

Special Regulatory Issues in Africa

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Ethical Review of Research in Africa

- Lack of experienced committee members and low investment = stretched committees overly burdened by administration
 - Increased number of trials needs to be matched with investment into the ability to review this research
 - Concern over slow review, overly cautious responses and requirements
 - Growing awareness and funding for capacity development for ethics review within Africa
 - WHO
 - European Developing Country Clinical Trial Partnership
 - Bill and Melinda Gates foundation
- TRREE, PABIN, MARC and Global Health Reviewers

Just some of many examples.

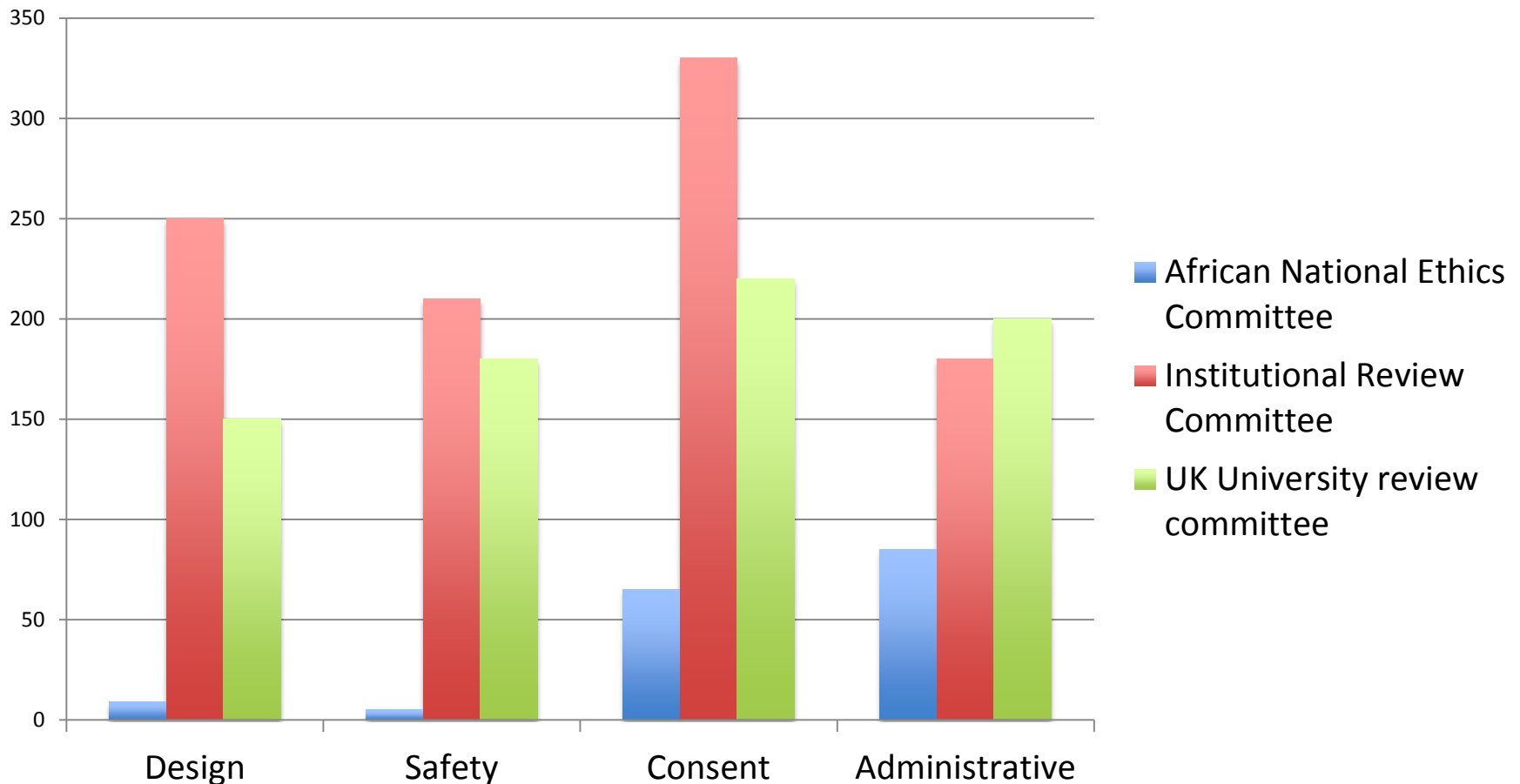
Key issues

- Old systems – paper heavy. Difficult for local investigators
- Burdensome reporting requests
 - Requesting all SAEs, meaningless & overwhelming, acting as DSMBs.
- One-size-fits all review. Lack of differentiation or understanding of minimal risk, social science etc. Monitoring Rapidly growing CRO industry
- FDA / EU OLD requirements and ICH-GCP applied to all types of research – lack of experience to apply or understand risk and complexity adjustments
- Newly introduced FDA type authorities in many countries are tasked with reviewing ALL trials and approving interventions (e.g. Saline)
- Indemnity is a massive issue = inappropriate market for insurance companies

What do African Ethics Committees Query?

Audit of all comments issues by 3 committees reviewing the same studies during a 12 month period

Preliminary unpublished pilot data.



What could be done

- Learn from the lessons of US and EU and not repeat them in a setting far less able to cope
- The the FDA and EU authorities keep in mind that developing countries follow their lead and apply with bells on!
- Research to understand the issues including metrics data and areas of difficulties to guide support (mixed methods research)
- Improve training and share knowledge and standards from other regions
- Global Health Reviewers, TRREE and MARC all working supporting better and more rational review

Open access platforms for accessing support, guidance and training

GlobalHealthReviewers.org

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Research Ethics Web
Mapping African Research Ethics Review Capacity

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The MARC project is developing an interactive map of health research ethics review capacity and drug regulatory capacity in Africa. MARC receives financial support from EDCTP and Pfizer to achieve this aim. This ongoing project invites self-uploading of information on African Research Ethics Committees (RECs) and Drug Regulatory Authorities. This information is then integrated into an existing country-based research system mapping structure to facilitate efficiency, sustainability and linkage of ethics 'maps' to health research system capacity. This integration allows for ethics capacity analysis in relation to general research system development, encourages comparisons between countries inside and outside Africa, and facilitates sustainability and knowledge sharing throughout the project.

Click on a country on the map alongside for current information.

The partners in the MARC project are EDCTP (The European & Developing Countries Clinical Trials Partnership), COHRED (the Council on Health Research for Development) and the University of KwaZulu-Natal (UKZN) – in particular, the South African Research Ethics Training Initiative (SARETI) located in the School of Psychology of the UKZN in Pietermaritzburg, South Africa. Aspects of the project are supported by a grant from Pfizer.

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