ethical collaboration.

The sessions with the external guests were divided thematically. With experts from the industry good practice cases around clinical trials and human participation were presented and discussed. The funder representatives were invited to talk about ethical issues in North/South research collaborations.

The outcomes will soon be available on the TRUST website.
On February 28 - March 2, 2017, representatives of the thirteen TRUST partners met in Kalk Bay, a small town south of Cape Town, South Africa. The main goal of this third plenary meeting was to obtain input from research councils and policy advisors.

A number of high profile external experts covering different research fields such as Agriculture, Biotechnology, Biodiversity and Animal Research were invited. But also expertise was received from Funders regarding Research Collaboration.

Their valuable advice was well received and will feed into future TRUST activities and deliverables.

Furthermore, the meeting served to discuss results achieved so far as well as the way forward.

Substantial work has already been done on the three main goals of TRUST: A Global Code of Conduct, a Fair Research Contract, and a Compliance and Ethics Follow-up Tool. The status of these deliverables and improvements were discussed with the external experts. TRUST will be proud to officially launch them soon.

A detailed report about this meeting will soon be available on the TRUST website.

Author’s Note

Benefit sharing book of TRUST Partner

The inspiration for this book came from the two vulnerable communities represented in TRUST, namely the San and the Nairobi sexworkers.

Whilst involved in a previous EU funded project on “benefit sharing” (GENBENEFIT), I realised that both these communities had in different ways experienced pressure from researchers who wanted access to their DNA. The questions raised by these communities led to the research on “equitable access to human biological resources in Developing Countries”.

By Dr. Roger Chennells

Book review available [here](http://www.trust-project.eu/).
Exploitation Risks and Research Ethics Guidelines

In our efforts to develop a Global Code of Conduct for North-South collaborations in research, another big step was taken. This deliverable builds upon the work undertaken for the report on Generic Risks of Exporting Non-Ethical Practices. All of the 88 risks that were identified previously were mapped onto major existing ethics guidelines. Read the full guidelines here.

Compliance Failures

This deliverable represents the second step towards one of the three main goals of TRUST: The Compliance and Ethics Follow-up Tool. Our report on Compliance Gaps furthers the work that was undertaken for a previous deliverable about National and International Compliance Tools. While the first step involved the reviewing and mapping of existing instruments and guidelines, this report focuses on gaps in adherence to ethical standards.

For this deliverable, members of the TRUST team embarked upon a major fact finding mission to identify existing failures to ethical standards. It includes regulatory and institutional gaps and also describes selected examples of challenges, gaps and failures in global ethical adherence.

Read the full report available on the TRUST website.

Russian and Chinese Ethics Review System

We at TRUST are proud to present two additional supplementary deliverables. Our advisory board members Professor Olgar Kubar and Professor Yandon Zhao, author/co-author of these reports write about compliance mechanisms in China and Russia. They have delivered an important evaluation of existing Ethical Review Systems in these countries.

The articles can be accessed here.

TRUST chosen as success story by funder!

The TRUST consortium is very proud to have been chosen as a success story by its funder, the European Union.

SiS.net, the international network for Science with and for Society in Horizon 2020, writes that TRUST supports political objectives that strengthen the EU in being a credible and strong global partner and that “the TRUST consortium is indeed ‘practicing what they are preaching’”.

Read the full success story here.
Governance and Ethics: Maintaining the Distinction

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When researchers complain about ‘obstructive’ research ethics committees (RECs) it is usually because the REC has failed to balance research governance with independent ethics review. The severest criticisms have come from the United States where RECs are constituted as IRBs (institutional review boards). The term ‘institutional’ should be enough to give the game away. IRBs have to protect the institution from any legal liabilities and always have an eye on insurance indemnity premiums in case errors in research processes cause participants to claim a grievance. Necessarily this makes them ‘risk averse’. What we need from a truly independent REC however is heightened ‘risk awareness’.

Researchers need additional advice, guidance and, possibly, ongoing mentoring. Facilitative guidance from a REC could raise researchers’ awareness of risk, without becoming obstructive. At times research can challenge existing norms and legislation – the TRUST project among many others demonstrates this – and if one is overly held back, then some of the risks that are a necessary element in the advancement of knowledge will not be taken and the pursuit of social justice can be undermined.

Of course research has to be ‘managed’ properly, so governance is an essential element in the process. But what must be guarded against is the pretence that a committee concerned with governance can also offer truly independent ethical advice. Governance must be done by an effective management process – if the institutional risk in conducting a project is too great, for example it cannot obtain ethical approval, then it will not be allowed to take place. But the ethics of a project can be assisted by a REC owing no allegiance to any corporate body, or any vested interests. This is best done by volunteers acting in the ‘public interest’ – which means the interests of researchers and research participants and, of course, the community or society at large. In doing so RECs can truly ‘advise and guide’, and perhaps also ‘warn’ against dangers not originally perceived by the researcher.

There are lessons for the integrity of research in all of this. The avoidance of fraud, corruption, plagiarism and misuse of data (violations of research integrity) cannot be prevented by legislation alone. Someone with illicit intent will always find a way around the law if there is both incentive and opportunity to do so. Scientific integrity relies upon the maintenance of a practice culture which proscribes such bad behaviour – researchers knowing when there are risks

of stepping beyond moral and legal guidelines and seeking the advice of all those involved to resolve their problems. Since research outcomes do depend upon a tacit partnership between all research collaborators, ethical research will necessarily be a mutual accomplishment between all these stakeholders: researchers, participants, funders, sponsors and reviewers.

Dr. Ron Iphofen

Publications

Books
Tomasselli, Kean (2005): Where global contradictions are sharpest – research stories from the Kalahari. Rozenberg Publishers Amsterdam. [Open Access here]

Articles
News from around the world

**Unexpected mutations after CRISPR gene-editing**
A study led by investigators at Columbia University Medical Centre (CUMC) suggests that CRISPR gene-editing technology can introduce hundreds of unintended mutations into the human genome.

**Call for Papers – AI Ethics: The Privacy Challenge**

**Online Course – Bioethics: The Law, Medicine and Ethics of Reproductive Technologies and Genetics**
Bioethics provides an overview of the legal, medical, and ethical questions around reproduction and human genetics and how to apply legal reasoning to these questions.

**Dozens of recent clinical trials may contain wrong or falsified data, claims study**
Fresh concerns over reliability of papers published in journals as suspicious statistical patterns prompt investigations into some of the identified trials.

**Major research funders and international NGOs to implement WHO standards on reporting clinical trial results**
Some of the world’s largest funders of medical research and international non-governmental organizations agreed on new standards that will require all clinical trials they fund or support to be registered and the results disclosed publicly.

**No more lab rats: Alternatives to animal testing sought at new Windsor research centre**
White mice and other animal test subjects might be an iconic part of the public’s image of a scientific laboratory — this might now change at the University of Windsor.

**WHO issued guidelines on ethical issues in public health surveillance**
The WHO Guidelines on Ethical Issues in Public Health Surveillance is the first international framework of its kind and it fills an important gap.

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**UPCOMING EVENTS**

Oxford Global Health and Bioethics International Conference

Lake Buena Vista, USA, 6–8 October 2017
Promoting Excellence in Clinical Research

Seoul, Korea, 25–28 October 2017
The 18th Asian Bioethics Conference (ABC18)

Illinois, USA, 2-3 November 2017
Call for Papers – Symposium on the Medicalization of Poverty

San Antonio, USA, 5-8 November 2017
Advancing Ethical Research Conference

Dunedin, New Zealand, 20-24 November 2017
Ethics Teacher Training Course at University of Otago’s Bioethics Centre

Columbus, USA, 19-21 March 2018
2018 Institutional Animal Care and Use Committee Conference