Double standards in research ethics

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Globalization of research

- Increasing volume of international research
  - Collaborative research that address Types I and II diseases
  - Increased funding for Type III diseases
- Increased awareness of the need to apply sound ethical principles to the conduct of research throughout the world
- Outsourcing of research to developing countries to take advantage of lax regulatory environment and lower costs
- Increased risk of exploitation of citizens of low-resource countries
- Need to develop research ethics programs and regulatory framework
Research misconduct in developing countries

- Higher prevalence in developing countries because of
  - Socioeconomic disparity between researchers and participants
  - Between sponsoring agencies and countries on one hand and host country/researchers on the other
  - High level of illiteracy
  - Ethnic and religious diversity
  - Colonial experience
  - Sociopolitical environment
  - Gender issues
  - Corruption
  - World view that shapes knowledge and perception of research
What is unique about doing research in Africa

- Focus on human identity and concepts of personhood
- Cultural traditions that impact belief about science and research
- Low literacy rates
- High rates of structural inequalities and poverty
- Political and ethnic tensions
- Weak health care infrastructure
What are the implications of these differences for research ethics

- Who is included and who is excluded and why
- Who benefits and who carries the risk
- Is the risk excessive
- Risk of exploitation
- Implication for the health needs and burden of the community
- Affordability of the products of research
Consequences of not conducting research in Africa

- As global capacity for solving health problems increases, that of Africa will reduce
- Africa will be denied the benefits of health research
- Potential for exploitation of the health care problems arising in Africa to other parts of the world
Stakeholders

- International collaborative research in Africa involves many stakeholders
  - Funding agencies and development partners
  - International researchers
  - Local researchers
  - International ethics committees
  - Local ethics committees
  - Participants – as individuals and as communities
Trust as the central ethical principle

- **Transparency** –
  - In description of research goals/risks, sharing of benefits and risks, knowledge and skills with local collaborators

- **Relevance**
  - Social value, health needs and disease burden

- **Creativity**
  - In approach to problems

- **Sustainability**
  - To maintain collaborations and ensure attainment of goals

- **Transformation**
  - Reciprocity and bilaterality
Research ethics as a meme

- Social Darwinian approach to understanding differences in fidelity to highest standards of health research ethics
- Meme as “social genes” that are under selection pressure
- Fitness determines survival
- Ethics regulatory agencies seek to promote best practices
Nigeria’s health research ethics regulatory infrastructure

- National Health Research Ethics Committee has been set up with the following membership:
  - Chairman appointed by Hon. Minister of Health
  - Membership representing Law, Pharmacy, Medicine, Nursing, Community Health Workers, Christians, Muslim, Researchers and 3 other persons
  - Ex-officio members from Ministries of Education, Environment, Women’s affairs, Agriculture etc.
    NAFDAC, NUC
Functions of NHREC

- Determine guidelines for the functioning of health research ethics committees
- Register and audit health research ethics committees
- Set norms and standards for conducting research on humans and *animals*, including norms and standards for conducting *clinical trials*
- *Adjudicate* in complaints about the functioning of health research ethics committees and hear any complaint by a researcher who believes that he has been discriminated against by a health research ethics committee
Functions of NHREC

- Refer to the relevant statutory health professional council matters involving the violation or potential violation of an ethical or professional rule by a health care provider
- Institute such *disciplinary action* as may be prescribed against any person found to be in violation of any norms and standards, or guidelines, set for the conduct of research under this Act
- Advise the Federal Ministry of Health and State Ministries on any ethical issues concerning research
Highlights of the Nigerian code

- Definition of research as systematic investigation designed to generate generalizable knowledge
- Identification of activities exempted from research and allocation of the power of determination to HREC, for example
  - De-identified publicly available data
  - Innovative medical practice
  - Audit and Quality Assurance studies
Highlights

- Registration of HRECs to create a National Database and Categorization of HRECs
  - HRECs being audit programs must have direct lines of communication with heads of proposing institutions
  - HREC members must complete NHREC approved training programs in research ethics
  - Institutions must provide HRECs with space, office, staff and infrastructure to enable them do their work
  - Institutions shall provide coverage of HREC members from liability
Highlights

- HREC membership must always include a lawyer
- Institutions can have more than 1 HREC

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Highlights

- Provision of liability coverage for members of HRECs
- HRECs shall include at least 1 lay person
- HREC members are bound by a perpetual code of confidentiality
- HRECs shall have continuing oversight of research – a review shall be conducted at least once a year or during the life of the study whichever is shorter
- NHREC shall categorize HRECs and define limits of activities
- Clear processes for expedited review, exception and amendment
Highlights

- HRECs can co-opt members
- Encourages researchers to be invited to HREC meetings
- Sets time limits for decision on research applications – 90 days
- All records relating decision must be kept for at least 10 years
- Clear process for suspension, revision of suspension and termination of research
- Clear adjudicatory mechanism to NHREC
Highlights

- Review of multi-institutional research
  - Procedure of 3 or fewer and more than 3 collaborating sites
  - Options for research review
  - Opportunity for central research review
  - Requirement for sharing ethics review from different ethics committees
  - Requirement for Materials Transfer Agreements, Benefits sharing, IPP, patent and other tangible and intangible benefits’ sharing
Highlights

- Only applicant(s) with qualification(s) and background sufficient to serve as principal investigator(s) and based in an institution in Nigeria that is capable of carrying out the research shall apply for review of research.

- HREC may adopt the result of review by another HREC rather than conduct a fresh review.

- NHREC may review research:
  - Nationwide research or more than 3 sites
  - Research referred to NHREC from HREC
  - There is no HREC in an institution and no collaborative agreement with an institution that has one.
Highlights

- NHREC review of research
  - Mandating review by a HREC anywhere in the country as the HREC of record
  - Constituting an *ad hoc* HREC
  - Constituting itself into a HREC
    - Oversight will still be provided by local HRECs

- Incorporation of ethics guidelines in code for guidance during research review

- Ethics guidelines goes beyond the “4” principles to accommodate recent advances in ethics and emphasizing the role of community, trust, truth telling, GCP and GLP
Highlights

- HREC may charge fees
- Informed consent documents must be legible and not more than 8 pages long
- All consent activity must be documented
- HREC must organize training for members and the community of the proposing authority
- HRECs may offer consultation services to researchers
- HRECs will demand that researchers submit evidence of recent training in research ethics
- NHREC will exercise oversight functions on HRECs
Highlights

- **HRECs have disciplinary and compliance powers**
  - Include suspension of research
  - Termination of research
  - Recommendation to NHREC for disciplinary action

- **NHREC disciplinary powers**
  - Debarment of researchers
  - Imposition of disciplinary measures
  - Report to police
  - Report to other ethics regulatory agencies in case of international collaborative research
Current activities

- Code has been released and can be found at [http://www.nhrec.net](http://www.nhrec.net) where you have the opportunity to either read or download it.
- Comments can be sent to secretary@nhrec.net, deskofficer@nhrec.net or chairman@nhrec.net.
- Sub-codes for children, pregnant women, prisoners, people living with AIDS, and others are in development.
- Standard Operating Procedures (SOPs), prototype MTA, consent forms etc are available on NHREC website.
Website and contact information

West African Bioethics Training Program
Acknowledgment

- Professor Adebamowo and the West African Bioethics Training Program are supported by NIH Research Grant No. D43 TW007091 funded by the Fogarty International Center and the National Human Genome Research Institute.