Good Practice for Research Collections and Biobanks

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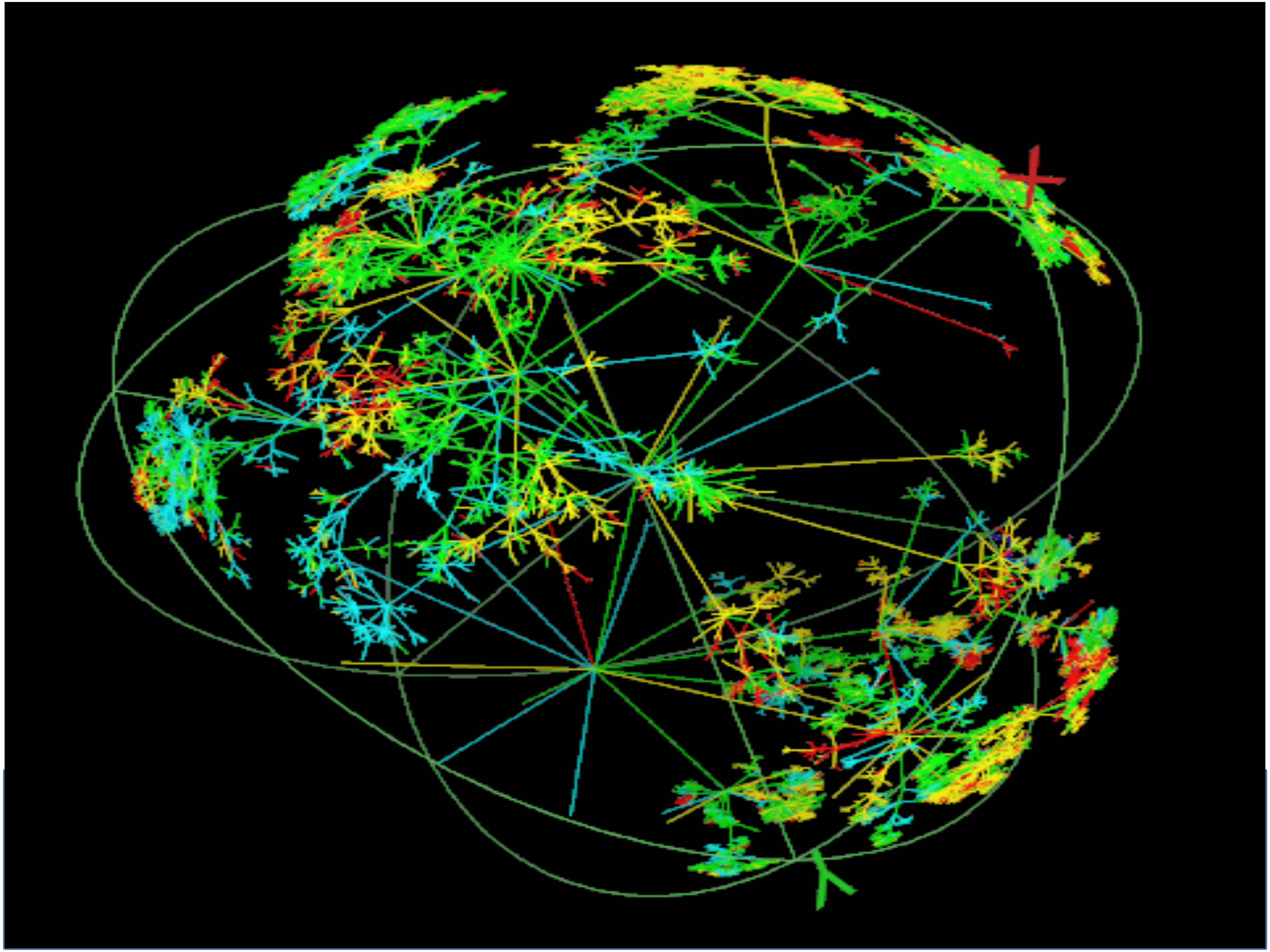
Structure of this talk

- Current Trends
- Key Issues
  - Consent
  - Withdrawal
  - Feedback
  - Governance Structures


SMEG


ATM
24 HOUR BANKING



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 research participants 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

Generic Approval

- 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

National Information Governance Board for Health and Social Care (NIGB)

- 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
- To ask for a broad consent for use of data for unforseen 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’

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?

3. Feedback

- 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. 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

In conclusion

- Wide scale data sharing and ‘networks within networks’ of research collections and biobanks are challenging many of the basic tenents of research practice
- In this talk I have addressed four keys areas and suggested possibilities for the development of best practice

Publications

- Heeney C, de Vries J, Hawkins N, Boddington P, Kaye J Assessing the Privacy Risks of Data Sharing in Genomics (accepted by *Public Health Genomics* October 2009)
- Kaye J, Boddington P, de Vries J, Hawkins N, Melham K, Ethical Implications of the Use of Whole Genome Methods in Medical Research *European Journal of Human Genetics* advance online publication 4 November 2009; doi: 10.1038/ejhg.2009.191
- Kaye J & Stranger M, (Ed) *Principles and Practice in Biobank Governance* (Ashgate December 2009)
- Caulfield T &Kaye J, Broad consent in biobanking: reflections on seemingly insurmountable dilemmas. *Med Law Inter* 2009; 10: 85–100
- Kaye J, Heeney C, Hawkins N, de Vires J, Boddington P, 2009 Data-sharing in Genomics: changing Scientific Practice *Nature Reviews Genetics* 10:5, 331-335

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