

How human rights, health law, and the judiciary can enhance protection of human participants in biomedical research: lessons from South Africa

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OVERVIEW

(a) Three examples of how legal instruments and the judiciary can protect the interest of research participants:

- Irrational decision to conduct pilot study to collect evidence when evidence already existed
- Irrational withholding of approval for clinical trial
- Illegal clinical trial reported to government but no action taken

(b) Other important laws

(c) Important factors to ensure protection of research participants

(1) Irrational decision to conduct pilot study to collect evidence on feasibility of drug when evidence already existed

- ❑ The government had restricted the provision of nevirapine to only eighteen test sites, claiming it was doing research to assess the feasibility of using this drug.
 - ❑ AIDS treatment lobby group, the TAC, demanded that this programme be instituted nationwide so that all women and children could benefit from treatment.
 - ❑ 2002: The Constitutional Court ruled that the government's policy was unreasonable and ordered nationwide roll-out of the drug.
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(2) Irrational withholding of approval for clinical trial

- o In December 2004, SA's drug regulatory authority, the Medicines Control Council (MCC) rejected an application by the University of KZN for the approval of a clinical trial which would involve the administration of Nevirapine as a prophylactic to babies in order to prevent the transmission of the HIV virus from HIV infected mothers to their infants during breast feeding.
 - o Appeal made to MCC's appeal committee
 - o Appeal committee rules in favour of investigator; MCC refuses to abide by decision
 - o Matter to taken to court
 - o 2007: Court orders MCC to approve study; leave to appeal denied
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(3) Illegal clinical trial reported to government but no action taken

- ❑ TAC learns of illegal clinical trial being conducted in poor black township;
 - ❑ Reports matter to MCC and the Minister of Health; no action taken by either.
 - ❑ TAC takes matter to court
 - ❑ 2008: Court orders Minister of Health to stop the trial
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Other important research-related provisions in law that protect research participants

□ South Africa's Constitution (1996)

- Section 12: Freedom and security of the person
 - "Everyone has the right to bodily and psychological integrity, which includes the right to make decisions concerning reproduction; to security in and control over their body; and not to be subjected to medical or scientific experiments without their informed consent.
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Other important research-related provisions in law that protect research participants

National Health Act (2003)

- Informed consent
 - Research on children
 - but overprotection can also harm the interests of research participants
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Conclusion

Important factors to ensure protection of research participants

- ❑ Specific laws that protect research participants
 - ❑ Active civil society and activist scientists
 - ❑ Independent, impartial, and competent judiciary
 - ❑ Respect for the rule of law on the part of government
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