

DEFENDING THE INDEPENDENCE OF RESEARCH ETHICS COMMITTEES

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REASA WORKSHOP

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Outline

- Why independence?
- Sources of threat to REC independence
- Possible ways of ensuring REC independence

Caveat: **these are my own reflections**

Guidance	Text
<p>CIOMS ‘International Ethical Guidelines for Biomedical Research involving Human Subjects’ (2016)</p>	<p>‘Research ethics committees must be formally established and given adequate mandate and support to ensure timely and competent review according to clear and transparent procedures.... Research ethics committees must have mechanisms to ensure independence of their operations. Guideline 23</p>
<p>World Health Organization (WHO) ‘Guidelines for Good Clinical Practice (GCP) for trials on pharmaceutical products’ (1995)</p>	<p>‘Prior to its commencement, the investigator must ensure that the proposed clinical trial has been reviewed and accepted in writing by the relevant independent ethics committee(s)’. Paragraph 4.9</p>
<p>International Conference on Harmonization (ICH) ‘Harmonised Tripartite Guideline. Guideline for Good Clinical Practice’ (1996)</p>	<p>‘A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion’. Paragraph 2.6</p>
<p>UNAIDS ‘Ethical Considerations in HIV Preventive Vaccine Research’ (2000)</p>	<p>‘HIV preventive vaccine trials should only be carried out in countries and communities that have the capacity to conduct appropriate independent and competent scientific and ethical review’. Guidance Point 6</p>
<p>WHO ‘Operational Guidelines for Ethics Committees that Review Biomedical Research’ (2000)</p>	<p>‘States should promote, as appropriate, the establishment of research ethics committees that are independent, multidisciplinary, multi-sectoral, and pluralistic in nature. Research ethics committees require administrative and financial support’. Paragraph 3</p>

WHO Operational Guidelines for RECs

- RECs should provide independent, competent, & timely review of ethics of proposed studies
- In their composition, procedures, & decision-making, RECs need to have **independence from political, institutional, professional, and market influences**
- RECs need to demonstrate competence and efficiency in their work

Independence of RECs

- Independence of RECs critical to ensure that assessments or reviews they carry out are fair, free from influence
- Independence of RECs helps to build trust and confidence
- Independence of RECs gives them credibility & legitimacy

Independence of RECs

- Independence of RECs occur at 2 levels: whole committee & individual members
- RECs decisions should not be influenced
- Each REC member must think independently
- A REC member should not have a personal interest in the research being assessed
- Membership into a REC should be refused when independence cannot be assured

Sources of Threat to REC Independence

- Governments
- Institutions
- Sponsors
- Researchers
- REC members
- Other RECs
- Inadequate financing

Government

- Repressive societies RECs may be understood as agents of state: prioritizing protection of state interests over research participants
- Governments may influence REC decisions to approve or not approve a study
- Government may be interested party e.g. HIV treatment drug developed locally
- Study not acceptable to govt. – MSM etc.
- RECs check with govt. before approving study



" They're all involved in the decision-making process. "

Institution

- Being institutional – work for institution's interest
- Appointment of members made by institution
- Not approving study may have consequences
 - ✓ Grant (financial)
 - ✓ Staff researchers (visibility, ranking etc.)
- Head of Institution may be a researcher with own research interests



Welcome to the Team. Remember, if you follow the University Motto, you'll do fine...



"I WOULD HAVE BEEN MORE DECISIVE, BUT I COULDN'T
DECIDE IF THAT'S WHAT YOU WANTED."

Sponsor

- Interested in their study being approved
- Funding of study by a funding agency
- Investigational product testing for registration
- May genuinely want to expedite the process as delays are too costly
- RECs must keep a safe distance from Sponsors

Researcher

- Well respected authority in the subject
- Desire for publications
- Desire for promotion
- Academic competition
- Student supervision
- Research teams – when am not the PI but a member of the team



"THERE'S JUST SO FAR YOU CAN GO WITH ETHICS,
AND THEN THE REAL WORLD KICKS IN."

REC members

- REC members busy, review proposals at no cost
- No remuneration may lead to delays or to inadequate reviews
- But, payment may compromise independence
- Often limited no. of people available with time & expertise required to be effective REC members
- Prospective reviewers with appropriate scientific background may be involved in the research, and thus have a potential conflict of interest

Other RECs

- In collaborative research once research has been reviewed in the sponsor's country, some RECs in developing countries may feel under pressure to concur with the opinion of the REC in sponsor's country particularly when reviewing research of which they have limited experience
- Failure to approve study by developing country REC will lead to study not being funded

Inadequate finances

- In developing countries, RECs may have access to only limited financial support
- Although costs of running RECs in developing countries is much lower, it is still a significant burden on limited resources
- To meet the financial costs, some RECs receive regular funding from government, donors etc
- This may compromise their independence

Ensuring the independence of RECs in developing countries

Possible solutions

- Institutions provide adequate funds to RECs
- Training of Institutional leaders, REC members
- SOPs to address independence e.g. funding from Sponsors, Pharmaceuticals etc.
- Legal framework to prevent Government from interfering with RECs
- Transparent procedures for appointing REC members

Possible solutions

- Strict requirements for REC membership
- Clear procedures for dealing with potential conflicts of interest
- Clear sanctions for REC members found to have been influenced in review of a proposal
- **? Whistle blowers - the case of a clinical trial in Kenya**

FOR SOME PEOPLE, THERE'S
ONLY ONE TIME THEY GIVE
ANY THOUGHT
TO ETHICS.

WHEN'S
THAT?



WHEN THEY GET
CAUGHT.





Thank You
for
Listening...
any
questions?