

Revision of the Declaration of Helsinki: Biobanks

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Biobank - Definition

"A stored collection of genetic samples in the form of blood or tissue that can be linked with medical and geneological or lifestyle information from a specific population, gathered using a process of generalised consent"

Wolf, et al., 2012



Varieties of Biobanks

- Prospective, recruitment of volunteers
- Linking existing data bases and tissue banks
- Disease specific





Why are Biobanks proliferating now?

Large epidemiological cohort studies are not new – BUT:

- Availability of huge numbers of genetic markers, from Human Genome Project
- New capacity to analyse very large numbers of biological markers
- Modern IT facilitates large and complex follow-up studies



Why do Biobanks warrant unusual consideration?

- **4** Very broad range of potential research
- Very broad range of future health information will be captured
- Very large scale, many participants, necessarily somewhat impersonal
- Broad range of researchers may access the data
- **4** Data will be available for very long time
- Increasing pressure to link internationally
- Consent has to be broad as future uses cannot be specified



How Can Biobanks Serve the Public Good?

- **4** Health as an international communal enterprise
- People not profit
- **4** How and who to define priorities?





Key Ethical Issues

Harm and Benefit

Consent

Feedback

4 Stewardship





Harm 3 types of possible harm

Physical

Psychological

4 Informational





Consent

Broad? Blanket? Generic? Implied?

- Extendable and Rescindable?
- Renewable? (How often?)
- Levels of withdrawal
 - No further contact
 - No further use or access
 - Total withdrawal (samples destroyed)



Feedback (1)

Excellent general communication essential to show enterprise worthwhile.

Feedback of individual health results from baseline tests (eg. BP) seems reasonable

But what of incidental findings and research results relevant to participants?



Feedback (2) Points against feedback of individual results later in project

- Huge volume of data on each person, genetic and phenotypic, applied to many different projects in aggregated form
- Unethical to release data which cannot be interpreted, without individual explanations and interpretations - genetic counseling?
- Most data will be meaningless until research completed
- Quality standards of testing in research setting below those of clinical laboratories



Feedback (3)

Arguments for Selective Feedback

If findings are: analytically valid, reveal substantial risk and clinically actionable

- If affected person wishes
- Relevance to others offspring, relatives



Stewardship

- Security Mechanisms
- Resisting Inappropriate Access
- Best Use of Depletable Resource



Best Use of Resource

The main ethical issue of the future
How to ensure fair usage?
Who decides?
Participants?
Researchers?
Governance Bodies?





Conclusions – Points to Consider in Revision of Helsinki Declaration

- Revision of Consent Provisions? (paragraphs 14 and 24)
- **Governance Issues Beyond Initial Ethics Approval**
- Appropriate Access and Fair Distribution of Benefits
- Should Declaration Comment on Feedback?



References

Campbell AV. The ethical challenges of genetic databases: safeguarding altruism and trust. *King's Law Journal* 18(2); 227-246 (2007)

Wolf, SM, et al. Managing incidental findings and research results in genome research involving biobanks and archived datasets. *Genetics in Medicine*, 14 (2012), 361 - 384