Informed consent: issues arising

Ruth Chadwick
Director, Cesagen

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD
E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

Outline

- Informed consent and harmonisation
- What counts as ‘informed’?
- What counts as consent?
- Special populations
- The impact of genomics
- Cultural issues

Informed Consent

- Why important?
- International standard but affected by context
- Not only cultural context but type of research

International debate and relation to social context

- Standardisation and harmonisation
- Issues of multi-site research and cross-border transfer

Harmonisation

- **Collective performance, as in singing the same text to different but interdependent vocal lines, can be regarded as the musical correlate of civilized democracy (Whittall, 2002)**
- What is the scope for variation?

Process: consent and the consent form

- "Consent" should not be *equated* with a signed consent form
- Consent forms : evidence that informed consent has been obtained:
  - Providing structure to the consent process
- Empirical research shows limitations of recall – so what is possible?

What counts as “informed”?

- Informed consent requires that research subjects understand relevant information, not merely that they are presented with it.
- What information must the research subject have?
  - Background information on the research
  - Details of what exactly the subject’s involvement will be

"Personally, I wouldn't have signed it."

What counts as “informed”?

- Details of risks related to participation, whether physical, social or psychological (which may also differ between contexts, e.g., stigmatisation)
- What benefits the subject may receive from participation – or not
- What will happen to the data that is collected
- What the consent process is and how it works, especially the voluntary nature of it.
- Withdrawal possibilities
- Future contact?

What counts as “informed”?

- A number of factors might affect information giving and recall:
  - The terminology used by the researchers and research subjects
  - The understanding and world view of research subjects

What counts as “consent”?

- A number of factors may undermine the voluntariness of consent:
  - Power imbalance between researcher and research subject
  - Inflated hopes of benefits arising from research
  - Lack of knowledge of alternatives

What counts as consent?

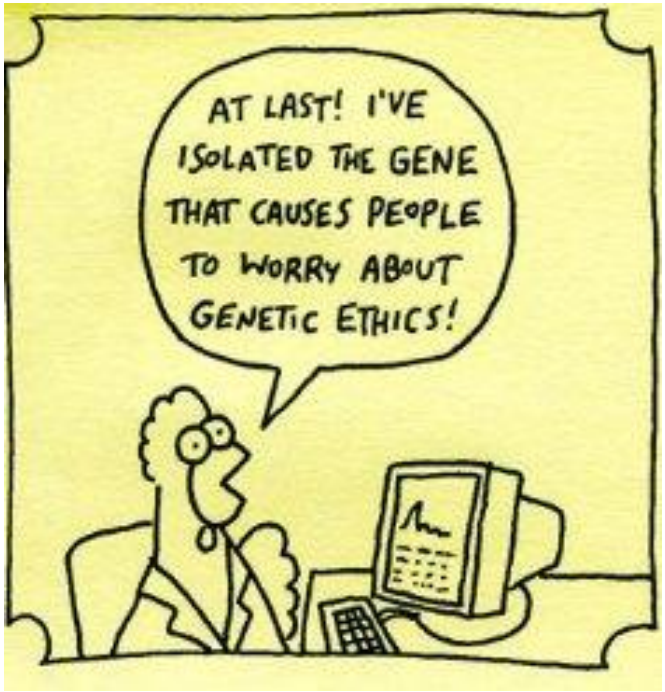
Issues of power differentials in the socio—cultural context

Special populations

- Some groups may be particularly vulnerable and ought to be treated with special care.
- Children
- Adults with a diminished capacity to consent
- The need to protect these groups from the harmful effects of research must be balanced against the potential harm from a failure to conduct research.

Current issues in genomics and consent

- Narrow consent [starting point]
- Broad consent [importance for genomic research]
- Open consent
- Dynamic consent



Broad consent

- E.g. Consent to be in a biobank or not
- Consent to a framework for future types of research

Broad consent in H3Africa?

- Consent needs to be broad enough to allow for future and secondary uses of data, in line with the opportunities to use such data in advancing knowledge to improve health

Argument for ‘open consent’

- Traditional informed consent does not work in biobanking
- Hence development of broad consent
- Privacy difficult to guarantee now
- Need for openness about that

Privacy no more…

Developments in both medical informatics and bioinformatics show that the guarantee of absolute privacy and confidentiality is not a promise that medical and scientific researchers can deliver any longer

(Lunshof, Chadwick et al, *Nature Reviews Genetics* April 2008)

Group privacy

- Whether it is based on genetic or other traits, conventional individual privacy ... does not work in the case of ... generalisations about groups in which the individual profile is indiscernible from the group profile.

Open consent

- Research participants expect that:
  - Their data could be included in an open access public database
  - No guarantees regarding privacy etc
  - Participation does not benefit participants in any way

Dynamic consent

- Keeping in touch with the study population, using IT
- Over-burdensome?

Cultural Issues

- Perceptions of health, inheritance, risks, benefits
- Scientific literacy and willingness to participate
- Community consent
  - Is individual autonomy suitable as a basis for consent in a particular cultural context?
- “All or nothing” consent is useful in biobanking, but may risk excluding whole groups. Cultural awareness in study design may help to ameliorate such risks.

Questions

- What do you see as the main practical and ethical challenges for consent in your study population?

- What do you see as the processes that could be put in place to address them?