CIOMS ethical guidelines for Biomedical Research

What is in for patients?

David Haerry, EATG, 30 January 2017

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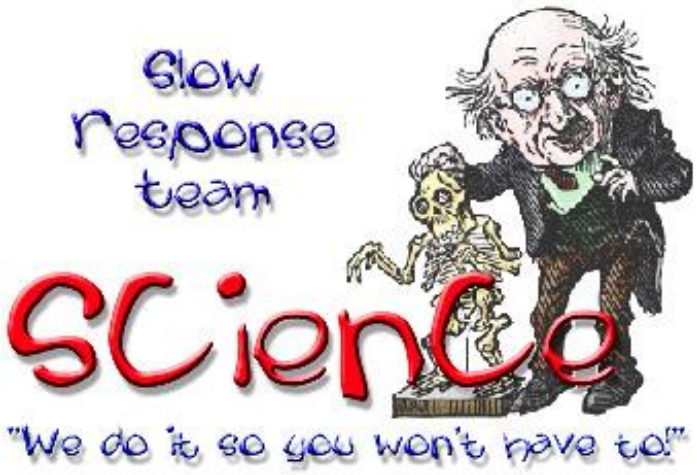
Scientific and social value – G1

- Ethical justification for doing health-related research with humans is scientific & social value:
  - Prospect of generating knowledge & means to protect & promote people‘s health
  - May be difficult to quantify, but generally grounded by 3 factors:
    1. Quality of the information to be produced
    2. Its relevance to significant health problems
    3. Its contribution to the creation or evaluation of interventions, policies, or practices that promote individual or public health

Emphasis on social value is new



Potential individual benefits & risks – G4

- To justify imposing any research risks on participants in health research, the research must have social and scientific value
- Potential individual benefits and risks of research must be evaluated in a two-step process.
  1. Potential individual benefits and risks of each individual research intervention or procedure in the study must be evaluated
  2. Aggregate risks and potential individual benefits of the entire study must be assessed and must be considered appropriate

Potential individual benefits & risks must also be evaluated in consultation with communities to be involved in the research

- Community values & preferences are relevant in determining what constitutes benefits & acceptable risks

Caring for participants health needs – G6

- Clinical trial context: adequate provisions for addressing participants' health needs during research needed, including for the transition to care when research is concluded.
- The obligation to care for participants' health needs is influenced, by extent to which participants need assistance & established effective care is available locally

- Continued access to beneficial interventions until available in public health system
- Important: consultation with relevant stakeholders (local health authorities, insurances, participants' community)

Community engagement – G7

- Important to address increased need to engage communities from planning to implementation phase of research
- Engagement needs to be proactive & sustained
- Engagement must happen at earliest opportunity, at planning stage

- Expresses respect for participants & traditions/norms they share
- Valuable for research translation into outcomes of clinical relevance AND meaningful for patients

Biological materials & data – G11, G12

- Quantum leap from research activity in individual projects to activities around research infrastructures (biobanks, databanks) ongoing
- Much needed guidance – poses many ethical challenges
- Current static informed consent model insufficient
- Need to authorise use of data, not its collection
- Adequate governance systems to substitute individuals loss of control over data / biological material
- Especially important as complete anonymisation increasingly difficult

Research involving vulnerable persons & groups – G15

- When vulnerable individuals and groups are considered for recruitment in research, researchers / ethics committees must ensure that specific protections are in place to safeguard rights & welfare of individuals & groups in research conduct

- Past: children and incompetent individuals explicitly labelled as vulnerable.
- Group approach to vulnerability no longer appropriate (routine exclusion of certain groups from research, has exacerbated knowledge gaps.
- Group approach could leading to underprotection because not addressing different ways in which people can be vulnerable (e.g. illiterate woman, low-resource setting, study on domestic violence)

Women as research participants – G18

- Women have been excluded from much health-related research because of their child-bearing potential (thalidomide scandal)
- Ethical dilemma - misunderstood vulnerability leading to higher risks in real life
- New: Women must be included in health-related research unless a good scientfic reason justifies their exclusion
- If potentially hazardous to foetus or woman if becoming pregnant, guarantee access to pregnancy tests, effective contraceptive methods before & during the research & to safe, legal abortion

Pregnant & breastfeeding women – G19

- Women have been excluded from much health-related research because of their child-bearing potential (thalidomide scandal)
- Ethical dilemma - misunderstood vulnerability leading to higher risks in real life

- **New** Women & breastfeeding women taking medication – therefore: Women must be included in health-related research unless a good scientfic reason justifies their exclusion
- If potentially hazardous to fetus or woman if becoming pregnant, guarantee access to pregnancy tests, effective contraceptive methods before & during the research & to safe, legal abortion

Use of data from online environment & digital tools – G22

- Impact of digitalisation on health research
- Who is collecting what kind of information, where and when
- Access to collected data

- People should be informed about purpose and context of data use, privacy & security measures & limitations of these measures despite safeguards

Requirements for establishing research ethics committees – G23

- Committees must include multidisciplinary membership in order to competently review the proposed research
- REC should have a clear procedure for researchers or sponsors to make legitimate appeals against REC decisions
- Membership normally must include physicians, scientists and other professionals (research coordinators, nurses, lawyers, and ethicists), as well as community members or representatives of patients' groups who can represent the cultural and moral values of study participants
- Ideally, one or more members should have experience as study participants since there is growing recognition that knowledge gained through personal experience as a participant can supplement professional understanding

To conclude


WELL-THIS MAY BE A REVOLUTIONARY PILL...
BUT I'M NOT SURE THE PUBLIC WILL BE WILLING TO SWALLOW IT...
djam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