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Special Regulatory Issues in Africa

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Sensible Guidelines Meeting

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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

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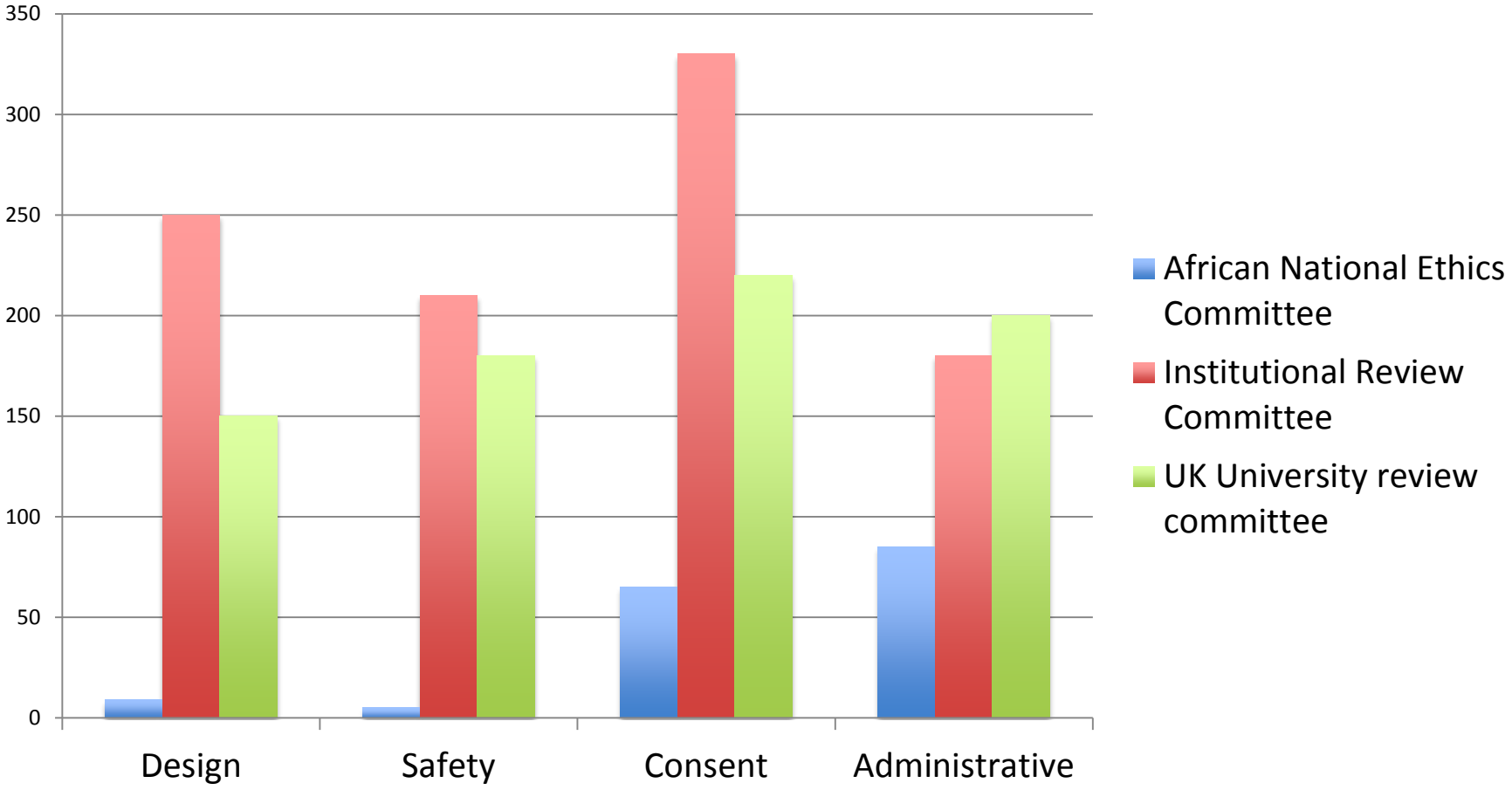
- Old systems – paper heavy. Difficult for local investigators
- Burdensome reporting requests
  - Requesting all SAEs, meaningless & overwhelming, acting as DSMBs.
- One-size-fits all review. Lack of differentiation or understanding of minimal risk, social science etc. Monitoring ….. Rapidly growing 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Preliminary unpublished pilot data.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

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- 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