Generic Risks of Exporting Non-Ethical Practices

TRUST
Equitable Research Partnerships

Citing suggestion: Kate Chatfield, Doris Schroeder, Klaus Leisinger, Jaci van Niekerk, Ngayo Munuo, Rachel Wynberg and Paul Woodgate (2016), *Generic Risks of Exporting Non-Ethical Practices*, a report for TRUST, available: http://trust-project.eu/deliverables-and-tools/.

Generic Risks of Exporting Non-Ethical Practices

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Project full title:	Creating and enhancing **TRUST**worthy, responsible and equitable partnerships in international research
Project acronym:	TRUST
Type of funding scheme:	Coordination and support action
Work programme topics addressed:	Reducing the risk of exporting non ethical practices to third countries, GARRI-6-2014
Project web-site:	www.trust-project.eu/
GRANT AGREEMENT No:	664771
Name of the Coordinator:	Prof. Doris Schroeder (dschroeder@uclan.ac.uk)

[1] Thanks to Julie Cook Lucas for editorial support.

Contents

Executive Summary

The potential to be exploited is part of the human condition. Even superheroes usually have an Achilles' heel,[2] or vulnerability. Take for instance, Superman, whose vulnerability is kryptonite.[3] Exploiters take advantage of others' vulnerabilities to promote their own interests. Whilst there is a morally neutral sense of exploitation (the exploitation of natural talents to create art, for example), the term is generally used to describe a moral failing. Exploiting others is morally wrong.

Saigon 1950

This report is about the *risks* for exploitation for defined entities, in other words, 'Achilles' heels' in research. *What makes exploitation more likely to occur due to vulnerabilities that can be exploited, either knowingly or unknowingly*?

After careful analysis of the relevant literature and case studies, as well as consultation with leading ethics committee chairs and representatives of vulnerable populations from low and middle income countries (LMICs), an exploitation risk table was produced. Risks were categorized according to the points at which vulnerability occurred, and were grouped according to four values which have to be present to avoid exploitation in North-South collaborations: fairness, respect, care and honesty. Trustworthiness is achieved when all four values are realized.

		Risks for					
		Persons	Institutions	Local communities	Countries	Animals	Environment
Values	Fairness						
	Respect						
	Care						
	Honesty						

[2] In Greek mythology a baby called Achilles was dipped in water which offered the powers of invulnerability, but the heel he was held by was left untouched. As a man, he fought in many great battles including the Trojan War, but a poisonous arrow eventually lodged in his heel and he died shortly afterwards. http://www.greekmythology.com/Myths/Heroes/Achilles/achilles.html

[3] A mineral from Superman's home planet, which has detrimental effects on his powers.

1. Introduction and Methodology

The word "exploitation" usually means taking advantage of something or someone to further one's own interests.[4] In the context of North-South collaboration, the exploitation of human beings needs particular attention, but the exploitation of resources, including animals and the environment, is also of concern. Exploitation of people is very often unjust, unfair, harmful, or just plain wrong, although some argue that it can, in some situations, be morally neutral and permissible.[5]

What is it then that distinguishes morally unacceptable exploitation? Some argue that exploitation is wrong because it is coercive.[6] If the only way for a woman in an LMIC to access anti-retrovirals to prevent the transmission of HIV to her unborn baby is to take part in a placebo-controlled clinical trial,[7] despite the existence of a proven standard of care,[8] then one could say she has been coerced into enrolling.[9] In this sense, exploitation occurs where one party takes advantage of another by making them an offer they cannot refuse; they are then coerced to accept simply due to lack of alternatives. Others argue that exploitation is wrong because it treats human beings as means rather than ends,[10] i.e. it instrumentalizes them. Yet others claim that exploitation is wrong because it disadvantages the vulnerable.[11]

> *Exploitation is wrong because it disadvantages the vulnerable.*
> Ruth Macklin

This report is about risks or vulnerabilities for exploitation, hence we are adopting Macklin's definition of exploitation. However, one thing has to be borne in mind: a situation that is conducive to exploitation does not *necessarily* lead to exploitation. For instance, if a pharmaceutical company is due to test new anti-retrovirals to prevent the transmission of HIV to unborn babies and the company operates in a country where poor mothers have no or very limited access to healthcare, it does not mean that exploitation will necessarily occur. For instance, the company may decide not to exploit vulnerable research participants and offer the standard of care to the control arm, and not a placebo.

[4] European Textbook on Ethics in Research, 2010:127, https://ec.europa.eu/research/science-society/document_library/pdf_06/textbook-on-ethics-report_en.pdf.
[5] Joel Feinberg (1988: 14) gives a good example of a morally neutral case of exploitation between humans, where one driver follows the lights of another car in dense fog.
[6] Schwartz, Justin. 1995. What's wrong with exploitation? Nous. 29, 158–164.
[7] A placebo-controlled trial involves some participants who are given a medicine with active ingredients, for instance a new drug against malaria, whilst others, the control group, are given a sham, a placebo treatment, which should have no effect, so that the outcomes can be compared.
[8] One speaks of a proven standard of care when a treatment already exists for the illness under consideration in a trial. Hence, the ethical demand of testing any new drug against an existing one rather than a placebo is known as the standard of care debate.
[9] For a discussion of the exploitative character of such studies see Annas G., Grodin M. Human Rights and Maternal-Fetal HIV Transmission Prevention Trials in Africa. "*American Journal of Public Health* April 1998;88(4):560–563.
[10] Wood, Allen. 1995. Exploitation. *Social Philosophy and Policy* 12, 150–151.
[11] Macklin, Ruth. 2003. Vulnerability and Protection. *Bioethics* 17(5–6)472–486, p.475.

Exploitation is usually a moral act, which requires a decision on the part of the potential exploiter. However, exploitation can sometimes also be based on ignorance. Hence, this report aims to raise awareness about the risks for exploitation to ensure that such ignorance cannot be claimed.

The main purpose of the report is to prepare for a Global Code of Conduct for North-South collaborations to counter the exploitation of human research participants and resources in LMICs. Based on the risks and values identified in this report, the code will be more than a compilation of already existing codes, many of which were not written with North-South collaboration in mind.

This report aims to raise awareness about the risks for exploitation to ensure that ignorance cannot be claimed.

Methodology

This report is to bring to light the critical vulnerabilities that engender susceptibility for exploitation in North-South collaborative research. Investigation of this vast subject would be impossible from a traditional literature based approach, or through investigation in a single geographical region. Many of these vulnerabilities are poorly represented in the literature and they can differ between countries, cultures and the nature of the research. For example, clinical trials, social science, animal experiments, environmental science, and research in emergency settings may pose a diverse array of risks that are largely dependent upon the local context in which they are undertaken. Consequently, a creative approach to data collection was needed to try and capture as many risks and vulnerabilities as possible.

In this regard it is very helpful that the TRUST project is an interdisciplinary collaboration between multi-level ethics bodies, policy advisors / makers, civil society organisations, funding organisations, industry, and academic scholars from a range of disciplines. With input from each of these perspectives, a broad based consultative exercise was possible which included input from these collaborators as well as more than 30 members and chairs of ethics committees in LMICs, representatives from vulnerable populations in LMICs, and an open call for case studies of exploitation in research in LMICs.[12]

A broad based consultative exercise was possible.

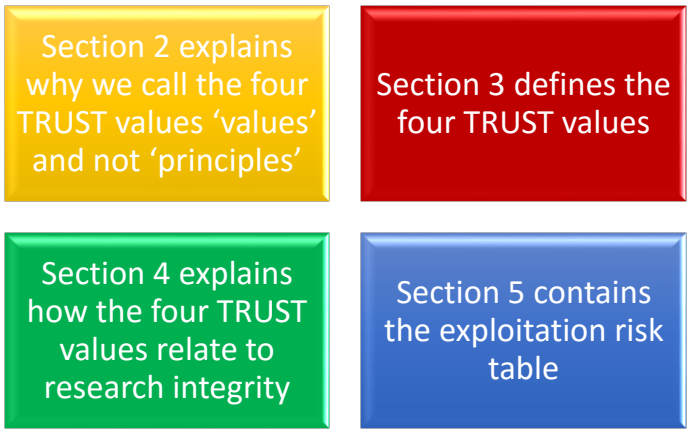
Individual vulnerabilities and risks of exploitation were extracted from the information provided as well as from any available literature, and then organised and tabulated on an excel spread sheet with source details and description of the vulnerability/risk. Care was taken to ensure that each individual entry was based upon real-world experience rather than hypothetical suppositions.

[12] This type of consultative exercise is of proven value in the development of ethical codes that are broadly representative and can have wide ranging impact. For example, the principles of the 'Three Rs', which are globally accepted as a reasonable measure for ethical conduct in animal research, arose from a broad consultation with stakeholders undertaken by Russell and Burch in the 1950s. See Russell, W.M.S., Burch, R.L. and Hume, C.W., 1959. The principles of humane experimental technique. London: Methuen & Co.

Once collected, the raw data were collapsed to group similar vulnerabilities together. For instance, there were many different examples of how people living in poor circumstances may be unfairly enticed to participate in research by the prospect of payment or reward. Such examples were grouped under the label of 'undue inducement'. Further thematic analysis resulted in distinction between the various potential subjects, or levels of risk for exploitation (persons, institutions, local communities, countries, animals and the environment); in the final stage of the analysis the vulnerabilities were grouped according to the four values of fairness, respect, care and honesty.

Structure of the Report

The main section of the report is the exploitation risk table. However, many readers may also have questions in relation to why we did what we did. By trying to anticipate some of these questions, we are also giving an overview of how we resolved questions that were raised internally, in particular:



2. Values, Principles and Standards

Unstructured risks or vulnerabilities for exploitation have less power to raise awareness and achieve understanding than risks that can be grouped according to certain mechanisms. We decided to use values as the structuring mechanism for this report; the values of fairness, respect, care and honesty. In sections 3 and 4 we will describe what we mean by these values and provide our argument for *using* those. But prior to doing so, we want to clarify how we distinguish values, principles and standards.

Values

The term "value" denotes that a specific mode of action / behaviour, an idea or an object is considered to be desirable, worthwhile, admirable, "good". In other words, it is valued.[13] In moral philosophy, values express a person´s conviction about what is morally "right or

[13] We are not interested in non-moral values, such as colour value, linguistic value, or mathematical value.

wrong", "good or evil". The correct values applied make a course of action right, proper, desirable. Values inspire, motivate and engage people to discharge obligations or duties. For instance, it feels good to be regarded as a fair person when agreeing workload models.

Values can be person-specific. Somebody might value exercise. Or they can be universal, e.g. what everyone values, whether as an end (such as health or pleasure), a means (for instance, adequate medical care or protection from bad weather), or both (e.g. companionship).[14] We are interested in universal moral values.

The *Millennium Declaration* – supported by the Heads of States and Governments that gathered at United Nations Headquarters in New York from 6 to 8 September 2000 – considered "certain fundamental values to be essential to international relations in the twenty-first century".[15] According to the *Millennium Declaration*, these are.

Freedom	Men and women have the right to live their lives and raise their children in dignity, free from hunger and from the fear of violence, oppression or injustice.
Equality	No individual and no nation must be denied the opportunity to benefit from development. The equal rights and opportunities of women and men must be assured.
Solidarity	Global challenges must be managed in a way that distributes the costs and burdens fairly ... Those who suffer or who benefit least deserve help from those who benefit most.
Tolerance	Human beings must respect one other, in all their diversity of belief, culture and language... A culture of peace and dialogue among all civilizations should be actively promoted.
Respect for nature	Prudence must be shown in the management of all living species and natural resources... Only in this way can the immeasurable riches provided to us by nature be ... passed on to ...
Shared responsibility	Responsibility for managing worldwide economic and social development, as well as threats to international peace and security, must be shared among the nations of the world...

The successor of the *Millennium Development Goals*, the *Agenda 2030 for Sustainable Development*, does not refer to values, but makes implicit value statements when expressing general goals and targets. For instance, under the heading *People*, the signatories note that they "are determined to end poverty and hunger, in all their forms and dimensions, and to

[14] Michael Davis, September 2014, contribution to unpublished glossary for Responsible Research and Innovation.
[15] http://www.un.org/millennium/declaration/ares552e.htm

ensure that all human beings can fulfil their potential in dignity and equality and in a healthy environment."[16]

The above values are very general, to cover all of life's eventualities. We are interested in values that are important in North-South collaboration in research; values in global research ethics.

Principles

A principle can be defined as a behavioural rule that must be followed in a decision or course of action as a logical consequence of one´s values. For instance, the Sustainable Development discourse emphasizes the principle "Leave no one behind"[17]; court decisions follow the "*in dubio pro reo*" principle[18]; or Mark Twain recommended the principle "When in doubt, tell the truth".[19]

In our "Global Code of Conduct" Deliverable, we will include a short discussion of why we depart from principlism,[20] the main philosophical approach in research ethics, developed in the US. However, it is already noteworthy that the UN use of the term "values" does not align with principlism. Their principles (beneficence, non-maleficence, autonomy and justice) would have to be called values.

Standards

Standards are measures that quantify and specify in technical terms certain agreements following negotiations. Some standards are helpful (environmental standards for cars) and others would be helpful but are not implemented for protectionist reasons (e.g. standard for electrical plugs in the EU).

For instance, ISO 26000 (International Organization for Standardization) "provides guidance on how businesses and organizations can operate in a socially responsible way. This means acting in an ethical and transparent way that contributes to the health and welfare of society."[21]

The following sections define the four TRUST values (for a general audience) that are essential in non-exploitative North-South collaborations. A link to the concept of research integrity and a further explanation of why we settled on those four values will be provided thereafter.

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[16] http://www.un.org/ga/search/view_doc.asp?symbol=A/69/L.85&Lang=E

[17] "As we embark on this collective journey, we pledge that no one will be left behind", https://sustainabledevelopment.un.org/post2015/transformingourworld.

[18] When in doubt, for the accused.

[19] http://www.working-minds.com/MTquotes.htm.

[20] An approach to moral decision-making, developed in medical ethics by Beauchamp & Childress, which uses autonomy, beneficence, nonmaleficence and justice as its main principles. http://www.encyclopedia.com/science/encyclopedias-almanacs-transcripts-and-maps/principlism

[21] http://www.iso.org/iso/home/standards/iso26000.htm

3. The TRUST Values

Fairness

The terms fairness, justice and equity are often used interchangeably. We have chosen the term fairness in the hope that it is / will be most widely understood globally. Philosophers commonly distinguish between four types of justice or fairness.[22]

Fairness in exchange

establishes the equity of transactions

Distributive fairness

deals with the division of existing, scarce resources amongst qualifying recipients

Corrective fairness

rights a wrong that one has brought upon another, usually through a court

Retributive fairness

establishes which punishment is appropriate for any given crime

Robert-Owen Wahl, free images

The most relevant fairness concepts in global research ethics are fairness in exchange, and corrective fairness. In North-South collaborations, as the name indicates, at least two parties are involved in a range of transactions. Typical fairness issues in global research ethics are:

- Is the research relevant to local research needs?
- Has benefit sharing taken place?
- Are LMIC authors involved in publications?

These are questions about **fairness in exchange**. For instance, LMIC research participants contribute to the progress of science, but this is only fair if the research is actually relevant to their own community.

Corrective fairness, which presupposes the availability of legal instruments and access to mechanisms to right a wrong (e.g. a complaints procedure, a court, an ethics committee) is also important in North-South collaborations. For instance, if no host country research ethics structure exists, corrective fairness is limited to the research ethics structure in the Northern country, which may not have the capacity to make culturally sensitive decisions.

[22] Pogge, T. (2006). Justice. In D. M. Borchert (Ed.), Encyclopedia of philosophy 2nd ed (Vol 4) pp862–70. Detroit, MI: Macmillan Reference.

The broader question of what the North owes to the South falls under **distributive fairness**. One can illustrate the difference between fairness in exchange and distributive fairness using the example of post-study access to successfully tested drugs. In the first case (fairness in exchange) one could argue that research participants have contributed to the marketing of a particular drug and are therefore owed post-study access to it (should they need the drug to promote their health and well-being, and should they not have access otherwise). In the second case (distributive justice) one could provide a range of arguments, for instance the signing of the *Universal Declaration of Human Rights*, to maintain that *all* human beings who need the drug should have access to it, and not just the research participants. In this report, we focus on fairness in exchange. Likewise, **retributive fairness** is less relevant as few ethics violations fall under criminal law, where the appropriateness of punishment must be discussed.

If no host country research ethics structure exists, corrective fairness is limited to the research ethics structure in the Northern country.

Respect

The term respect is used in many ethics frameworks. For instance, the *Declaration of Helsinki* notes in Article 7 that:

> Medical research is subject to ethical standards that promote and ensure *respect* for all human subjects and protect their health and rights.[23]

Its ubiquitous use, however, does not mean that it is a clear term. In everyday life, it is used in the sense of deep admiration. For instance, somebody could say, "I respect the achievements of Nelson Mandela". However, that is not what is meant by respect in research ethics. The statement from the *Declaration of Helsinki* does not mean that research participants must be admired. To be respected in research ethics is almost the opposite. It means that one must accept a decision or a way of approaching a matter, even if one disagrees strongly. A typical case in point is to respect the decision of a competent adult Jehovah's Witness to refuse a blood transfusion, even if this means certain death.

bought from istock

Respect is therefore also a difficult value, as there is always the possibility that one *cannot* accept another's decision. For instance, if a researcher learns about female genital mutilation (FGM) being used as a "cure" for diarrhoea in female babies,[24] respecting this approach to health care is likely to be the wrong decision - particularly as the practice is likely illegal - or at the very least a decision that would leave the researcher with a serious conflict of conscience. But being a value that may be

[23] http://www.wma.net/en/30publications/10policies/b3/ our emphasis.

[24] See case study 5 in TRUST Report on Paradigmatic Case Studies, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

difficult to operationalize in North-South collaborations does not mean that one can dispense with respect.

The entries in the risk table related to respect which we provide below are based on consultation with two vulnerable populations (sex workers and indigenous peoples), as well as the literature. The importance of respect in North-South collaborations cannot be ignored and there are many possible ways of showing respect that do not create conflicts of conscience. For instance, illiterate San community members should not be enrolled in research studies without contacting San leaders first, in accordance with the community norms. Or, Northern researchers should not insist that LMIC ethics committees must accept the format of their own preferred ethics approval submission, but instead submit the study for approval in the format required by the LMIC committee.

Whilst it is possibly difficult to imagine a situation where a Northern researcher is accused of being too fair, too honest or too caring, it may be possible to be accused of being 'too respectful', e.g. when faced with major violations of human rights. To find a balance between imperialist-type imposition of approaches and careless acceptance of human rights violations may sometimes be difficult, but it is what researchers should strive for.

Care

Sometimes one word describes different concepts. That is the case with "care". If somebody said, "I care for my grandmother", it could mean two diametrically opposed things. First, it could mean that the person is very attached to her grandmother but hardly ever sees her. Second, it could mean that she is the person who injects her grandmother with insulin, cooks her meals, and makes sure that her needs are taken care of on a daily basis, even if there is great dislike between them.

What we mean by the value of care in the context of global research ethics links more to the second use of the term; to look after or take care of somebody or something. As a main priority, one should take care of those enrolled in research studies to the extent that one always prioritizes their welfare over any other goals. In line with Article 8 of the *Declaration of Helsinki* this means:

> While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.[25]

As a main priority, one should take care of those enrolled in research studies to the extent that one always prioritizes their welfare over any other goals.

This care applies across disciplines, not just in medical research, and is also not restricted to human research participants. Article 21 of the *Declaration of Helsinki* extends the care for welfare to research animals.[26] Likewise, care for environmental protection is increasingly

[25] http://www.wma.net/en/30publications/10policies/b3/
[26] Ibid.

included in research ethics processes and frameworks for responsible research. For instance, the Horizon 2020 ethics review process includes establishing potentially negative impacts on the environment as part of the review process. And Richard Owen et al define responsible research and innovation as, “a collective commitment of care for the future through responsive stewardship of science and innovation in the present",[27] a statement which has clear relevance to environmental protection.

Researchers who take care to avoid negative impacts in their work will not ‘helicopter’ into a research area they are not familiar with, but will use systems of *due diligence* to ensure that risks are first assessed and taken care of. For instance, a Northern research team which strips a local area of all doctors and nurses by attracting them into their high-tech research facility does not act carefully and ethically. Acting carefully also means taking obligations in relation to research ethics seriously. For instance, an ethics review committee that exists, but is poorly staffed and trained, cannot take care effectively of the interests of research participants.

Bas van der Pluyom, free images

Ideally, researchers who take good care combine the two elements that were mentioned at the outset: they care about research participants, in the sense that they are important to them, *and* they feel responsible for the welfare of those who contribute to their research, or might suffer as a result of it (including animals and the environment).

Honesty

Honesty is a value that does not need complicated explanations or definitions. In all cultures and nations represented on the TRUST team, “do not lie” is a basic prerequisite for ethical human interaction. It is so basic a value that its synonyms are often broad ethics terms. For instance, according to the Google synonyms, they are:

> “moral correctness, uprightness, honourableness, honour, integrity, morals, morality, ethics, principle, (high) principles, nobility, righteousness, rectitude, right-mindedness, upstandingness”.[28]

However, what does need explaining is the scope of the value of honesty in the context of global research ethics. Lying is only one possible wrongdoing in the context of a broad understanding of honesty. For instance, in research ethics it is equally unacceptable to leave out salient features from an informed consent process. For instance, if eyes are removed and replaced with artificial ones in a research study that uses paediatric corpses, it is highly

[27] Owen Richard, Jack Stilgoe, Phil Macnaghten, Mike Gorman, Erik Fisher, and Dave Guston. 2013. "A Framework for Responsible Innovation." In Responsible Innovation edited by Richard Owen, John Bessant, and Maggy Heintz, 27-50, London; John Wiley.
[28] https://www.google.de/search?q=honesty&ie=&oe=

unethical not to inform the consenting parents or guardians of this fact.[29] Whilst no lie might strictly be involved, hiding salient information also violates the value of honesty. For this reason, research ethicists often use the terms *transparency* or *open communication* to ensure that all relevant information is provided so that research participants can make an informed choice about participating or not.

In addition to lying and withholding information there are other ways of being dishonest, in the sense of not communicating openly and transparently. For instance, in a vulnerable population with high levels of illiteracy, it is predictable that a printed information sheet about research is not going to achieve *informed* consent. The same can be said for a refusal to overcome language barriers in a meaningful way. For instance, leaving highly technical English terms untranslated in information sheets can easily lead to misunderstandings.

Diagram 1: Honesty

Importantly, honesty is also related to research conduct other than interaction with research participants. Most prominently, the duties of honesty are described in *research integrity* frameworks: Do not manipulate your data. Do not put your name onto publications to which you have not contributed. Do not waste research funds, to give only three examples. However, whilst the latter prescriptions for conduct with integrity in research are very important, they are not directly linked to exploitation in North-South collaborations, and are therefore not included as exploitation risks in our table. Instead, the next section summarizes the relationship between the four TRUST values and research integrity.

4. The TRUST Values and Research Integrity

Research integrity is a topic that has become highly prominent, alongside more traditional research ethics discussions. The 2010 *Singapore Statement on Research Integrity*[30] lists 14 principles, namely: integrity and trustworthiness of the research, adherence to regulations, using appropriate research methods, keeping accurate research records, sharing research

[29] Information from case study submitted to the TRUST team, currently being verified and potentially made available on our website in 2017.
[30] http://www.singaporestatement.org/statement.html.

findings, proper authorship, proper acknowledgements, engaging in peer review, disclosing conflicts of interest, appropriate professional comments, reporting irresponsible research practices, responding to irresponsible research practices, creating research environments that encourage integrity, and taking account of societal considerations.

Diagram 2: Topics of the Singapore Statement on Research Integrity

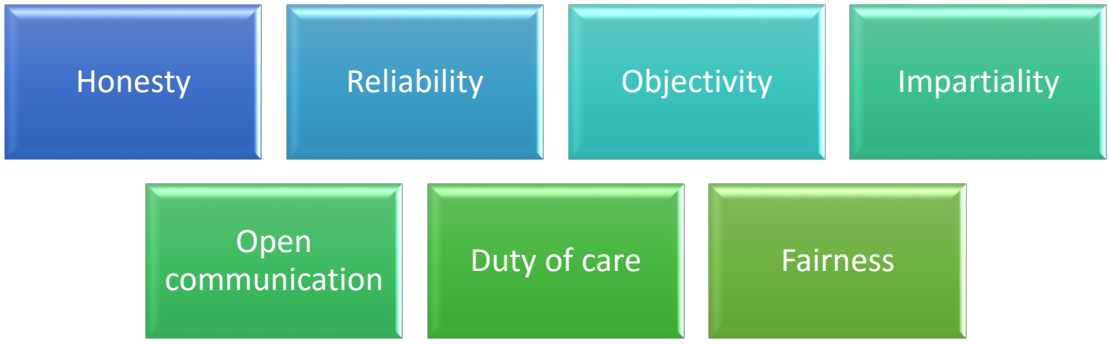
Since then, other bodies have engaged with Research Integrity. For instance, Universities UK have issued the *Concordat to Support Research Integrity*.[31] The UNESCO chairs in Bioethics of the University of Barcelona and the Catholic University of Portugal, with support from Obra Social "la Caixa" Foundation, have just launched the first *Declaration of scientific integrity on responsible research and innovation*.[32] Notably, the European Commission strengthened efforts to achieve research integrity in July 2016, when it issued a new model grant agreement for Horizon 2020 grants. [33] Article 34 of the agreement, "now explicitly calls for beneficiaries to respect the principles of honesty, reliability, objectivity, impartiality, open communication, duty of care, and fairness and responsibility for future science generations".[34]

Carlos Moedas, European Commissioner for Research, Science and Innovation, said: "The new rules will help promote a culture of research integrity and transparency in all research organisations. This will not only boost scientific excellence, but it will eventually show to the public that European science is above reproach." [35]

[31] http://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/the-concordat-to-support-research-integrity.pdf.
[32] http://www.bioeticayderecho.ub.edu/en/first-declaration-scientific-integrity-created-latin-countries-now-presented.
[33] The current framework program for funding research by the European Union, 2014-2020.
[34] https://ec.europa.eu/programmes/horizon2020/en/news/commission-moves-strengthen-research-integrity.
[35] Ibid.

The seven principles[36] of research integrity listed in the EC communication are: honesty, reliability, objectivity, impartiality, open communication, duty of care, and fairness and responsibility for future generations.

Diagram 3: Principles of Article 34 *Model Grant Agreement* Horizon 2020



Most ethics committee members recognise the dispute between those who say that "bad science is bad ethics", and those who say that the scientific merit of a study can be separated from the ethical conduct of the study. The former tend to make judgements on the science of a study whilst undertaking an ethics review, arguing that it is a waste of resources and research participants' time to promote a study that is not scientifically valuable or conducted well. The latter separate the two topics, e.g. the European Commission ethics review for Horizon 2020 practices the separation of the two processes, but of course would not approve a 'good' scientific project that was ethically unacceptable, nor support a project that was ethically commendable but scientifically unsustainable or flawed.

For TRUST, we have concluded that one can separate the above research integrity principles into three categories: those that are mostly relevant to good science, those that are mostly relevant to avoiding the exploitation of research participants and resources, and those that apply to both, see table 1.

Table 1: Research Integrity Principles according to Categories

Good science	Non-exploitation	Good science and non-exploitation
Reliability	Duty of care	Open communication
Objectivity	Honesty	
Impartiality	Fairness	

TRUST work on the exploitation risk table and the forthcoming Global Code of Conduct has been developed around the same three principles / values for non-exploitation as the EC's approach to research integrity, with two provisos. First, open communication with research participants is part of 'honesty' (e.g. feedback and informed consent), and therefore not a separate principle / value. Second, in North-South collaborations, the principle / value of respect is essential.

[36] Please note that according to our definition of values and principles, these should be called values, but we keep the originator's terminology.

5. The Exploitation Risk Table

In the following table the entries are themed by the relevant value and the potential subject, or level of risk, to which they are most closely aligned. Each entry describes a vulnerability that could lead to exploitation (deliberate or unintentional) in North-South research collaborations. Whilst each entry is grounded in real world experience or a case of actual exploitation, individual examples are not detailed in the table. For a fuller description of each entry and examples of how the vulnerability may be exploited, please click on the individual entry, which will bring you to a hyperlinked endnote.

It has to be noted that some entries could have been linked to more than one value. For instance, if a research participant suffered from a therapeutic misconception, the researcher might not have taken enough *care* to explain that research is different from treatment (possibly because s/he is not aware that this might be problematic in some settings), or because of a deliberate, dishonest avoidance of explaining the difference, in which case the value of *honesty* would have been violated. To avoid overburdening the tables, we made a decision which value to prioritize in each case.

Exploitation Risks – Fairness in exchange

	Risks for:					
	Persons	**Institutions**	**Local communities**	**Countries**	**Animals**	**Environment**
	Fairness in exchange					
Fairness	● In medical research: multiple trial enrolment[1] ● In all research: undue inducement[2] ● In medical research: no post-study access to treatment[3] ● In all research: no access to results or benefits of research[4]	● Research priorities driven by Northern partners: • Mismatch to local research needs[5] ● Poor representation of southern (host) partners on research teams: • Responsible for menial tasks only[6] • Not acknowledged or represented appropriately in publications[7] ● 'Helicopter research' by Northern partners: • No knowledge transfer or capacity building/ strengthening[8]	● Research priorities driven by Northern partners: • Mismatch to local research needs[9] • No or little input from marginalized communities into research[10] ● Undue inducement[11] ● No benefit sharing or feedback[12] ● Support for foreign-sponsored research drains local system of staff[13]	● No universal access to healthcare for population: • Differences in standards of 'usual' care[14] • Placebo controlled trials approved[15] ● Support for foreign-sponsored research drains local systems and resources[16] ● Medical science research shaped by the 'para state'[17]		● Study leads to reduction of natural resources[18] ● Lack of benefit sharing for the environment[19]

Exploitation Risks – Corrective Fairness

	Risks for:					
	Persons	**Institutions**	**Local communities**	**Countries**	**Animals**	**Environment**
Fairness	***Corrective fairness***					
	• Difficult or no access to legal system or legal aid[20] • Human rights violations not taken up by civil society[21]	• Lack of protection of IPR for LMIC institutions[22] • Lack of clear standards for operating systems and timelines for RECs[23] • No capacity / procedures for study oversight to ensure compliance with REC decisions[24]	• Lack of protection of IPR or traditional knowledge (TK) for local communities[25] • Human rights violations not taken up by civil society[26] • Absence of systems for community approvals[27]	• No relevant legal instruments for ethics committees[28] • Poor research governance frameworks to ensure adherence to ethical standards[29] • No cross-border legal recourse in cases of exploitation[30] • Discriminatory laws that may create stigmatised minorities[31]	• Variations in regulatory standards for animal experimentation[32] • Inadequate systems to ensure compliance with animal welfare standards[33]	• Variations in governance of natural resources[34] • Variations in procedural rights[35] • Environmental protection not well 'policed' by civil society[36]

Exploitation Risks – Respect

	Risks for:					
	Persons	**Institutions**	**Local communities**	**Countries**	**Animals**	**Environment**
Respect	• Unequal power relations • High trust in authorities [37] • Individual spiritual and religious priorities incompatible with or ignored by Northern partners[38] • Researchers and / or ethics committees deciding 'what is best'[39]	• Research protocol and papers imported from Northern partners and not tailored to local needs[40] • Ethical approval sought only from Northern partner[41]	• Diverse interpretations of important values[42] • Local requirements for effective community engagement ignored[43] • Diverse ethical priorities for matters such as: • gender equality[44] • sexual relations[45] • Particular spiritual and religious priorities incompatible with or ignored by Northern partners[46] • Localised social effects from research team presence[47] • Local customs may violate laws of the country and / or human rights[48]	• Research protocols and practices which fail to take account of national traditions and legislation[49]	• Variations in customs, norms and attitudes towards animal welfare and inhumane practices[50]	• Variations in customs, norms and attitudes towards the environment[51]

Exploitation Risks – Care

	Risks for:					
	Persons	**Institutions**	**Local communities**	**Countries**	**Animals**	**Environment**
Care	• In medical research: • Therapeutic misconception[52] • Misunderstanding of research aims[53] • Procedures for informed consent not tailored to individual[54] • Lack of possible actions to address adverse effects of participation: • Direct such as physical side effects[55] • Indirect – such as stigmatisation[56]	• No host country research ethics structures or inappropriate match with requirements[57] • No capacity on existing REC[58] • RECmembers are poorly trained and lack specialized expertise to review ALL types of research protocols[59] • Schedule of REC meetings is either too few or too sporadic[60] • REC does not have local / national government / ministry support to conduct its activities[61]	• Localised physical effects from research team presence[62]	• Insufficient data security measures[63] • Insufficient safeguarding protocols[64] • Lack of risk management approaches to biosafety[65] • Lack of risk management approaches to biosecurity[66]	• Animal research centres established in countries where regulation is less stringent[67] • Lack of resources for humane animal care[68]	• Inadequate consideration of unintended consequences for biodiversity and the environment[69] • Inadequate consideration of local environmental contexts[70] • Disregard for long-term effects upon local environment[71] • Lack of resources for environmental protection[72] • Insufficient information for assessment of environmental effects[73]

Exploitation Risks – Honesty (Transparency)

	Risks for:					
	Persons	**Institutions**	**Local communities**	**Countries**	**Animals**	**Environment**
Honesty	***Honesty through transparency***					

	• Inability to provide fully informed *individual* consent:
	  • Incomplete information provided[74]
	  • Information provided in an inappropriate format[75]
	• Potential effects of participation not fully explained[76]
	• Dual roles of researcher[77]
		• REC not fully independent[78]
		• Secrecy of research procedures[79]
			• Inability to provide fully informed *community* consent:
			  • Incomplete information provided[80]
			  • Information provided in inappropriate format[81]
			• Potential effects of participation not fully explained[82]
			• Dual roles of researcher[83]
				Lack of data sharing[84]		• Incomplete information about potential risks / harm to the environment[85]

Exploitation Risks – Honesty (Integrity)

	Risks for:					
	Persons	**Institutions**	**Local communities**	**Countries**	**Animals**	**Environment**
	Honesty through integrity					
Honesty	• Personal data protection breeches[86] • Unauthorised secondary use of samples[87] • Use of samples for commercial purposes without consent[88] • Deliberate withholding of information[89] • Deliberate obfuscation of research aims[90]	• Bribery on existing REC[91] • Ingrained institutional unethical practices or institutional culture of disregard for legal requirements[92]	• Dishonoured commitments[93]	• Data sharing without consent because of lack of strict privacy arrangements[94]	• Deliberate obfuscation of experimental conditions[95]	• Results from Northern research inappropriately applied in Southern context[96]

6. Conclusion

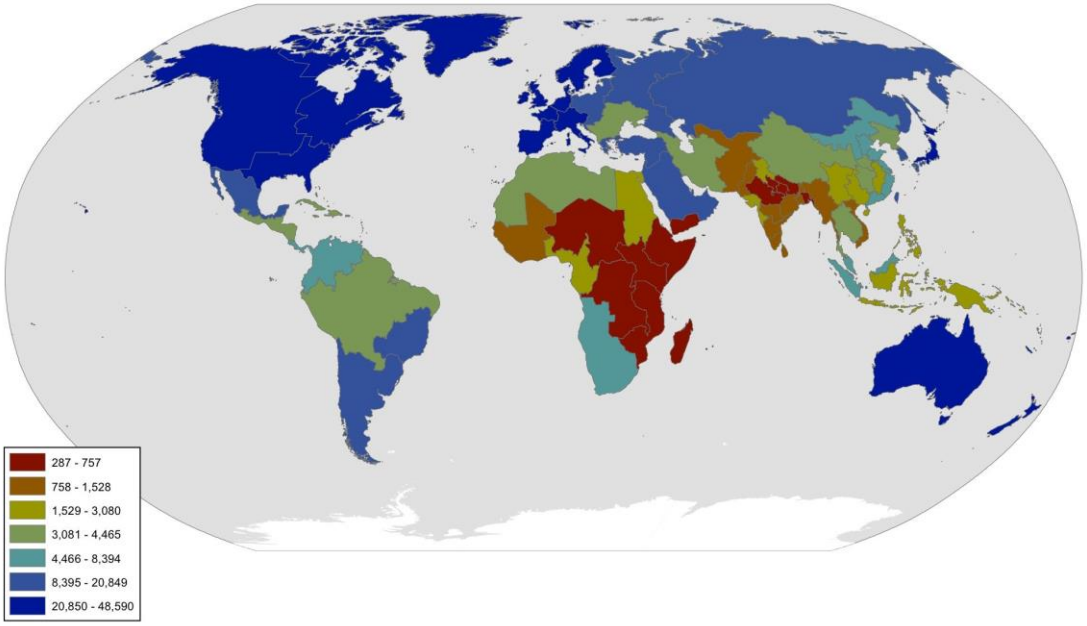
Our Exploitation Risk Table is the conclusion of work undertaken globally and co-operatively in the relevant part of the TRUST project. We could therefore have stopped with Section 5. However, in this conclusion, we would like to draw attention to three 'elephants in the room',[37] which go beyond individual boxes in our table, namely:

- extreme differentials in available income, i.e. serious poverty
- past history of colonialism, and
- extreme differentials in power

Serious Poverty

The most obvious risk for exploitation in North-South collaborations in research is the extreme difference in affluence across the world. The following diagram shows gross domestic product (GDP) per capita, 2009 in US$ using the Demic framework.[38]

Diagram 4 – GDP 2009, Demic Framework



[37] Elephant in the room is an English metaphorical idiom for an obvious truth that is going unaddressed. The idiomatic expression also applies to an obvious problem or risk no one wants to discuss https://en.wikipedia.org/wiki/**Elephant_in_the_room**

[38] "*The Demic Atlas* rests on the proposition that socio-economic comparisons work best when based on comparable units, framed at approximately the same scale of analysis. The obscure term demic — "pertaining to populations of people"— highlights the demographic egalitarianism central to the project. Ideally, regions of equal population should be compared against each other; otherwise, the individual inhabitants of some parts of the world are weighed more heavily than those of other areas. Conventional comparisons based on sovereign states necessarily violate this principle, effectively giving the residents of small countries far more attention than their counterparts in big, densely populated states. The premise of the *Demic Atlas* is that deploying roughly comparable categories will yield a more illuminating picture of global development." http://www.geocurrents.info/economic-geography/introduction-to-the-demic-atlas#ixzz4QdC8sK4t

Many of the individual points in the risk table have their origins in extreme poverty. Researchers cannot resolve this problem, but they can show heightened awareness of it and try to do their best for local improvements, e.g. by equitably involving local researchers, by focusing their research on local research needs, and by obtaining input from local populations etc.

Past History of Colonialism

One could ask, how the history of colonialism bears upon research *today*, and perhaps question whether it is indeed an elephant in the room. We believe it is, which can be shown with the experience of indigenous peoples in research.

Writing from an Australian Aboriginal perspective, Linda Tuhiwai Smith has powerfully shown that indigenous peoples often consider research a "dirty word". She describes how "imperialism frames the indigenous experience" and how "indigenous peoples had to challenge, understand and have a shared language for talking about ... colonialism".[39]

Imbalance - Bought from istock

One of the most popular research populations globally is the San population of Southern Africa, due to the fact that they have lived longer continuously in one location than any other population in history.[40] Research involving the San covers medical research, non-medical genetic research (for ancestry tracing), social science research, anthropological research, legal research, and ethics research (e.g. benefit sharing). The San population is represented in the TRUST consortium and has had an opportunity to provide input for this Deliverable. Past exploitation, including during colonial times, is manifested strongly in the San experience and was raised during TRUST meetings.

Extreme Differentials in Power

Differentials in power between the North and the South is a topic that has filled books, audience halls, television programs and various other spaces. It is also a very broad and unspecific claim. Since this report is about awareness raising, we are only going to give one brief but very prominent example, the UN Security Council's veto rights.

The UN Security Council's main responsibility is the maintenance of international peace and security. As such the Council can release resolutions, coupled with sanctions, against any

[39] Linda Tuhiwai Smith (2012) "Decolonizing Methodologies: Research and Indigenous Peoples", Zed Books.
[40] Lee RB, Hitchcock R, Biesele M (2002) Foragers to first peoples. Cult Surviv Q 26(1):9–12.

nation that threatens international peace. For instance, United Nations Security Council Resolution 1696 – passed on 31 July 2006, required that Iran suspend all activities that could lead to nuclear weapons through uranium enrichment and invoked a range of sanctions should the resolution be breached.[41] Any decision made within the Council, which has 15 members (five permanent, 10 rotating), can be vetoed by the permanent members, all of which are from the North (four high income, one upper middle income).

> "For all the rhetoric about council reform being heard … in New York, the world is not close to rejuvenating the 15-member body's roster. The council has the same five veto-wielding permanent members — the United States, Russia, China, Britain, and France — that it did when it opened for business in 1946."[42]

We would like to end on a general comment. As the TRUST gender advisor, Prof. Fatima Alvarez-Castillo has noted to the TRUST group at a plenary in Nairobi:

> A culture's worldview, expressed in language, contains norms and values about power and relations of power. For example, the word "expert" embues 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.

We hope we have succeeded in going beyond expert opinions in embedding the reality of the lives of vulnerable populations in this report. Thanks to the representatives of the San population and the sex worker peer educators from Nairobi for their input.

TRUST Nairobi plenary May 2016

[41] http://www.un.org/press/en/2006/sc8792.doc.htm.
[42] http://foreignpolicy.com/2015/09/29/the-united-states-doesnt-want-to-reform-the-u-n-security-council/

Appendix

The following endnotes provide further explanations, examples and references for the vulnerabilities that are listed in the Exploitation Risk Table. To return to the risk table please click on the 'Click here to go back' links.

Click here to go back

[1] Payment for participation in studies may induce some people to enrol in multiple studies simultaneously; in such circumstances payment for participation may be a critical component of their income. This is most common in pharmaceutical studies that rely upon the testing of new drugs in healthy volunteers prior to testing in diseased persons. See case study 6 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[2] The offer of some type of payment in return for participation is not uncommon in clinical studies but this practice can raise concerns if participants are believed to be unduly influenced by the offer, thereby compromising the voluntariness of consent. The potential for undue inducement is greater in low-income settings. The emphasis on individual choice in low-income settings often ignores the fact that biomedical research enrolment may be the only accessible or easiest route to healthcare. This essentially narrows the parameters within which many prospective participants are asked to make a choice about whether or not to participate to such an extent that individuals are effectively presented with an 'empty choice'. Kingori, P., 2015. The 'empty choice': A sociological examination of choosing medical research participation in resource-limited Sub-Saharan Africa. *Current Sociology*, *63*(5), pp.763-778.

[3] For participants in a clinical study, the end of a study may also result in the end of their healthcare treatment. This is especially distressing for people with long-term conditions for whom participation is their only means of gaining access to quality healthcare. See group 1, case 3 in *TRUST Project Mumbai Meeting Report* at http://trust-project.eu/trust-workshop-in-mumbai-the-report/

[4] This occurs when the research is designed to be of benefit to people in other countries or environments and has no chance of ever benefitting the individuals who contributed to the study. For example, this happened with a Hepatitis B vaccine. The research was undertaken in Kenya but for many years, people in Kenya could not afford to purchase the vaccine and therefore could not benefit. See K Bhatt in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[5] Where LMIC partners are dependent upon funding and association with their high income partners for research, the research aims may be shaped by the high income partners and not tailored to the preferences and skills of the local workforce.

[6] Local LMIC researchers can be exploited when used for tasks such as data collection only.
See K Bhatt and A Guantai in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

Click here to go back

Click here to go back

[7] Local LMIC researchers can be exploited when, having participated in a research project, they are then not represented, or not properly represented, in subsequent publications. See K Bhatt and A Guantai in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[8] A further exploitation of local LMIC researchers occurs when they are used for certain tasks in research without any accompanying capacity building. In such circumstances, local researchers will not be able to develop the skills needed to lead and conduct projects for themselves in future.

[9] Local LMIC communities can be exploited in research when aims are driven by, and in the interests of, high income researchers/institutions with no real benefit to the local community. If the research is of no potential benefit to the local community, we must ask why is it being conducted there? See K Bhatt in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[10] For example, stigmatised minorities may be reluctant to come forward as participants or contribute to research for fear of the legal or social consequences of being identified. In such cases researchers need to act with great sensitivity and take special care to ensure anonymity. See 'Concerns for sex workers' in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[11] Just as it is a concern for individuals, whole communities can also be induced unfairly to engage in research. See endnote 2

[12] For example, when the research is designed to be of benefit to people in other countries or environments and has no chance of ever benefitting the communities who contributed to the study. See A Steenkamp and R Chennells in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[13] For example, if a community nurse is needed for the research then their time spent in training and on project activities is time that the community may be short of one (and perhaps the only) nurse.

[14] As well as being a contributory factor to undue inducement in medical research, a lack of consistency in the basic standard of care is also of great concern in comparative studies, where new interventions are compared with 'usual' care. If the usual care comparator is 'no care' or 'inadequate care', then both the ethical status and the integrity of the research must be questioned. See case study 13 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

Click here to go back

Click here to go back

[15] According to the *Declaration of Helsinki*, placebo controlled trials should only be used in certain circumstances where they are deemed methodologically necessary and where there is no risk of serious harm to the participants. Wherever possible, new treatments should be compared with the best available existing treatments. It is not acceptable to deny participants access to the best available existing treatment in a placebo controlled trial just because the best available treatments are not normally part of their 'usual' care (e.g. because they are in a resource poor setting).

[16] Whilst collaboration in research activities can bring benefits to LMIC countries, they can also be a drain on resources and capacity as LMIC partners engage in research that is primarily of benefit to their high income partners. Additionally, researchers who have been educated and trained in LMICs may be tempted away from their home countries to work in higher income environments, a situation for which there is no obvious solution, as the free movement of people is also to be valued and respected.

[17] Through the example of medical science, Geissler et al (2015) describe how, in Sub-Saharan Africa, nation states have morphed into 'para-states' as a result of, 'economic and political liberalization and globalization, intertwined with epidemiological and technological changes'. National governments have a crucial role in medical care, but NGOs, universities, pharmaceutical companies and other non-state actors play a significant role in medical research and treatment. Consequently, the fragmented medical science landscape is largely shaped and sustained by transnational flows of expertise and resources, rather than being governed purely by the nation state. Geissler, P.W. ed., 2015. *Para-states and medical science: making African global health*. Duke University Press.

[18] For example, where research that is led by Northern partners results in inappropriate environmental recommendations

[19] For example, research agreements focused on the use of biodiversity and traditional knowledge typically ignore the environmental component. The common approaches to benefit sharing emanating from research activities involve only humans. However, some have advocated that this is anthropocentric. Stone C.D., *Should trees have standing? Should Trees Have Standing? Law, Morality, and the Environment* 3rd Ed (2010) Oxford University Press.

[20] Individuals who are harmed by their participation in research may have no means of seeking retribution or compensation if they cannot afford legal representation and there is no form of legal aid.

[21] For example, a lack of personal support from civil society may arise because of a lack of resources to support civil society organisations in their activities. It may also take the form of 'turning a blind eye' when research is undertaken with stigmatised minorities.

[22] Lack of awareness and expertise within the LMIC institution may lead to the loss of intellectual property rights (IPR) for local knowledge and the products of research. See case See case study 9 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

Click here to go back

Click here to go back

[23] This may lead to exploitation of weaknesses in ethics review processes. For example, pressure from the high income partners for a quick turnaround in the approval process may prevent full and fair consideration of the research proposal. See A Guantai in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[24] Very few ethics committees in LMICs have the capacity for ensuring adherence to their recommendations. See E Bukusi in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[25] Lack of awareness and expertise, or too much trust in the researchers, may lead to the loss of intellectual property rights (IPRs) for local knowledge and resources.

[26] For example, a lack of community support from civil society may arise because of a lack of resources to support civil society organisations in their activities. It may also take the form of 'turning a blind eye' when research is undertaken with stigmatised minorities.

[27] In some localities community approval is normally required for activities that will have an impact in that locality and / or on members of that community. Without explicit systems for seeking such approval, or any legal requirement to do so, researchers may disregard (knowingly or unknowingly) community norms.

[28] For research ethics committees to function effectively they need to be backed up by relevant legislative and regulatory instruments.

[29] Research personnel from high income settings, when working in a relatively looser regulatory environment, might exploit the systemic loopholes and regulatory 'vacuum' of the LMIC host country, either intentionally or otherwise, and seek improper benefits through potentially illegal acts. See case study 9 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[30] Researchers from high income countries who choose to ignore or flout the research ethics and legal requirements in the host LMIC can be difficult to police. It is especially problematic in localities where there is a lack of resources and / or infrastructures to ensure ethical compliance throughout the entire research process and where the home institutions in high income countries do not ensure compliance with requirements for their employees.

[31] For instance, in Kenya where both sex work and homosexuality are illegal, this results in large groups of people who are stigmatised and fearful of being 'discovered'. See endnote 10

Click here to go back

Click here to go back

[32] What is legal for animal experimentation in some countries may be illegal in others. This encourages the export of animal experimentation to countries where there is less stringent regulation.
See case study 2 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[33] Even in countries where there are well developed ethical standards for animal experimentation, without means to ensure compliance with these standards, inhumane practices may be widespread.

[34] Customary forms of governance of natural resources are not well understood by Northern research institutions, leading to inappropriate research interventions. There are different 'contextual rights.' South Africa's environmental laws for example, extend the common law duty of care to include specific measures for the environment.

[35] For example, public participation. In the context of the environment, procedural justice within a country / community would involve *inter alia* the right of indigenous and local communities to participate in decision making and to Free, Prior and Informed Consent (FPIC) with regard to any research activities or recommendation thereof that may affect human health and well-being.

[36] It is not only people who rely upon the support of civil society. Input and support from civil society organisations is also essential for effective environmental protection. See case study 6 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[37] In some environments it might be deemed rude to say 'no' or to ask questions about the research. In other situations, it may be that people are too afraid or lack the confidence to say 'no' or to ask questions. Either way, the power imbalance between researcher and participant can impact upon the consent process.

[38] Individual customs, traditions, or religious and spiritual beliefs may be very different to those of the researcher. For example, from an African cultural point of view, human body parts are sacred, whether they are obtained from living or deceased persons. Hence, the removal of blood or other body parts for research may have a profound impact that needs to be acknowledged and addressed in a manner that is sensitive to the wishes of the individual.

[39] Personal autonomy may be disregarded in cases where researchers and ethics committees make decisions on behalf of research participants 'for the greater good'. In such cases autonomy has been overruled in favour of beneficence, and individuals are treated as if they are not capable of making reasonable informed decisions. For instance, if eyes are removed and replaced with artificial ones in a research study that uses paediatric corpses, it is highly unethical not to inform the consenting parents or guardians of this fact. (Information from case study submitted to the TRUST team, currently being verified and potentially made available on our website in 2017.)

Click here to go back

Click here to go back

[40] The import of documents from Northern partners without being adapted to suit local needs, may have a negative impact if they lack cultural sensitivity. For example, an information sheet or questionnaire that is intended for teenagers may be deemed inappropriate if asking about behavioural patterns that are more common in Northern teenagers. See group 4, case 2 in *TRUST Project Mumbai Meeting Report* at http://trust-project.eu/trust-workshop-in-mumbai-the-report/

[41] Research ethics committees in Northern institutions may lack the relevant experience and knowledge of ethical priorities and issues that need to be addressed in the relevant LMIC.
See case study in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[42] This is particularly evident with the concept of autonomy. The liberal interpretation of autonomy that prevails in the North may not be easily transferred to all environments in the South where 'community' or 'group autonomy' is also highly valued. See K Bhatt in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[43] Appropriate methods for community consultation may vary greatly for different groups of people and in different environments. See group 4, case 1 in *TRUST Project Mumbai Meeting Report* at http://trust-project.eu/trust-workshop-in-mumbai-the-report/

[44] This may affect what is asked of participants and how it is asked. For example, in some communities it is traditional for a husband/father to provide their consent for a woman to participate in research, in addition to the individual consent a researcher will require from her.

[45] The accepted norms for sexual behaviour vary greatly between countries, communities and religious orientation. See endnote 16

[46] Local customs, traditions, and religious and spiritual beliefs may be very different to those of the researcher. For example, from an African cultural point of view, human body parts are sacred, whether they are obtained from living or deceased persons. Hence, the removal of blood or other body parts for research may have a profound impact that needs to be acknowledged and addressed in a manner that is sensitive to the wishes of the local community. See 'Concerns for sex workers' in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[47] The research team 'on the ground' may be unaware of local traditions, customs and expected norms. As such, their behaviour and interactions may be considered inappropriate and cause offence. See G Luc in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

Click here to go back

Click here to go back

[48] Researchers can face serious ethical dilemmas, and communities can be put at risk, if the research reveals behaviour that is illegal or in contravention of human rights. For example, the revelation of female genital mutilation (FGM). See case study 5 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[49] May lead to participants unknowingly transgressing their own national laws.

[50] What is considered as 'animal cruelty' or 'inhumane practice' in animal experimentation varies greatly between cultures. Additionally, some animals are awarded greater protection in certain cultures than others, for example, dogs and cats in the UK, and cows in India. Animal experimentation with non-human primates is particularly controversial in most countries, but in some countries (such as Kenya and China) certain non-human primates are viewed as 'pests'. See case study 2 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[51] Respecting the fact that different partners may have different philosophies related to the environment. Environmental protection is sometimes regarded as a colonial construct that has negative impacts on local communities in the global South, and research agendas are considered to follow suit. There may therefore be a philosophical or paradigmatic difference between research partners.

[52] This can happen if participants are mistaken about the potential therapeutic impact of the study treatment. For example, a mistaken belief that a treatment for HIV/AIDS will protect them from infection. See 'Concerns for sex workers' in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[53] Where care is not taken to explain the aims of the research in a manner that potential participants can understand. See case study 9 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[54] Variations in spoken language, levels of literacy and use of terminology are just some of the issues that need to be taken into account when developing a process for obtaining informed consent.
See 'Concerns for sex workers' in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[55] When participants are harmed as a direct result of participation (e.g. side effects of treatment) they may not have any way of seeking help or recompense. Side effects can happen long after the study is over. See case See case study 13 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

Click here to go back

Click here to go back

[56] As well as direct harmful effects from research participation, participants may also be at risk of indirect harmful effects such as stigmatisation. For example, when the San people were disparagingly referred to as 'hunter gatherers' in subsequent academic publications. See case study 4 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[57] Most LMICs are developing processes for ethical approval of research but they may not yet have the appropriate systems in place to review all types of research. See A Guantai in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[58] Even where research ethics committees are well established, they may only have limited capacity and be overstretched at times. See A Guantai in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[59] The wide ranging nature of research that requires ethical approval calls for wide ranging expertise on the research ethics committee(s). Members need an understanding of both research ethics and the nature of the research. This can be particularly challenging in resource poor areas. See A Guantai in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[60] Lack of resources and capacity can mean that ethics committees can only meet infrequently. Consequently, when they do meet, they may be under pressure to review protocols very quickly. See A Guantai in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[61] Ethics committees cannot act in a vacuum. The appropriate legal and regulatory procedures need to be in place in order for them to hold any authority.

[62] The mere presence of a research study can have a great impact upon the local community. For example, research teams require food and accommodation, purchase local goods and services and form relationships with local people. See G Luc in *TRUST Project Nairobi Plenary Meeting Report* at http://trust-project.eu/vulnerable-populations-in-north%e2%80%90south-collaborative-research-nairobi-plenary-2016/

[63] For example, there is a risk of exploitative use of data where there are insufficient measures in place either to keep the data secure (e.g. from hackers) and / or to place clear and ethically acceptable limitations on the use of data. See case study 3 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[64] For example, where there are poor structures in place for protection of participants, researchers and institutions. See case study 9 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

Click here to go back

Click here to go back

[65] The rapid emergence of high-risk applications of technologies such as genome editing (e.g. applying genome editing technologies to human embryonic stem cells) not only challenges safety risk assessments but also challenges existing governance tools. This creates an environment where risky experiments might be carried out in countries with no legal framework, or in countries where although legal frameworks exist, their implementation cannot be achieved due to limited resources.
See case study 1 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[66] For example, the creation of harmful agents relevant to the bioweapons context, or human enhancement in a military context, and the medium and long-term implications for international security. The rapid emergence of high-risk applications of these technologies not only challenges security risk assessment but also challenges existing governance tools. This creates an environment where risky experiments might be carried out in countries with no legal framework, or in countries where although legal frameworks exist, their implementation cannot be achieved due to limited resources. See case study 1 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[67] Centres or 'hubs' for animal experimentation, including for primate research, are commonly located in countries where the standards for legal and regulatory governance are lower than they might be for example in the EU. 'Helicopter research' is encouraged in these locations as researchers from Northern countries may find them 'more convenient'. See case study 2 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[68] The requirements for experimental animal care that are demanded in the EU for example, can be costly in terms of facilities and training of the handlers. Research facilities in LMICs may not have the level of resources necessary for meeting these requirements.

[69] For example, research programmes may introduce exotic species which deplete water resources, displace traditional varieties thereby impacting upon agricultural biodiversity; or introductions might 'escape' and become invasive, thus threatening biodiversity.

[70] Environmental concerns can be extremely sensitive because they involve both a social context and an ecological context.

[71] For example, where research is intended to meet a short term need without consideration of long-term consequences. See case study 7 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[72] In the context of research, risks may arise due to different levels of resources available to ensure adequate environmental protection.

[73] Inadequate environmental information in the global South means research decisions and directions may develop in a vacuum.

Click here to go back

Click here to go back

[74] For example, where there are omissions and / or inappropriate or misleading language for the context in which consent is being sought. See case study 11 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[75] For example, where potential participants (some of whom may be illiterate) are not taken through any kind of suitable consent process but are, instead, provided with written information sheets to take home and told to come back with a signed consent form. See case study 11 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[76] For example, where the information does not fully explain the potential (and possibly harmful) consequences of participation. See case study 9 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[77] For example, where the researchers are also aid workers or healthcare providers, potential participants may believe that they have to participate in order to receive the aid or treatment. See case study 5 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[78] For example, where members of the ethics committee have a vested interest in the research or are under any form of duress or obligation to make certain decisions and recommendations.
See case study 11 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[79] A lack of transparency concerning research processes or personnel can make it very difficult to hold anyone accountable when things go wrong. For example, where numerous bodies are engaged in collaborative research and their individual activities and responsibilities are not clear, then it may be impossible to say where things have gone wrong and who is responsible.

[80] See endnote 74
[81] See endnote 75
[82] See endnote 76
[83] See endnote 77

[84] The recycling and combining of data can provide access to maximum knowledge for minimal additional cost and could potentially help speed the pace of health research. However, there are sensitive ethical issues to address and systems that need to be put in place for this to be undertaken in a responsible manner. Some countries may be excluded from data sharing because they lack these systems. Pisani, E. and AbouZahr, C., 2010. Sharing health data: good intentions are not enough. *Bulletin of the World Health Organization*, *88*(6), pp.462-466

[85] For example, when research proposals and information do not include the findings from environmental risk assessment.

Click here to go back

Click here to go back

[86] People can be put at risk when sensitive personal data is not sufficiently protected.

[87] The use of blood or other samples for purposes other than those for which original consent was sought is a controversial topic, with some believing that this is fine as long as the samples are anonymised, and others believing that, without consent, the samples must not be used under any circumstances. This topic is problematic because researchers are not normally aware of all the potential uses before the original study. See group 3, case 3 in *TRUST Project Mumbai Meeting Report* at http://trust-project.eu/trust-workshop-in-mumbai-the-report/

[88] For example, when blood samples or data are sold for profit without the knowledge or consent of the participants. See group 4, case 1 in *TRUST Project Mumbai Meeting Report* at http://trust-project.eu/trust-workshop-in-mumbai-the-report/

[89] Consent that is based upon partial disclosure does not constitute 'informed consent'. In fact, it may be considered as worse than no consent at all, and tantamount to *deceit*.

[90] When researchers believe that, in the interests of research, they can justify overruling the autonomy of the individual through the provision of deliberately misleading information about the research. See group 2, case 1 in *TRUST Project Mumbai Meeting Report* at http://trust-project.eu/trust-workshop-in-mumbai-the-report/

[91] Members of the research ethics committee are not acting in a free and impartial manner.

[92] In some institutions, certain unethical practices may become the norm, and even those workers who object may feel unduly pressurised to comply with this norm.

[93] For example, where the researchers have promised to return to the site with feedback about the research and then fail to do so. See case study 5 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[94] If legislation and systems are not in place to protect data, they are more open to exploitation. See case study 9 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[95] Where standards of animal housing and care are not high, obfuscation of the conditions in which the animals are kept may occur for two main reasons: 1. for the process of gaining ethical approval from the Northern partner, and 2. for publication of the experimental results. (Many academic journals that publish results from animal experimentation stipulate requirements that the studies have been conducted in a manner that is consistent with high ethical standards such as EU Directive 2010/63). See case study 2 in *TRUST Report on Paradigmatic Case Studies*, at: http://trust-project.eu/wp-content/uploads/2016/03/TRUST-664771-Paradigmatic-Case-Studies-WP1-Final.pdf

[96] For example, the application of results from genetically modified field trials of non-native species in Northern environments to justify decisions made in the South.

Click here to go back