



# TRUST

Equitable Research Partnerships

## ***Vulnerable Populations in North-South Collaborative Research Nairobi Plenary 2016***

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## Background

This report describes the second plenary of the TRUST project, co-organised by Partners for Health and Development in Africa (PHDA), and UCLan. At this meeting, representatives of the thirteen project partners came together with project advisors and an additional nine invited guests representing Kenyan ethics committees, and peer education for sex worker groups participating in research studies, to exchange ideas on how to create and enhance trustworthy and equitable partnerships in international research.



*TRUST project members and invitees in Nairobi, 23-25 May 2016*

### **Present at this meeting:**

#### From the TRUST project:

Prof. Fatima Alvarez-Castillo, Prof. Pamela Andanda, Dr Francesca Cavallaro, Dr Kate Chatfield, Dr Roger Chennells, Solveig Fenet, Dr Francois Hirsch, Dr Joshua Kimani, Dr Nandini Kumar, Prof. Klaus Leisinger, Gwenaelle Luc, Dr Michael Makanga, Dimitris Micharikopoulos, Dr Vasantha Muthuswamy, Bettie Rugendo, Prof. Doris Schroeder, Michelle Singh, Andries Steenkamp, Elena Tavlaki, Jacintha Toohey, Jaci van Niekerk, Anthony Tukai, Dr Jane Wathuta, Prof. Rachel Wynberg.

#### Invited guests:

Catherine, John, Josephine, Joyce, Rosemary (peer educators for sex workers cohorts in Nairobi), Prof. K. Bhatt (University of Nairobi / National Bioethics Committee), Prof. Elizabeth Bukusi (Kenya Medical Research Institute, KEMRI), Prof. Anastasia Guantai (University of Nairobi, Kenyatta National Hospital, , UoN-KNH), Lillian Omutoko (UoN).

## Day 1. 23 May 2016

### Programme overview

Topic	Delegate
Welcome Remarks	Dr Joshua Kimani and Peter Mwaura Prof. Doris Schroeder
Introduction of all participants	All
Aims of the Workshop	Prof. Doris Schroeder
Concerns for Kenyan ethics committees when approving North-South collaborative projects	Prof. Elizabeth Bukusi Prof. Anastasia Guantai
Concerns for sex workers taking part in North-South collaborative projects – Part 1	Peer educators for sex workers – Rosemary / Joyce / Catherine / John / Josephine
Making use of a Due Diligence Process in the context of clinical trials in LMICs	Prof. Klaus Leisinger

### Welcome

The day began with a warm welcome to Nairobi from Peter Mwaura, the Chief Executive Officer of Partners for Health and Development in Africa (PHDA), and Dr Joshua Kimani our host in Nairobi from the same organisation.

One of PHDA's programs, the Sex Workers Outreach Program (SWOP), undertakes community engagement and provides clinical and preventative

services to sex workers residing in Nairobi and its environs. The sex workers would otherwise find it difficult to access medical services in the public health facilities due to rampant stigma and discrimination. At the same time those enrolled in the sex workers cohort for HIV prevention services are free to volunteer for available research studies after providing informed consent. The majority of the studies are on the epidemiology of sexually transmitted diseases and the host genetic factors that influence infectivity and disease progression.

Dr. Kimani:

*We are most fortunate to have five peer educators from the SWOP program with us at the Nairobi meeting to tell us directly about their experience of engaging in research. In addition, we have two guest professors today, Prof. Elizabeth Bukusi and Prof. Anastasia Guantai, who will talk about their experience chairing prominent research ethics committees in Kenya.*

Peter Mwaura added his greetings and welcomed all the delegates to the workshop.



A welcome from TRUST project lead, Prof. Doris Schroeder, was met with delight as she greeted the guests at the meeting in Swahili.

Doris reminded us of the main aims of the Nairobi workshop:

- to hear about risk factors for exploitation in research from the sex workers’ peer educators and indigenous peoples;
- to obtain input from Kenyan stakeholders / ethics committees on their concerns about international collaborative research and,
- to brainstorm TRUST Deliverables, including the project’s global code of conduct.



*Dr Joshua Kimani, Dr Vasantha Muthuswamy, Prof. Doris Schroeder*

Following an introduction by each participant, Prof. Schroeder provided a brief overview of the TRUST project for the benefit of the invited guests and explained where the Nairobi workshop fits in.

## Concerns for Kenyan ethics committees when approving North-South collaborative projects – Part 1

Professor Elizabeth Bukusi: Deputy Director (Research & Development), Kenya Medical Research Institute (KEMRI)



*Prof. Bukusi*

Prof. Bukusi has worked in HIV prevention and care for the past 22 years. She began her talk by explaining how she first became involved with ethics as a result of her own frustration as a researcher. The systems were not working for her and she wanted to know how to improve them.

The national regulatory systems in Kenya are governed by the National Council of Science and Technology (NCST), which coordinates all scientific research in Kenya, and advises the government on all matters related to research. Any research planned to be undertaken in the country requires clearance and authorization. Ethical clearance is mandatory for biomedical research.

NCST has the authority to accredit institutions and there are currently 21 accredited ethics committees (ECs) within Kenya. These ECs have permissions

for areas to review (e.g. animals, humans, clinical trials). Any research that involves drugs or medical devices must be reviewed by an expert clinical trials committee. All such trials must be approved by their home institution before being presented to one of these expert committees. KEMRI, has 11 different centres in Kenya, working on 6 different research programs, see Figure 1.

Figure 1: Six Research Programs of KEMRI



KEMRI was reported to be in the process of putting together a resource centre for all issues related to research ethics. This centre will provide support to those who need to apply for ethics approval, especially for the first time; how to phrase matters, how to navigate the system etc. The particular aspects of research proposals that are considered include:

- |                            |                          |
|----------------------------|--------------------------|
| Confidentiality            | Standard of care         |
| Vulnerability              | Compensation             |
| Choice of control group    | Oversight and regulation |
| Study design               | Study monitoring         |
| Fair participant selection | Post-trial access        |
| Informed consent           |                          |

Many of the ethical issues that are specific to low and middle income countries (LMICs) originate from the potential vulnerability of local stakeholders. Some overall considerations apply to all research projects in LMICs:

1. Researchers should obtain approval from the host country, which will judge the ethical acceptability of the research in accordance with the customs and traditions of the society concerned.
2. Research must abide by relevant local and international laws and guidelines.
3. Research must be responsive to the research needs of the country where it is carried out.
4. Sensitivity must be shown to the local conditions.
5. Results should be made available in the LMICs.

## Concerns for Kenyan ethics committees when approving North-South collaborative projects – Part 2

Prof. Anastasia Guantai: Kenyatta National Hospital, University of Nairobi (KNH-UoN)

The KNH-UoN ethics research committee has been in existence since 1974 and is the oldest in Kenya. It has broad membership and covers many specialities. The committee has an extremely heavy workload that is rapidly increasing. Prof. Guantai began by describing some of the main challenges that have emerged from the review of North-South collaborative proposals.

- Inappropriate and unclear project budgets
- Extremely late attempts at gaining ethics approvals
- Inadequate information on sample collection and storage
- Insufficient attention to cultural differences
- Inappropriate compensation to research participants
- Southern partners' tasks restricted to obtaining data, no capacity building
- Perception that research participants are used as guinea pigs by Northern researchers
- No provisions made for language difficulties

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*“We, the research ethics committee need to see that the partners do see this as a ‘partnership’ that will share benefits.”*

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Prof. Guantai also pointed to the weak and overworked systems for ethical oversight in LMICs, which can be taken advantage of. She concluded her remarks by requesting equitable partnerships.

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*“Northern partners can take advantage of weak systems.”*

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Prof. Andanda, Prof. Guantai, Lillian Omutoko

## Discussion Points

The following were some of the main views expressed:

- Whenever a research project is undertaken in a community with severe deprivation, it is the responsibility of Northern partners to address the specific problems. An example: If we are researching the effects of clean water then it is the responsibility of the Northern partners to provide clean water. It is morally proper that the provision of clean water should be within the budget of the research.
- We may not be able to provide the clean water but we can advocate for clean water. If a problem is found, then it should be highlighted.
- Why would Northern partners go there if not for the specific diseases in that region? If the disease is specific to that region, then we must question whether compensation is necessary because that region will ultimately benefit from the research. It would kill research if the researchers were held responsible for redressing problems. Most probably researchers would systematically leave out communities that are badly challenged and there would be no benefit at all.
- It is not possible for researchers to solve all the problems in the world.
- The issue of post-trial responsibility is crucial. There has to be a balance between what the researchers/funders get and what the participants get. We cannot put all of the responsibility onto the researchers.
- I think it is dangerous for researchers to provide development. It is more important that the research is needs driven.

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*“I think it is dangerous for researchers to provide development. It is more important that the research is needs driven.”*

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Doris concluded this session by thanking the two professors for highlighting the challenges for North-South collaborations so clearly.

**Note:** A full and analysed version of the ethics committee chair presentations from Day 1 and Day 2 will later become available as a publication.



## Concerns for sex workers taking part in North-South collaborative projects

Nairobi peer educators for sex workers – Rosemary / Joyce / Catherine / John / Josephine

The main concerns that were highlighted are presented in summary form and not attributed to individuals. The most general statement given was that, **“Sex workers know and value research and they would like to benefit from the results instead of just being the guinea pigs.”** Concerns were further expressed in five main areas, see Figure 2.



*Dr Joshua Kimani with peer educators of sex workers in a preparatory meeting for the Nairobi Plenary*

Figure 2 - Areas of Concern for Sex Workers involved in Research



### Consent

- Informed consent documents may be written in simple language and translated – but not all sex workers can read. Anyway, we often do not read the information sheet. People often participate for the money without considering the long term effects. We need you to tell us

everything in black and white. Just tell us, just be honest. Even if there is no prospect of benefit tell me so I can make a decision.

- We need to address the fears that come up in research as rumours begin very easily. Researchers need to provide enough education and not wait until problems have escalated.
- What do I stand to gain from this research?
- What happens if I suffer a side-effect when I am alone in my own house? What happens to me?
- We must be guardians for the younger sex workers. When we go to hot spots we talk to everyone, regardless of age. We have a lot of under 18s out there working as sex workers who are too young to come to the clinic.<sup>2</sup> Would it be okay for younger sex workers to engage in research if the older ones act as mentors? Age of consent for participation in research is 18.
- We have many untrue rumours that go around so we need the right information. We (the ambassadors) can act as gate keepers. We can help explain the study and what it will mean to the sex workers.
- Most of us go into it (research) because of the cash and possibility of health benefits.



*Peer educators of sex workers with Prof. Leisinger and Prof. Schroeder*

### **Feedback**

1. We need feedback to the community from the research in simple and non-scientific language. Some results have been fed back to us in the past but I did not know what they meant. Do not give us results in scientific language. It puts us at risk if we do not understand the results. Like one study on a treatment for HIV, some sex workers were confused and interpreted their

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<sup>2</sup> The clinic is open to all sex workers keen to access health services, but only enrolls those over 18 years and who provide informed consent into research studies.



treatment as a vaccine for HIV that led them to believe they cannot contract infection and hence no need to use normal protection.. We may not need to understand all of the results – just give them to us in a way we can understand.

2. Come back with the results and tell us how we can make our lives better.

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*“Come back with the results and tell us how we can make our lives better.”*

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### **Involving research participants in research at all stages**

- Sex workers would like to have a voice, and be included in the design stage of the study.
- When we have a community of people assisting with research they should receive a salary or other compensation.
- We need to have a guarantee that we will not be exposed to ‘parachute research’ and we need to agree as a community about what to do if that happens.
- In clinical trials the community representative needs to be consulted.
- The research assistant should be fully trained and never impose their own values.
- Some sex workers have appropriate qualifications and could be hired to work in projects. This might help improve research literacy and willingness to participate in studies.

### **Specific needs of sex workers**

- Mental health is a big concern for sex workers. There are many addicts in sex work: alcohol, drugs.
- The addictions need to be taken into account.
- Many sex workers engage in alcoholism because the alcohol can give you the courage to talk to clients. For many of them, they have to be high to engage in the sex and it may be very difficult to use condoms and behave responsibly.
- Some of us who are HIV positive get the impression we are stigmatised. We are at risk because of our health status – at risk of many diseases.
- Sex work is illegal in Kenya so there is always the fear what will happen about confidentiality.

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*“Sex work is illegal in Kenya so there is always the fear what will happen about confidentiality.”*

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### **Cultural sensitivity**

- We know that the samples that are collected from us are sometimes sent to other countries. What happens to them? In my culture – if my blood is taken, it must come back to me and I bury it. If you do not bring it back to me then you must tell me where it goes. We need to know what happens to left-overs and we are keen to benefit from the use of these samples.
- In our country, local and cultural values should be taken into account.



*Joyce, peer educator*

## Discussion Points

The following were some of the main views expressed:

- The stigma for sex workers is not getting any better. That is why we are emphasising confidentiality.
- Many sex workers trust researchers if they approach us through the SWOP clinic.
- Hospitals will not treat sex workers with dignity, hence they must lie about their behaviours. There is a lot of prejudice everywhere: insults, sarcasm.
- The issue of sex is never spoken of openly in this country. Issues of culture and religion. You are becoming immoral if you talk about sex.
- There is a lot of stigma for HIV positive people. People do not disclose their status. But many sex workers are now coming out, openly disclosing their status because the community needs to encourage responsible sex behaviour to prevent the spread of AIDS.
- In India we are in the process of revising our guidelines and we have a section for vulnerable groups, including sex workers. In light of your comments we will look at our own guidelines. There are people in other countries with the same concerns. Sometimes, as a researcher, we do not understand other perspectives so it is good to hear yours. We have to be careful to understand the perspectives of others, not just the researchers' perspectives.
- In 2009 gay men did not exist in Kenya! The situation is a little better now.

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*"In 2009 gay men did not exist in Kenya! The situation is a little better now."*

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Prof. Doris Schroeder:

*"Thank you for bringing your concerns here so honestly. I hope we can come back to you with what we are suggesting to do and get your input again. You are peer educators, your input would be very valuable going forward."*

## Making use of a Due Diligence Process in the context of clinical trials in LMICs

Prof. Klaus Leisinger, Foundation Global Values Alliance

Policies, guidelines, declarations, and codes of conduct are important normative guideposts which are definitely necessary means to describe the scope of responsibilities, but they are not sufficient, as they are:

- too general in their meaning, and
- only as good as the people who apply them in practice.



Hence, we need them, but only as one element in a longer chain of efforts. Due diligence can be defined as an investigation of a specific state of affairs prior to starting work in a specific environment; it can also be defined as a certain standard of care. Due diligence is a normal part of business transactions and takes different forms depending on its purpose.

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*Due diligence can be defined as an investigation of a specific state of affairs prior to starting work in a specific environment.*

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The main point is that we can only manage risks if we know about them. We must know what the specific risks are for specific people and not just apply a generalised approach, even if it is well-intentioned. We need to know exactly what is happening to all people in the process.

The initial steps in conducting human rights due diligence are:

- to identify and assess the nature of the actual and potential adverse human rights impacts with which a business enterprise or research organization may be involved. The purpose is to understand the specific impacts on specific people, given a specific context of operations;
- to identify who may be affected;
- cataloguing the relevant human rights standards and issues; and
- projecting how the proposed activity and associated relationships could have adverse human rights impacts on those identified.

The process should involve meaningful consultation with potentially affected groups and other relevant stakeholders. It is not something that one can just do at the beginning of a project and then forget about.

Klaus described five important steps, see also Figure 3:

1. Setting the tone (including involvement of senior management).
2. Assessing the impacts proactively (including assessment of impacts upon human rights).
3. Integrating human rights awareness into clinical trial operations (including assignment of responsibility for human rights).
4. Tracking performance (with specific key performance indicators).
5. Setting up grievance mechanisms (with appropriate sensitivity to needs).

Figure 3: Steps in Due Diligence



Some important areas of concern are the same all over the world such as non-discrimination (race, colour, religion, gender, age, social status, disabilities, sexual orientation – and other vulnerabilities). But human rights violations materialise in local situations. We need to sensitise people to local issues and use the language that people understand. We can learn from experience – that is why it has been so valuable to hear from the sex worker peer educators here today. Real concerns for real people.

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*It is easy to manage risks that are known but we need to get to those that are unknown. We can only do that through stakeholder dialogue.*

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It is easy to manage risks that are known but we need to get to those that are unknown. We can only do that through stakeholder dialogue.

We must recognise complexity, this is not a linear process. It is helpful to bring people together to address complex issues. I have learned that we must begin with incremental changes. It does not help if the researchers learn, only if the communities learn as well.

It is the responsibility of the funder or the company that will receive the commercial benefit to ensure that these things happen.

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*I wondered when listening to our colleagues, “are they part of an ethics committee?” If not, why not? We really need to involve people if we want a fair assessment of the risks and benefits.*

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I wondered when listening to our colleagues (the sex worker peer educators), “are they part of an ethics committee?” If not, why not? We really need to involve people if we want a fair assessment of the risks and benefits.

Klaus presentation was well received and Joshua ended the day by thanking everyone, especially the sex workers, for their input.



*Dr Joshua Kimani closes the workshop on Day 1*

## Day 2. 24 May 2016

### Programme overview

<b>Topic</b>	<b>Delegate</b>
<i>Welcome and Aims of the Day</i>	Dr Joshua Kimani, PHDA and Prof. Doris Schroeder
<i>Concerns for indigenous populations taking part in North-South collaborative projects</i>	Andries Steenkamp and Dr Roger Chennells
<i>A global code of conduct for North-South collaborative projects?</i>	Prof. Doris Schroeder
<i>Concerns for the Kenyan National Bioethics Committee when approving North-South collaborative projects</i>	Prof. Kirana Bhatt and Dr Simon Langat, National Bioethics Committee, Kenya
<i>Brainstorm on global code of conduct</i>	All
<i>Case studies in emergency research amongst vulnerable populations – an overview</i>	Gwenaelle Luc
<i>Funder concerns about the ethics of research</i>	Dr Michelle Singh
<i>Gender sensitive writing training module</i>	Prof. Fatima Alvarez-Castillo
<i>Concerns for sex workers taking part in North-South collaborative projects – Additional thoughts from the representatives</i>	Sex worker peer educators, Rosemary / Joyce / Catherine / John / Josephine
<i>The most useful cases from India – an overview</i>	Dr Vasantha Muthuswamy and Dr Nandini Kumar, Ferici
<i>The case studies competition</i>	Dr Francois Hirsch and Solveig Fenet, Inserm

The second day began with another warm welcome from our host, Dr Joshua Kimani and an overview of the aims of the day from Prof. Schroeder.

### Concerns for indigenous populations taking part in North-South collaborative projects

Andries Steenkamp and Dr Roger Chennells (SASI)

As Andries passed away unexpectedly three months after the Nairobi meeting, this, his last presentation, will be reworked into a publication for more long-term impact. The publication will be available on the TRUST website in the future.



*Andries Steenkamp*

## Discussion

The following were some of the main views expressed:

- This presentation shows that there are common structures and concerns everywhere.
- There are ambiguities with leadership consent. Some leaderships are of an exploitative nature. It is not a case of either / or leadership or individual consent. We need both.
- There is a power imbalance in many situations and where we have this imbalance we need to give more than just the small print in a contract, consent needs to be more engaged in such situations.
- There is also the issue of the State. Not all countries are supportive of the San. In some you have to apply for State permission to undertake research with the San (Namibia and Botswana). Where does this fit in with a new code of ethics that the South African San are developing?
- Part of the vulnerability for indigenous people is that their State does not understand or support them either.
- Researchers need to think about forms of community engagement that suit the particular community they are working with. Most use community engagement models from the North. This is not appropriate for all.
- There is a huge gap in the social sciences. Researchers can take the attitude that RECs interfere with academic freedom. Under whose jurisdiction do they fall? The community? The REC?

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*“Community engagement is essential.”*

*Andries Steenkamp*

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The last word came from Andries:

Community engagement is essential. In some ways it is easier for the San people because they already have some structures in place. It is not so clear for the sex workers in Nairobi, as sex work is not even legal in Kenya.

## A global code of conduct for North-South collaborative projects?

Prof. Doris Schroeder

For the TRUST project we have to develop three tools, and one of them is a global code of conduct that applies across disciplines in North-South research.

The entire research ethics review process was developed in the North around 50 years ago. It assumes a lot! For example, that people have a choice, that they understand what they are signing for, and that they are literate. This process is heavily influenced by the American approach to research ethics, sometimes called the Georgetown Mantra, which focuses on beneficence, non-maleficence, justice and autonomy. There are many critics of this approach but it is almost universally used for ethics training. It is also focussed upon rules and legal requirements. There is a heavy reliance upon systems that were developed in medical research; which are then extended and applied to other disciplines, such as the social sciences. At the same time, the approach is becoming more and more legalistic (e.g. see data

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*The entire research ethics review process was developed in the North around 50 years ago. It assumes a lot!*

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protection), making it difficult for even highly trained ethics experts to stay on top of the field, never mind to provide capacity building effectively.

We have the privilege of being able to develop a global code of conduct for North-South collaborations with EU funding. But this cannot be just another piece of paper. Doris presented a vision of a new type of global code of conduct, which is a Deliverable later in the TRUST project and therefore not reproduced here.

## Discussion

The following were some of the main views expressed:

- The idea of using non-technical terms is very good. RECs have become obsessed with consent and autonomy. Something like, ‘free and informed decision-making’ might be a better way to describe the process.
- If international committees have something like this, together with the *Declaration of Helsinki*, it would fill in the gaps.
- The three values listed as examples have parallels in what some African social scientists are trying to do. They speak of ‘humanity, humility and morality’.
- What of the environmental and non-human concerns? Perhaps we need intergenerational equity to capture environmental concerns?



*Prof. Doris Schroeder was presented with a picture of the Nairobi workshop by Betty Rugendo, PHDA.*

## Concerns for the Kenyan National Bioethics Committee when approving North-South collaborative projects

Professor Kirana Bhatt: National Bioethics Committee, Kenya

Professor Bhatt is an employee of the University of Nairobi, and currently the Chair of the National Bioethics committee. Before taking on this role, she chaired the ethics committee of Kenyatta National Hospital at the University of Nairobi, and was also a member of the Kenya Medical Research Institute’s (KeMRI) ethical review committee. The National Bioethics committee does not

review any protocols, unless there is some controversy. Its function is mainly to oversee the various ethics committees in the country.



*Prof. Kirana Bhatt*

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*Nine years ago there were only three well-functioning ethics committees in Kenya. Now we have 22.*

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What happened over the years is that many research institutions and universities have started research projects dealing with, and / or involving human participants. Hence, there was a need to establish more ethics committees which could review the various proposals. Nine years ago there were only three well-functioning ethics committees in Kenya, and they were clearly overburdened with the amount of work they had to carry out.

Another problem we had at that time was that the National Bioethics Committee communicated little with the committees on the ground. When I was appointed its Chair, six years ago, the first thing I wanted to do was to improve the communication between the ethics committees on the ground and the National Bioethics Committee. Now we have national accreditation guidelines, so that a committee which aims to be recognised can follow those guidelines and fulfil the requirements. Currently we have 22 RECs which are recognised in Kenya and there are many others on the way. At the national level we oversee the functioning of these ethics committees, but financial constraints prevent us from conducting a thorough review of their challenges and problems. Some of the problems we meet with North-South collaborations are as follows:

1. Exploitation

Local researchers are often exploited and used only for conducting data collection. Intellectual Property Rights (IPR) are often held only in the North. There is an imbalance between North and South researchers. We do not approve projects where there is no reasonable participation of the local researchers.

When a proposal is rejected by one committee the researchers often simply go to another.

2. Relevance

The research should be relevant to us, in Kenya. Generally, North-South research is developed by the Northern partner. For example, the development of an insect repellent for the US army. The study team wanted to conduct their research with the local community and expose them to mosquito bites. We said, 'You have soldiers, why don't you research on them, given that they are going to be the beneficiaries!' The study was not approved.

3. Post-study access

Sometimes studies are undertaken that are highly relevant locally, but we do not have access to the resulting products or services. For example, this happened with the Hep B vaccine. The research was undertaken in Kenya but for many years we could not afford to purchase the vaccine and therefore could not benefit.

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*Why does biological material need to be shipped? Why not conduct the research here in Kenya?*

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4. Biological materials

Why does biological material need to be shipped? Why not conduct the research here in Kenya? What happens to left over samples when the study is finished? Are they used for another purpose without consultation?

5. Communication

Researchers are supposed to report back to the RECs that granted approval but this does not always happen. This also involves copies of publications, which are not provided locally.

Likewise, we sometimes request community engagement to be added to protocols, as these were not planned by the applicant.

## 6. Reimbursement.

This is a difficult topic because of the tension with undue inducement.

## Discussion

Q: How do you deal with discrepancies in community advice?

Prof Bhatt: If a chief is interested in financial gain he may be happy to say, “Just go and do whatever you like.” This used to happen a lot. Not so much now. Some researchers give seminars and invite people from the communities to listen. They can leave their names if they are interested in participating and will then be seen one-to-one for individual consent.

Q: How would a global code of conduct benefit you?

Prof Bhatt. A global code of conduct will never be ideal for every country but it will help. People who cannot get approval in their own country come and do their research here in Kenya, on humans and animals. A global code of conduct could help to prevent this.

Two other interesting pieces of information about Kenya were given:

- Some communities are over-researched and there can be multiple enrolment. They might be in two different drug trials at the same time. A biometric register is now being used to try to minimize the risk of double enrolment.
- We have training for all postgraduate medical students. They undertake an intensive course in research methods and ethics. Collaborative research is part of that curriculum.

## Case studies of research in emergencies amongst vulnerable populations

Gwenaelle Luc: Action Against Hunger (ACF)

Gwenaelle Luc works for Action Against Hunger (ACF), an international organisation that takes a multi-sector approach to ensuring nutrition security. ACF intervenes in situations where nobody else can, such as during and after conflict situations, as well as natural disasters, where there is little or no other support. Hence, ACF operates in settings of extreme distress.

ACF undertakes humanitarian projects, working to ensure clean water, sanitation, and mental health care, and so on. Additionally, they undertake research, primarily to ensure that their interventions fit with local needs. They currently have projects in approximately 50 countries.



The research participants in these situations are often refugees, living in remote areas and most often illiterate. There is a significant power differential between the researchers and the participants. Gwen noted that she will focus upon some of the main challenges today, and the unbalanced risk/benefit ratio and consent.



Gwen Luc, ACF

In the meeting yesterday we heard from the participants about possible trauma, stigma or economic risk from participation in research. This implies that we expect the participants to take those risks. In emergency situations the risks are poorly investigated, monitored or followed-up. In some countries we cannot protect the most vulnerable people because we are not familiar with the local customs and situations. It is not possible for us to assess all the risks for all communities. The types of risk include the following:

#### Side-effects

Imagine, as an example, that 20 researchers arrive in a community. They rent cars, buy products etc. leading to local economic inflation (as a side-effect). We try as much as possible to involve local staff but this can also cause problems. For example, if we need a nurse, the community is without a nurse for two days while we provide training.

#### Dishonoured commitments

This can happen, for example, when we promise medication but then, for some logistical reason, we cannot fulfil the promise. Other times participants reveal unethical behaviour (like rape or genital mutilation) and I am left facing a dilemma. I am from an international NGO and these are violations of human rights. What should I do? Should I betray their trust?

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*I am from an international NGO and these are violations of human rights. What should I do? Should I betray their trust?*

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#### Assumed needs

Sometimes we can assume what is needed rather than responding to local needs or priorities. We implement research assuming that they need something when they may want something completely different. We must involve the community right at the start. Often the research is not driven by the needs of the community but by other factors.

#### Unfair compensation or benefit

Why should the locals participate? The researchers are getting paid, it is their job. But what about others who help with research?

#### Obtaining consent under influence

Participants may view the research as being linked with the provision of help and aid and feel that they cannot say no. Aid workers and researchers often wear the same shirts so the difference between them is not obvious. We may recruit research participants from people who are in the queue for a health centre. The lines are not clear.



### Individual and community consent

For example, in Nigeria, we ask the chief of a village for his leadership approval and then the chief will tell everyone to participate. No one will disobey their chief. It can be the same type of thing with married women. They may need the consent of their husband, and the wife has to participate if the husband has consented. We realise that there has to be community consent but we must also make sure that there is individual consent. How can we ensure that this is freely given? One possibility is that we can seek feedback after participation, asking people whether they were happy to participate.

We have learned it is important that we do not rush into research in an emergency situation.

## Discussion

The following were some of the main views expressed:

- What should we give people in return for their participation? We should ask them.
- On the matter of incidental knowledge of illegal acts, do we warn participants prior to the study that we will report any revealed illegal acts or assume there will be none?
- On the matter of who should provide the consent, it must be the people who take the greatest risk.

## Funder concerns about the ethics of research

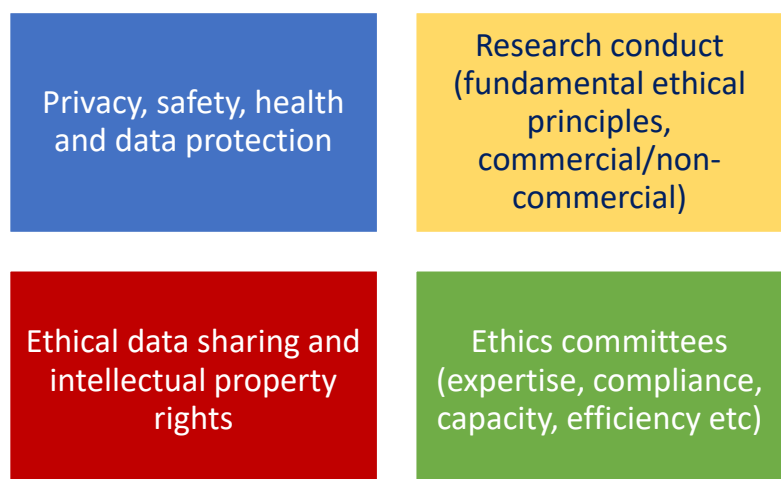
Dr Michelle Singh: The European & Developing Countries Clinical Trials Partnership (EDCTP)

Michelle works for the EDCTP, an organisation that aims to support collaborative research which accelerates the clinical development of intervention tools against HIV, tuberculosis, malaria, neglected infectious diseases & new emerging diseases of relevance to Africa.

To date, 146 projects have been completed including development of drugs, vaccines and diagnostics, as well as ethics and regulation. Concerning ethics calls, 75 grants (4 million Euros) have been awarded for strengthening the operation and function of ethics committees, and establishing ethics committees in countries with no or limited support. The following diagram shows the four major funder concerns for research participants in LMICs.

Figure 4 – Funder concerns for research participants in LMICs

The EDCTP is funded by Horizon 2020 (the European Union’s research funding programme) and therefore researchers must complete the Horizon 2020 ethics



issue checklist concerning the following issues:

- Human embryos and foetuses:
- Human beings
- Human cells or tissues
- Personal data
- Animals
- Non-EU countries
- Environment, health & safety
- Dual use
- Exclusive focus on civil applications
- Potential misuse of research results
- Other

There are various tools and follow-up mechanisms for ethical compliance including:

- Ethics appraisal (EC H2020 self-assessment)
- Scientific and Ethics review (independent experts)
- EDCTP H2020 model grant agreement (inclusive of IPR & data ownership)
- Institutional Review Boards / National Ethics Committees
- National Regulatory Drug Authorities
- Community Advisory Boards
- Data Safety Monitoring Boards
- Training (Good Clinical Practice / HSRP)
- Adverse Event Reporting (SAE / EAE)
- Sponsor Visits
- Clinical Trial Registration
- Clinical Trial Insurance
- EDCTP site visits (\*selected)



Dr Michelle Singh, EDCTP

Michelle concluded by saying that the EDCTP hope that TRUST will provide the missing links, and be the key to the perfect fit for research ethics evaluation.

## Gender sensitivity: writing and language

Professor Fatima Alvarez Castillo: Institute for Social and Health Sciences, UNISA & University of the Philippines Manila

Prof. Tim Alvarez Castillo is an advisor to the TRUST project and provided a briefing on gender-sensitive writing to the project consortium.

### Language as symbols

Language is a system of communication which is full of symbols; the most often used are words. Words contain the meanings we attach to things (or phenomena). But the meanings are cultural artefacts because language is part of our culture, and the words we use and the meanings we attach to them are inherited from each culture.

But meanings of words also change. For example, think of the word 'family'. We traditionally envisaged "family" as father (man), mother (woman) and children. Nowadays however it can often mean something very different, for example gay marriage is allowed in

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*Language is a system of communication and it is full of symbols. When we belong to the same community, we understand the meaning.*

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some places. Some groups are pushing for the reconstruction of the meaning of “family”. The reconstruction of the meaning or symbolism of a word often follows a challenge to the traditional understanding of it, as we can see in the cultures which have legalised gay marriage.

In language is embedded a culture’s worldview, or the ways a culture makes sense of various phenomena. According to the constructionist view of the world, phenomena (things/events) do not have meaning independently of the meaning that we as humans attach to them. Any culture’s system of meaning contains among others its norms, values and beliefs. Oftentimes, we are not conscious of this and we use words as if they are neutral or have universal meanings. Thus it was only when our understanding of “family” was challenged that we realized that our usual understanding could be only one of many possible interpretations. The example of “family” forces us to recognize that words as symbols reflect our cultural norms. Gender-sensitive writing is about challenging those accepted norms.

#### Language and power

A culture’s worldview, expressed in language, also contains norms and values about power and relations of power. For example, the word “expert” imbues persons with authority and assigns higher credibility to their claims than those of non-experts. The public is expected to defer to their opinions on matters of their expertise. It was not until about the 1960s when the usual understanding of expertise was challenged by feminists, who argued that unschooled women have more expertise about their own situation than the experts. This ushered in a new research philosophy that valorizes poor women’s stories and their own versions of their realities.

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*Gender-sensitive writing is about challenging the accepted norms.*

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The English language has specific historical and cultural contexts / origins but it is being globalised, regardless of important differences between those who speak it. For example, there is no term for “thank you” in some cultures. In many Western societies, where “thank you” is said many times a day, this would seem most impolite. And Australian aboriginal gestures for the past and the future are the opposite to what we might imagine and use. But we can also see how it makes sense to gesture forwards for the past (even though we do not do that) because we know our past. We can see it in front of us, if we want to. Our future is the unknown, the thing that is behind us; we cannot know it.

Thousands of languages in the world have been marginalised. English has become the dominant language. This implies, among other things, that a specific culture and worldview dominate while others are marginalized.

#### Gender and political correctness

The concept “Gender” is a social construct that assigns men, women, boys and girls their roles, privileges, power and duties in each society. It was a concept that has been used by women’s advocates to expose and oppose structures and practices that are unjust to women and girls. It used to be a struggle to have the concept of gender and what it creates recognized in government sectors. Now it has become very popular or mainstreamed for political correctness. The problem is however, that it is being misused, which is exemplified in the use

of gender (social roles not actually based in biology) for sex (the biological category of male/female). This misuse, even by the WHO, and the UN among others, has watered down the political significance of including the term.

Let us clarify the distinction of some popular terms:

- Gender neutral language: Does not discriminate on the basis of gender
- Gender sensitive language: Is considerate of and sensitive to specific vulnerabilities resulting from gender
- Gender fair language: Expresses / symbolises fairness between genders

<b>Discriminatory term</b>	<b>Neutral term</b>	<b>Sensitive term</b>	<b>Fair term</b>
Prostitutes	Sex workers	Single mother sex workers	Highly vulnerable sex workers

Writing and speaking is culture in practice and practice can change. These examples demonstrate different ways of naming groups:

- Mankind becomes Humankind
- Fisherman becomes Fisherfolk
- Housewives and / or house husbands
- ‘Them’ instead of his / her

The last example is a good one because it illustrates that even rules in English grammar can and do change to reflect social progress. It used to be incorrect to use the plural “Them” for the singular (one person/individual) which had to be written as “He” or “She”, but now “Them” “They” is increasingly used in formal as well as informal language, for example to avoid the awkwardness of repeatedly putting He/She all through a report.



*Prof. Fatima Alvarez-Castillo*

Some guiding principles for gender-sensitive writing:

- Think about the context and the purpose or use of what you are writing; do not abstract simply to be politically correct
- Strive to do no harm (discriminate, exclude / include; stigmatize)
- Do not contribute to maintaining patriarchy
- Mindfulness & Carefulness
- Look for better terms outside of the English language and import them into your writing. Many English speakers the world over are waiting for those terms to help their own progress towards more inclusive writing. In this way your gender-sensitive writing can make a difference.

## Discussion

- Constructionism is the single most important thing that we need to understand. People look at different things in different ways and interpret them from their own cultural / individual perspective. People see the world in totally different ways.



## The most useful cases from India – an overview

Dr Vasantha Muthuswamy and Dr Nandini Kumar: The Forum for Ethics Review Committees in India (FERCI)

Much of TRUST's work is built on case studies. Dr Muthuswamy and Dr Kumar presented a short overview of the Mumbai workshop meeting in March 2016 (Full report available <http://trust-project.eu/trust-workshop-in-mumbai-the-report> ).

The cases that were presented and discussed at that meeting have been refined and combined, resulting in 16-17 case studies that describe problematic scenarios for North-South collaborative research. There were some examples of good practice cases and some that described exploitation. Similar issues are described in these cases to the ones we have heard here in Nairobi.

In India, potential collaborative research is considered by the Health Ministry's Screening Committee. They are looking for:

- Sensitivity of information
- Protection of Indian scientists on IPR issues
- Compliance with ethical guidelines & regulations of India



*Dr Nandini Kumar*

Community engagement is important to avoid exploitation in many ways. It can be used for:

- Developing Community Centred Research Agendas by incorporating the knowledge and expertise of community members.
- Using Scientific Knowledge for Community Benefit by facilitating the balance between the scientific agenda and the benefits to the community being researched.
- Bridging the gap between research participants, communities in which they live, and researchers.

A model of community engagement was described which involves many different stakeholders, and is chaired by a community representative. Members of the Community Advisory Board (CAB) are sent for ethics training which aids capacity building, and there is also education of the community through:

- Formal training
- Visits to site clinics
- Group activities

CAB members are actively involved in protocol development and help to obtain relevant socio-cultural inputs into the study design. They can also contribute to the development of consent forms. For example, consultative meetings involving community representatives at the national level, were held for an AIDS vaccine trial. The goal was to simplify the language and the process to be explained.



*Prof. Fatima Alvarez Castillo and Dr Vasantha Muthuswamy*

Some community-friendly tools have been developed with community inputs on matters such as:

- Explaining dosage
- Explaining placebo
- Explaining randomisation

## The case study competition

Dr Francois Hirsch and Solveig Fenet: Institut national de la santé et de la recherche médicale (Inserm)

Francois spoke about the task for Inserm, to organise a case study contest. Thousands of emails were sent out calling for case studies about potential exploitation in North-South research. The call was opened in December 2015 and 19 cases were received. The eligibility criteria were:

- Relevance to research situation
- Situation of “ethics dumping”
- Original
- Engaging writing style



Solveig described how the case studies from the competition may be integrated into the case studies Deliverable for the project, which is available here: <http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf> .

*The TRUST plenary was closed by Peter Mwaura and Dr Joshua Kimani showing the appreciation of all the insights achieve and looking forward to future collaborations over the next 2.5 years.*