Donors and Good Practice

Research Integrity Seminars
8th November 2010
1. Informed Consent

- The overall plan and the possible risks and benefits of the research project;
- Before being asked to consent to participate in a research project, the persons concerned shall be specifically informed, according to the nature and purpose of the research;
- Of the nature, extent and duration of the procedures involved, in particular, details of any burden imposed by the research project.

WMA Declaration of Helsinki amended 2008
Difficulties with Informed Consent

- Designed for physical harm and ‘one project’ research
- Is required at the beginning of the research process and all the details of the research must be specified at the time of collection
- Difficult to inform donors at the time of collection of all the research uses and who will use it
  - Data shared and technology changing
- Difficult to anticipate all the informational risks
Anonymised Tissue

• Certain RECs may now grant ‘generic’ approval to ‘research tissue banks’ (RTBs)
  • 2006 NRES Standard Operating Procedures for RECs
  • Permits a range of research to be carried out within the conditions of the ethical approval
  • Do not need seek any further, project-specific REC approval
• To get generic approval, an RTB must meet various conditions
  • HTA approval
  • Ensure that samples are anonymised
Personal Information

- PIAG was replaced by the National Information Governance Board for Health and Social Care (NIGB) under Responsibility for administering Section 251 powers transferred to the National Information Governance Board on 1 January 2009.
- National Health Service Act 2006, ss 251–252
  - Allows the supply of ‘patient information’ (including identifiable information) without consent in limited circumstances.
  - Permits the common law duty of confidentiality to be set aside in specific circumstances for medical purposes.
  - Where it is impracticable to obtain consent, and where anonymised data will not suffice, for certain medical purposes in the public interest.
Good Practice?

• To tell people all that you can at the time of collection about the research planned

• Current practice is to ask for a broad consent for use of data for unforeseen research by unknown researchers in the future

• To ask consent for a research ethics committee to make decisions on behalf of the individual ‘consent for governance’

• To have appropriate governance mechanisms in place
2. Withdrawal

• Research participants should be able to withdraw from research at any time
• Is this possible?
  • Tiny samples
  • Data used in multiple research projects
  • Need to have archived datasets
Good Practice?

• Tell people that they can only withdraw from this time onward
• Previous information and sample will be retained
3. Feedback

• If it is increasingly difficult to make information anonymous
• Increased amount of information on individuals also increases the likelihood of identifying serious treatable conditions and incidental findings
  – Whole genome sequences
• Is there an obligation to feedback?
Good Practice?

• Websites to inform individuals
• Newsletters
• Management Pathways for serious treatable conditions and incidental findings
4. Maintaining Privacy
• ... subject to [certain] qualifications ... an individual’s personal autonomy makes him – should make him – master of all those facts about his own identity, such as his name, health, sexuality, ethnicity, his own image ... and also of the ‘zone of interaction’ ... between himself and others. He is the presumed owner of these aspects of his own self; his control of them can only be loosened, abrogated, if the State shows an objective justification for doing so.

• Laws LJ *Wood v Commissioner of Police for the Metropolis* [2009] EWCA Civ 414 at §21
Good Practice

• To tell participants how samples and data will be used
• Use of coding, firewalls and IT mechanisms
• Privacy Impact Assessments
• Safeguard public trust and ensure ongoing support
5. Governance Structures
Governance Structures

• Necessary for: -
  – Accountable, transparent decision-making
  – To ensure ethical and lawful research
  – Act on behalf of research participants if necessary

• Build frameworks to ensure that the ethical, legal and social issues can be addressed over time
Good Practice?

• Bodies that can make policy and decisions
  – Advisory Bodies
  – Management structures
  – Involvement of research participants

• To make sure that governance structures are appropriate and do not duplicate
Future Practice?
1. Research is Global
2. Maintaining the Chain of Trust
3. Embedding Biobanks
In Conclusion

• Biobanks should be seen as anchored in global networks
  • Develop governance systems that facilitate this
• Embed biobanks within the healthcare structure to aid translational research
• Regard donors as partners in research
  • Use new forms of technology to enable this
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- EnCoRe Project http://www.ensemble-project.info/index.html
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