Ethical issues in international collaborative research. 
An Indian perspective

Dr Vasantha Muthuswamy

The scope of international co-operation and collaboration in biomedical and health research has gained greater momentum in recent years and India is an important player in this globalization. On the one hand, the “global share of CTs [clinical trials] in India grew from 0.9 percent in 2008 to 5 percent in 2013.” On the other hand, “it is estimated that 80% of donor funded antiretroviral medicines in Africa come from Indian generic manufacturers.”

Global collaboration in medical research is underpinned by an interest in a humane, healthy civil society, which accepts universal ethical principles and applies them to all research participants across the globe. In practice, such global collaboration can be exploitative when Southern country research participants are used in repetitive experimentation to obtain results for Northern country institutes and industries. At the same time, exploitation concerns can arise even when there is no formal collaboration between countries, but the research is undertaken with assistance from international organisations as sponsors or agencies (whether public, private or philanthropic).

To avoid exploitation and guide different types of collaborations, a framework that is based on equity and equality is needed, also incorporating other ethical principles that should provide appropriate regulation for different levels of development in terms of infrastructure, expertise, social and cultural perceptions, laws relating to intellectual property rights, ethical review procedures, informed consent requirements, adherence to human rights compliance etc. The immediate necessity for such a framework has gained global importance in view of the growing international collaboration between high income and low and middle countries (LMICs).

Appropriate selection of research participants, equitable study design, identifying the vulnerabilities of the local population and adopting mitigating principles and procedures, access to post study benefits and appreciating the local cultural norms have become the hallmarks of such collaborations.

In India, there are formal inter-country bilateral/multilateral collaborative arrangements between Indian federal research bodies and similar bodies of several other countries. The Indian federal Ministry of Health and Family Welfare and the Indian Council of Medical Research have issued guidelines to facilitate the review, conduct, and monitoring of international collaborative research.

At each research site, Institutional Ethics Committees must make themselves aware of the different requirements of various funding and regulatory agencies and serve as an oversight body to protect the rights, safety and welfare of the human research participants especially when the social contexts of the proposed research can create foreseeable conditions for exploitation of the participants or increase their vulnerability to harm. It is particularly important to look out for the following situations which can result in potential violations of ethical principles.

Obtaining informed consent from research participants becomes a mere formality due to inherent issues related to vulnerability (such as economic status), illiteracy, therapeutic misconception, undue faith in the treating physicians, or inability to understand and assess overly lengthy and complex participant information sheets.

The risk-benefit analysis by the ethics committees is too crude, as the committee members have not been trained appropriately to pick up the risk categories and undertake an analysis based on incomplete information. Hence a detailed analysis of the true nature of the research purpose is not provided.

Continued on page 2

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/
The principle of justice and what it entails is not understood by members of ethics committees as this would require continued education on current developments, which are not easily available (e.g. changes in international conventions).

Ethics committee requirements are accepted on paper but not realized in practice. Due to the inherent difficulties in implementation of specific policies (e.g. on post study access to successfully tested drugs) many of the ethics committee recommendations remain on paper to satisfy requirements (of for instance, an overseas ethics committee) but have never been implemented to the benefit of local communities.

Enthusiasm to take part in internationally funded studies leads to a weakening of local ethics requirements. Enjoying the financial and job security benefits available for international research collaborations may tempt investigators in LMICs to compromise on certain ethical requirements at the cost of patient/participant safety.

The above potential areas for exploitation are not theoretical assumptions but have been detected in real life case studies in India. The TRUST project recently held a meeting in Mumbai to discuss cases of exploitation in research and a small selection will be published in a deliverable in August 2016 (http://trust-project.eu, Report on paradigmatic case studies).

An effective tool to overcome these issues can be the development of world-class expertise as an outcome of growing international collaboration. In other words, the equitable and equal partnerships that are required in the conduct of health research are also required in the simultaneous research on bioethics. Knowledge transfer and local capacity building have to be understood as two-way streets, both in science and in ethics research. For instance, relevant quality control of joint-trials with reputed global players can result in building expertise for both. Partnerships between public and private sector entities in India and international organizations are a great way to increase expertise for both parties. Guidelines for the global conduct of ethical research could be agreed so that learning occurs through such partnerships. Finally, one of the main hindrances to equitable research partnership is the understaffing at Indian facilities. It is therefore necessary that human resource planning is done carefully and with specific reference to the research under consideration. Molecular diagnostics, molecular epidemiology or social science research techniques have different funding needs, as the equipment required for the former is not necessary for the latter. With appropriate planning it can then be ensured that the required expertise is available at each participating centre in an equitable manner.

It is the duty of international scientists and ethicists to step in at this important juncture of international collaboration and build equitable research partnerships with Indian organisations.

Notes

TRUST MEETINGS

TRUST kick-off meeting in Paris
The TRUST kick-off meeting, co-organised by UNESCO and UCLan, was held in Paris on 4-5 October 2015. At this meeting, representatives of the thirteen partners came together with project advisors and representatives of three funding bodies. The project objectives and strategic outputs were highlighted and expectations from the participants about the project outcomes were collected. For instance, Dr Monachello from the Commission’s REA said “I am impressed by the expertise assembled here and also the geographical spread […] An operational code of conduct would be very important for the European Commission”.

The workshop report is available here.

TRUST in Kimberley (1)
On March 23-25, 2016, SASI organised a preparatory meeting in Kimberley with 28 San representatives and leading researchers from South Africa. The workshop addressed examples of past ‘good’ and ‘bad’ cases of research studies focusing on San people and San heritage. Main ethical issues of these case studies were highlighted, and changes to the way the research community should approach the San people were proposed. Prof. Himla Soodyal, a principal investigator on the Genographic Project, was one of the invited speakers, and gave a speech about ethical issues and community engagement in genetic research. The workshop report will soon be available on our website.

TRUST in Nairobi
On May 23-25 the TRUST consortium met in Nairobi for a case studies workshop organized by TRUST’s partner PHDA. The workshop represented a unique opportunity for the consortium to hear about risk factors and exploitation in research directly from two of the most vulnerable and frequently researched populations in low and middle-income countries, sex workers and indigenous peoples. Senior Kenyans in the field of research ethics also joined the event, expressing their concerns about international collaborative research. More news about this event and a report will soon be made available on our website.

TRUST in Kimberley (2)
On May 31-June 1, SASI organised a follow up meeting to the Kimberley workshop held in March. Two fundamental outcomes of the meeting were: a) the revision of the San Research and Media contract, b) the drafting of a San Code of Ethics that will help the South African San in managing their involvement in research and heritage studies. The report of the event and a film made with the involvement of the participants will later be available on our website and YouTube Channel.
The TRUST case studies meeting in Mumbai

On March 11-12, 2016, TRUST’s partner FERCI, the Forum for Ethics Review Committees in India, hosted a two-day case studies workshop in Mumbai. Dr Vasantha Muthuswamy, Dr Urmila Thatte and Dr Sandhya Kamat organised a very successful event. Thirty leading bioethicists from India came together with a small number of guests from Europe to discuss cases of exploitation and good practice in research that had been previously identified by the participants. This workshop forms part of the fact finding activity in the early stages of the TRUST project, gathering information about cases of exploitation and good practice in research involving low and middle income countries (LMICs) from around the world.

The minutes of the event are available [here](http://www.trust-project.eu/eNewsletter2016,Issue1).
TRUST Case Studies Competition

The TRUST Case Studies Competition is now closed, and full submission of selected case studies was due on 13 June, 2016. The aim is to collect case studies from across the world identifying the risks of exporting non-ethical research practices to low and middle-income countries.

The competition opened on 14 December, 2015, with a first deadline on 2 March, 2016, was relaunched with a new deadline for submission of abstracts on 25 April, 2016. Ten winners were selected and ranked from 1 to 10; cases ranked from 1 to 5 will receive €2,000 and cases ranked from 6 and 10 will receive €1,000.

The ten winning case studies will be made available to the public via publication on the TRUST website at the end of the peer review process.

Publications

Books


Articles


House DR, Marete I, Meslin EM. (2016) To research (or not) that is the question: ethical issues in research when medical care is disrupted by political action: a case study from Eldoret, Kenya. J Med Ethics 2016; 42:61–65 [Open Access here]


Reports


Upcoming Events
Paris, France, 7-8 July 2016
Second Global Conference on Health and Climate

Barcelona, Spain, 25-29 July 2016
1st Conference on Social Impact of Science (SIS2016)

Leuven, Belgium, 8-10 September, 2016
30 Years of European Bioethics: EACME Conference

Innsbruck, Austria, September 26-27, 2016
Healthcare in Europe - A safe haven?

Lusaka, Zambia, 6-9 November 2016
Eighth EDCTP Forum

Nairobi, Kenya, 21-24 November 2016
2nd High Level Meeting of the Global Partnership for Effective Development Cooperation (GPEDC)

Harnessing Digital Health Innovations

Mangalore, Karnataka, India, 15-17 November 2017
Fifth International Conference on Ethics Education: Curricular innovations in ethics education
Avoiding exploitation of participants or resources in Africa when foreign researchers are involved - The ‘Process Equilibrium’ approach

Dr Samuel J. Ujewe

Research in African settings, conducted by foreign researchers, is often well intentioned. Yet there are still cases of exploitation of research participants and/or resources in recent years in some African countries. Either or both of two conclusions can be drawn from such cases, namely that the researchers:

i. have limited understanding of the context dynamics, and mostly impose result-oriented perspectives; and/or
ii. deliberately exploit loopholes in the national or international standards for conducting research in low-and-middle-income countries.

Whereas exploitation resulting from a limited understanding of the context may be considered an unfortunate outcome of well-intentioned research, the second represents a case of self-interest, the ultimate interests being those of the researchers or their sponsoring establishments. Among the recognised strategies for addressing questions of exploitation by foreign researchers in Africa, ‘Community Engagement’ (CE) appears to be prominent. CE has been described as: “…a process of involving populations in a defined area in research; identifying priority interventions within a social context and recognising environmental problems, as well as implementing intended interventions in a culturally acceptable manner”. It “…has been presented by bioethicists and scientists as a straightforward and unequivocal good which can minimize exploitation and ensure fair distribution of research benefits in developing countries”.

However, one major shortcoming of CE and the underlying ethical benchmarks is that they are postulated as generics for use in countries of similar income levels, even if these countries are culturally and socially different. For instance, a low income country in Africa will not share all the characteristics of its counterpart in Asia.

It may be fair to say that CE and other relevant approaches mostly focus on ‘what’ should be done, rather than on ‘how’ responsible research should be conducted in African contexts. This leaves the research process and its integration with the relevant communities’ expectations at the sole discretion of researchers, who may be unfamiliar with the contexts and ill-equipped if the aim is to integrate local processes with the research aims and outcomes, thereby perpetuating exploitation of research participants or resources. My view, as explored in my PhD thesis, is that ‘process’ should be an integral feature of conducting research, if we hope to minimise exploitation by foreign researchers in African settings. Process is a function of African moral thought and an African conception of justice. In terms of research, this would mean that:

- the researcher is expected to present the facts about the research to the relevant communities or population group in ways they can understand;
- the communities or population group must accept such explanations as constituting the wholeness of the research; and
- the research must aim to restore, enhance or sustain the well-being of the community or population group.

A ‘Process Equilibrium’ (PE) as the relevant approach that underpins essential guidelines for conducting research in Africa opens up the way to responsible research in Africa, i.e. research informed by an African methodological approach, as established against a background of African process. PE requires an equitable relationship between the researchers on the one hand and the participants or the relevant community whose resources are being used on the other hand. Here, the researchers do not single-handedly determine the research process, but always in harmony with the moral expectations of participating communities or population groups – for moral expectations constitute an essential determinant of risk of exploitation. This would mean that the research process has been:

• understood in the light of African socio-ethical contexts;
• interpreted against African modes of shared meaning;
• viewed through the existential dynamics of African harmony; and
• actualised through the practical dimension of the African dialogic process.

Establishing research against the backdrop of PE would ensure that not only the research aims and outcomes are understood (as in obtaining consent), but also that the motivations are shared between the researchers and the relevant communities or population groups. By implication, participation in research or allowing the use of certain resources would result from the recognised harmony between the well-being of the populations and the anticipated outcomes of the research. Where this obtains, exploitation should not be a question.

Notes
1. See: Silberberg et. al. ed. (2011); Lavery et. al. (2010); Asante et. al. (2013); Tindana et al., (2007).
5. Ibid.,. p.123ff
6. Ibid.,. p.171ff
7. See Ibid., p.187-194

News from the world

The first South Africans fight for their rights
Control of the land is at the heart of politics in South Africa and a new party, the Khoisan Revolution party, is calling for justice for the country’s oldest inhabitants. More at http://www.bbc.com/news/world-africa-36516241

Brazilian ethics clash exposes science culture gap
In an attempt to reduce bureaucracy, Brazilian humanities and social scientists have pushed for changes in the ethical and legal framework of all types of research involving human beings, an issue that has caused discontent among researchers [...] More at http://www.scidev.net/global/ethics/analysism-blog/brazilian-ethics-clash-exposes-science-culture-gap.html

The Human Factor: who makes policy and how?
Dr Kathryn Oliver (University of Oxford) argues that we need a clearer understanding of who is already influencing policy, and how, if we want to increase the role of academic evidence in policymaking [...] More at http://www.alliance4usefulevidence.org/the-human-factor-who-makes-policy-and-how/

A biotech company has been given permission to try to resurrect the clinically dead
A US biotechnology company, Bioquark Inc., has been given permission to recruit 20 clinically dead patients and try to bring their central nervous system back to life. The Bioquark team, which together with Indian biotech company Revita lifesciences, was granted permission from an institutional review board at the US and Indian national institutes of health to begin clinical trials whenever they’re ready [...] More at http://www.sciencenews.com/a-biotech-company-has-been-given-permission-to-try-and-bring-dead-brains-back-to-life

Fairer way to distribute last-ditch drugs gets real-world trial
‘Compassionate-use’ laws in the United States allow pharmaceutical companies to provide unapproved drugs to patients in desperate need, but many firms provide little or no information on how to request these treatments [...] More at http://www.nature.com/news/fairer-way-to-distribute-last-ditch-drugs-gets-real-world-trial-1.20046

Planting the Seeds for Better Harvests in West Africa
The West Africa Agricultural Productivity Program (WAAPP) is working with Côte d’Ivoire – and other countries in West Africa – to revive and strengthen seed systems that were previously decimated due to a lack of infrastructure and funding. Seeds from seed multiplication farms are better in quality, more resistant to pests, and can yield up to 50% more than traditional varieties [...] More at http://www.worldbank.org/en/news/feature/2016/05/12/planting-the-seeds-for-better-harvests-in-west-africa

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Coordination and Support Action/CSA. Grant Agreement n 664771