Developing and applying integrity policies in a global context

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Outline

► Research integrity - part of the definition of science
► Non-compliance with “ethical standards,” and “offshore research”
► Grey areas
► Exploitative relations
► Creating “no man’s land”
► Recommendations

Notes
Scientists enjoy a special *covenant* with the public as the hunters of new "*truths*"

This covenant is

- underpinned by limits and guidelines
- predicated upon their *honesty*
Research integrity should entail complying with the relevant international, national and institutional “codes of conduct and ethical standards.”

These may be

- legally binding
- made compulsory by funding, approval, licensing or other agencies.

Deliberate evasion of such regulations should be considered violation of research integrity.
in non-academic research as well..

- In industrialized countries, most scientists are not employed by academic institutions
- Most **basic research** funded by government agencies
- Huge amount of **applied research** conducted by industry
- Pharmaceutical industry occupies a giant share of research: has left arms manufacture behind in profits.
- **Contract Research Organizations (CROs)** taking over drug trials from pharmaceutical companies
  - 20% of drug research and clinical trials outsourced by US industries to “offshore” companies (in some pharma companies more than 50% of drug trials)
  - to Africa, Latin America, Eastern Europe, India..

Regulatory instruments for medical and pharmaceutical research

► International “ethical standards”
  - International Code of Medical Ethics (WMA, 1949)
  - Declaration of Helsinki (WMA, 1964; last revision 2004).
  - UN declarations, if nationally ratified, legally binding; “customary international law.”

► European Parliament and the Council of the European Union
  - Convention on Human Rights and Biomedicine
Regulatory mechanisms: approval, certification

► International and national agencies
  - FDA (does not require oversight of offshore data, accepting applications with solely overseas data)

  - EMEA (European Medicines Agency)
Regulatory mechanisms: funding

► European Commission funding
  ▪ conditional on compliance with EU norms, and with institutional and national ethics committee reviews. (However most national “standards” not binding but voluntary).

► US Federal government funding, NIH
  ▪ conditional on compliance with US standards (independent of venue). Industries and CROs not bound by funding constraints.
Grey areas: confirmatory studies

Repeating drug trials in different countries: Research or Re-search?

- Justification: different populations or conditions
- Commercial interests: an advertising gimmick?
- Waste of resources
- Less than the truth? Medical doctors/ test subjects given to believe they are participating in research?
Gray areas: genetic research

► Both legal and ethical problems: Pluralism in laws/guidelines even within the same country (US case) or research area (EU)

► evading local constraints by moving to a different locale - the “right” thing?

- basic research: Embryo Stem Cells
- applications / informal research: GM crops
  - huge impact on biological diversity, dependence on few industrial corporations for seeds, restructuring the agricultural sector with strong social impact
Cutting corners? Or Illegal Research?

► Drug trials time consuming and expensive
  ▪ National ethics committees catching up

► Exploiting the desperately needy?

► Informed consent – “treatment” or trial?

► Amendments to the Declaration of Helsinki
  ▪ “access to the best proven...treatment identified by
  the study” → “identification of post-trial access to
  appropriate care.”
  ▪ use of placebos – only in absence of proven therapy
  → “compelling and scientifically sound methodological
  reasons”
No man’s land of state security

► Neurobiological research
  ▪ brain imaging for “fingerprinting”
  ▪ new devices affecting thought processes?
  *The Future of the Brain,* Steven Rose

► Danger of continued use of humans in the military for medical experiments involving biological weapons or prophylactics
  *Undue Risk: Secret State Experiments on Humans,* Jonathan D. Moreno

Recommendations

► International regulatory agencies and those in the home country should
  ▪ ensure compliance with international standards also in research conducted outside the mother country
  ▪ assist in setting up effective monitoring within the host countries or institutes (Example: Pasteur Inst./Turkey, 1994)
  ▪ curb unacknowledged research

► Encourage education in research integrity and science ethics
notes

1. Slide 5: More than 20% drug research outsourced to overseas companies.
   “14.5 billion USD budget for outsourcing ..”
   “(in some giants > 50%)” Note 27 of Chapter 1 of Shah (2006), to Julie Smith,

2. Slide No. 6.
   James Lavery, June 2004. The challenge of regulating international research with
   human subjects. Science and Development network, policy briefs.
   http://www.scidev.net/dossiers/index.cfm?fuseaction=policybrief&dossier=5&policy=5

3. Slide No. 7. FDA accepting applications with solely overseas data [provided by the CROs].

4. Slide No. 7. “Safe Oversees Human Testing Act” requiring home-country oversight of
   offshore drug tests did not pass US Congressional committee, 2006. see
Also see The Columbia University Medical Center site.

6. Slide No. 11 National ethics committees catching up.
Good examples, see [http://www.nhrec.net/nhrec/](http://www.nhrec.net/nhrec/)
NHREC (National Health Research Ethics Committee, Nigeria) now has United States Federal Wide Assurance

NHREC now has United States Federal Wide Assurance so that when the NHREC functions as an ethics committee according to the National Code and reviews protocols, such protocol review meets the requirements of United States Federal Government funded research.
Also citizen’s initiatives being set up: Nigeria Health Watch. (See [http://nigeriahealthwatch.blogspot.com/](http://nigeriahealthwatch.blogspot.com/))
notes, ctd.

7. Slide No. 10. Exploiting the needy/ “treatment” or “trial”? It was not made clear to the children or the families that the administration of Trovan (reg.) to the children was an experimental trial, rather than the proven antibiotic available, and in fact being administered in the other health outposts. [http://www.wsws.org/articles/2007/jun2007/pfiz-j04.shtml](http://www.wsws.org/articles/2007/jun2007/pfiz-j04.shtml)

8. Slide No. 12.
