

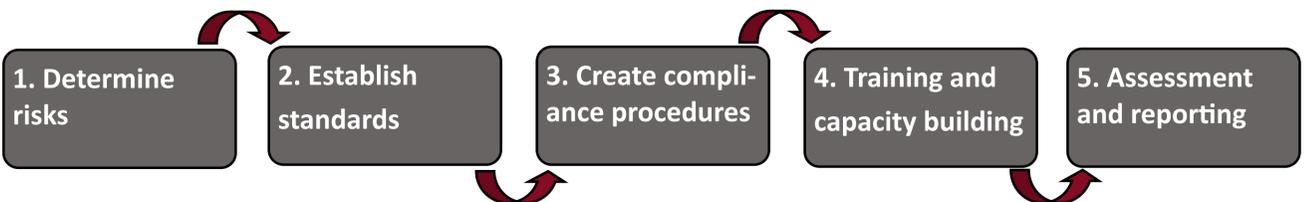
ETHICAL CHALLENGES FOR TRIALS WITHIN COHORTS IN LOW AND MIDDLE INCOME COUNTRIES

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TRUST is an EU-funded, Horizon 2020 project that aims to improve adherence to high ethical standards and avoid 'ethics dumping' around the world.

Ethics dumping involves the export of unethical research practices to low- and middle-income countries (LMICs) and, for a number of reasons, clinical trials in LMICs are highly sensitive to this problem. The aim of the TRUST project is to address the global problem of ethics dumping by agreeing *generic risks* for research in LMICs, developing a *global code of conduct* and *providing tools* that vulnerable populations can use themselves to avoid exploitation. The overall steps in the TRUST project are as follows:



We have reached the end of our first year with the TRUST project and have identified a large number of ethical risks for research in LMICs. The four main areas that have direct relevance for the TwiCs design are considered here.

My thanks to representatives of vulnerable populations in Kenya and South Africa for their quotations included in this poster

Lack of Resources

- 'Usual' care often = no care
- 'Usual' care can vary greatly across a cohort
- Participation in a trial is often the only hope of treatment
- Participating in trials can be a significant source of income
- Simultaneous enrolment in multiple trials
- Undue inducement

"We get given consent forms and documents, often in a hurry. We sign because we need the money and then end up with regret. It feels like a form of abuse."

Cultural differences

- 'Autonomy' can have different interpretations
- Community permission may be required, in addition to individual consent
- Local needs and priorities can differ greatly from those of the researcher
- Local traditions, customs and belief systems can vary greatly

"We know that samples are collected from us and sometimes sent to other countries. What happens to them? In my culture, if my blood is taken it must come back to me and I must bury it. If you don't bring it back, you must tell me where it goes."

Lack of education

- Many people lack literacy skills
- Misunderstanding of research aims
- Misunderstanding of potential risks and benefits

"Due to ignorance and poverty, many do not read the information."

"Not all of us can read. Tell us everything in black and white. Just tell us. Even if there is no direct benefit so I can make a decision."

"So much is assumed with consent. A signature is supposed to mean that you understand everything."

Lack of infrastructures and governance

- Attrition rates from cohort studies are high
- Causes of illness and death may be recorded inaccurately or not recorded at all
- Local research ethics committees may not be fully functioning
- Local research collaborators may be treated as 'poor relations'
- Lack of oversight procedures to ensure ethical compliance
- No benefits assured for the local community



Implications for TwiCs in LMICs

- Poor populations face the greatest burden from disease and disability¹
- Global research attention to diseases tracks the global market for treatment and the ability of patients to pay for care²

"We know and value research and we would like to benefit from the results instead of just being guinea pigs."

"We need to do more research in Africa for Africans."³

- Logistical and ethical challenges for the conduct of any cohort studies in LMICs are significant
- The 'ideal' conditions required for most RCTs are not found in LMICs
- The TwiCs design offers real world applicability of results
- Community engagement and local ownership are essential for sustainability
- Research should be driven by local needs
- Research should offer the potential for significant local benefit

References

1. Viergever, RF. (2013) <http://dx.doi.org/10.3402/gha.v6i0.22450>
2. Evans, J. et al. (2014) <http://dx.doi.org/10.1371/journal.pone.0090147>
3. Oluput-Oluput, P. (2011) *Saving African children* <http://www.economist.com/node/18775987>

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