

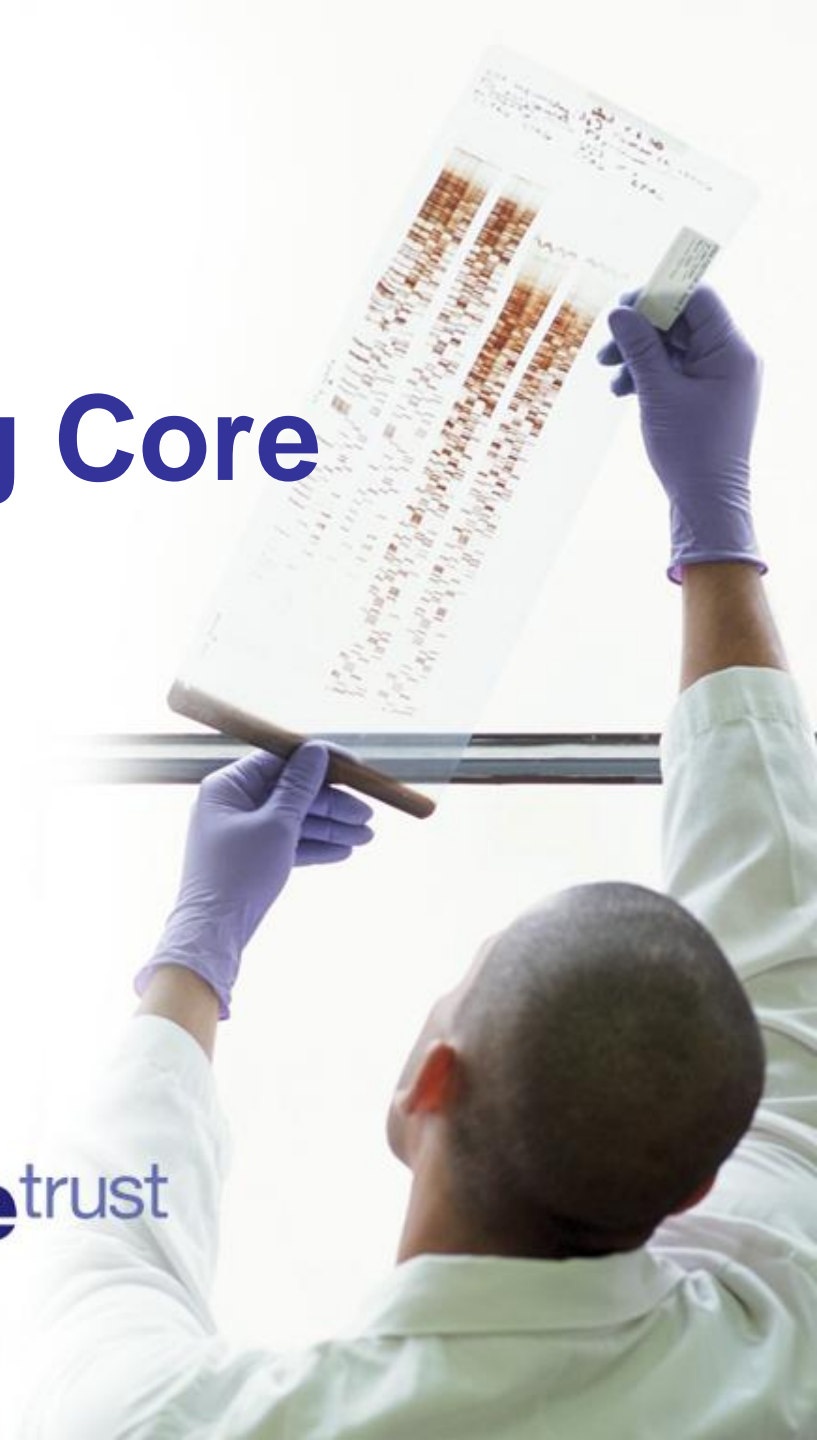
P3G Data Sharing Core

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Outline of this Talk

- 1. Where is the Core based?**
- 2. Why have a Data Sharing Core?**
 - Trends in Genomics**
 - Testing Current Research Governance Mechanisms**
- 3. What have we achieved so far?**

1. Where is the Core Based?



University of Oxford

- Department of Public Health
 - 8 research groups
 - Based in the Medical Sciences Division
 - Led by Prof. Harold Jaffe
- Transition
 - Research team Health, Law and Emerging Technologies
 - Ethox Centre led by Prof. Mike Parker
 - First Stage 30th September 2009
- Part of the Oxford Bioethics Network



Health, Law and Emerging Technologies

- To understand the relationship between law, ethics and practice in medicine
- Use socio-legal methodology, drawing on tools from sociology, law and philosophy
- Focused on practice, in order to be able to generate insights for more effective policy making
- One of the key themes of this programme is data-sharing



Projects

- The Governing Genetics Databases project (2006-2009)
- EnCoRe project (2008-2011)
- The Administrative Data Liaison Service (2008- 2011)
- Uniting Themes
 - Data sharing
 - Governance
 - Relationship between Law and Practice



1. Why have a Data Sharing Core?



1. Trends in Genomics



Changing Scientific Agenda

Focus in the scientific agenda on common diseases has led to:

- need for rich genotypic and phenotypic data of large numbers of samples
- well-characterised datasets
- establishment of biobanks but also recognition of the worth of existing collections
- Initiatives to develop common standards for recruitment, collection and access

Advances in Technology

- Advances in bioinformatics and ability to organise, interrogate and integrate datasets
- Next Generation Sequencing
 - Whole genome sequences
 - Move away from concern with DNA samples to genomic information
- Development of approaches such as Genome-Wide Association Studies (GWAS)

Open Access Policies

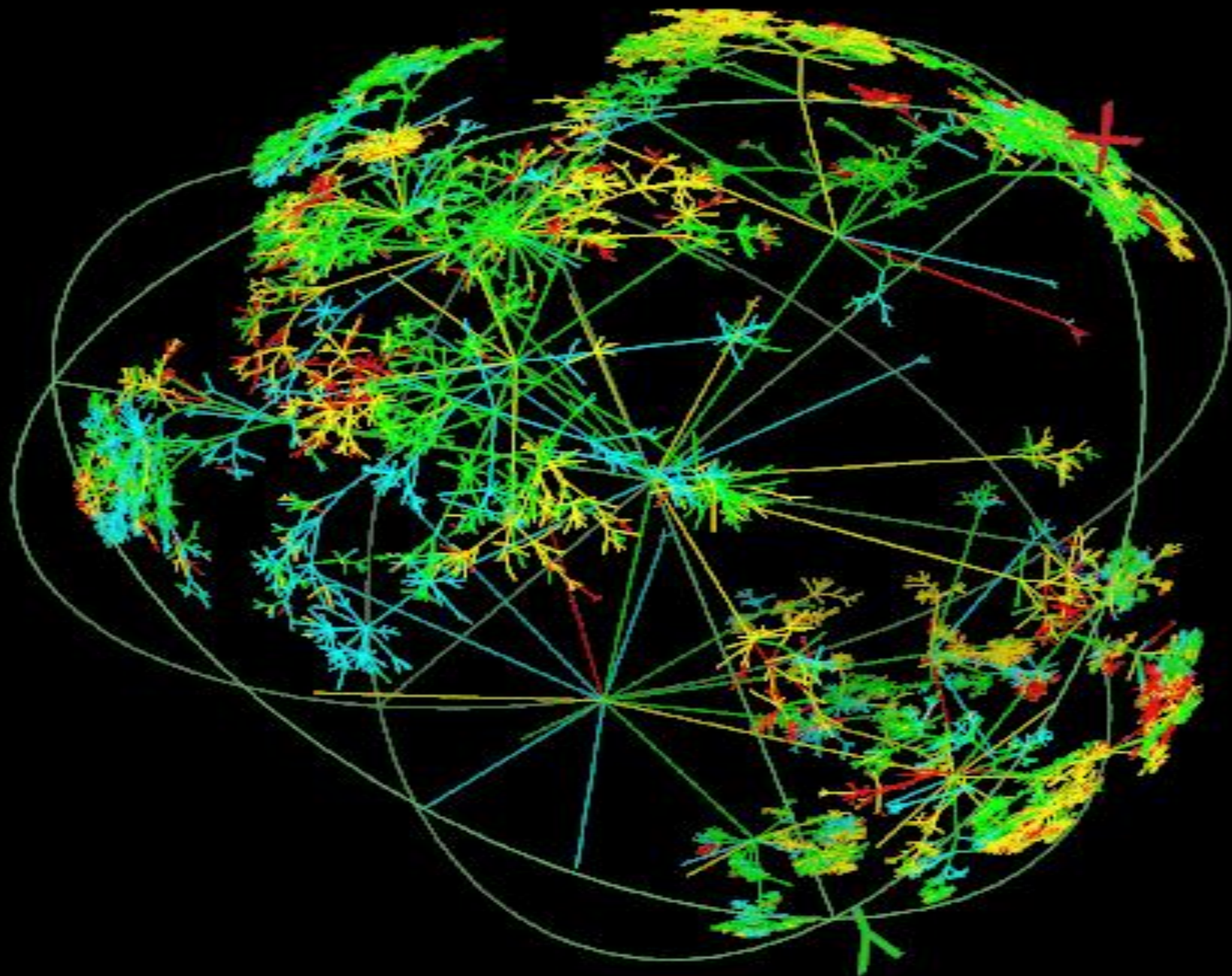
- Implementation of open access policies
 - Bermuda Principles 1997
 - Fort Lauderdale 2003
 - Toronto 2009
- Rationale that publicly-funded research should be used optimally for the public good
- Question is now *how* to share data rather *whether* data should be shared
- This has had a significant effect on scientific practice

Building of Resources

- Networking or building of infrastructures
 - BBMRI within Europe; Platforms for GWAS
- Aim to link different research collections
- To have certified biobanks & biological resource centres
- Globally harmonized processes
- For both academia and industry

New Types of Research Models

- Direct to consumer testing companies
 - Focussed on the individuals and return of results to them
 - Interactive model
 - ‘Customers’ rather than passive providers of information
 - Web 2.0 approach



Significant Effect on Practice

- Interdisciplinary Teams
- Global networks
- Existing structures within research create barriers to share resources, knowledge, expertise or data
 - Career structures
 - Publishing acknowledgements



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2. Testing Current Research Governance Mechanisms

Why do we need Governance?

- **CERTAINTY AND EFFICIENCY**
 - People know what the rules are, what happens and when
- **UNIFORMITY AND EQUALITY**
 - Everyone and the same issues are treated the same
- **PROMOTES GOOD THINGS**
 - Enables problems to be anticipated
 - Ensures that when things go wrong there are procedures and people to deal with it
- **ENSURES ETHICAL AND LAWFUL RESEARCH**
 - Accountable, transparent decision-making
- **PROTECTS INTEGRITY OF THE RESEARCH COMMUNITY**
- **PROMOTES PUBLIC CONFIDENCE AND TRUST**

Governance Mechanisms

- Laws, regulations and guidelines
- State and informal bodies
 - ‘Polycentric’ number of actors performing different regulatory functions
 - Different kinds of enforcement powers
 - Nationally based
- Procedural mechanisms
 - eg informed consent forms
- Professional culture and values

Kaye et al *Governing Biobanks – Understanding the Interplay between Law and Practice* (Hart forthcoming 2010)



Key features

- Generic system designed for all types of research
- ‘One project/one institute’ model
- Oversight is ‘front- loaded’ (Gostin & Hodge Jurimetrics 1999)
 - Emphasis on ethics approval and informed consent
- Ethics committees are gatekeepers
- Based on ‘information altruists’ (Kohane & Altman - New England Journal of Medicine 2005)
- Nationally-based systems



Generic System

- Research governance system designed for all types of research
 - Problematic for new projects and research
- ‘One project/one institute’ model
- Principle Investigators usually held responsible for monitoring use of samples and data
 - Difficult to be responsible for secondary researchers



Front-Loaded Systems

- Focus on approval before research commences
 - Emphasis is on the informed consent form
 - Getting through the ethics committee requirements



Front-Loaded Systems

- Impossible to obtain informed consent
 - Currently difficult to obtain a new consent for every secondary use of data
 - All the uses of data and the researchers cannot be stipulated when consent is originally obtained



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Front-Loaded Systems

- Ethics committees are gatekeepers
- Focus on approval for research
 - Few enforcement powers once research commenced
 - Enforcement powers are variable
 - Authority is nationally based



Ethics Committees

- Ethics Committees do not have the expertise to assess the risks of global data sharing
- Decision-making is committee specific
 - Variation in decisions within regions within countries as well as between countries
 - Difficult for projects that cross borders



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New Oversight Mechanisms

- Beyond mandate of research ethics committees and expertise
 - establishment of Data Access Committees (DACs) for each dataset
 - Policies still being developed
- No one body that has oversight of all data linkages
- Individuals rarely involved in decision-making



Underlying Agreement

- We can no longer promise confidentiality of personal information (Lunshof et al 2008)
 - DNA is a unique identifier
 - Data can be replicated indefinitely
 - Data is shared globally
 - Genome sequence is becoming more accessible to people other than researchers through ancestor tracing and 23andME
- Yet participants are still expected to be altruistic



Withdrawal and Feedback

- Withdrawal cannot be promised when data and samples are shared widely
 - Computer datasets containing personal information must be continually archived
 - It is difficult to claw back minute segments of sequence spread over a global network
- Increased possibility of incidental findings because of richness of data
 - Should secondary and tertiary researchers be held responsible?



Nationally Based Oversight

- Laws, guidance and requirements differ between jurisdictions
 - Also for tissue and information
- Creates obstacles for global research
 - Time-consuming and costly to find out what the requirements are
 - Protection for participants in question
 - Ultimately detrimental to research
- We are asking nationally based governance to oversee global research



In summary

- Current governance systems are ill equipped to deal with global data sharing

- Do not promote certainty and efficiency
- Everyone and the same issues are not treated the same
- There is not transparent, effective and accountable oversight
- Proportionate oversight of the right things

- Long-term participation and commitment is required on the part of research participants

- But, at the same time the research community can no longer guarantee anonymity, cannot provide information to satisfy the requirements of informed consent and cannot ensure complete withdrawal.



1. What have we achieved so far?



Articles

•Kaye J., Heeney C., Hawkins N., de Vries J., Paula Boddington P., (2009) **Data Sharing in Genomics – Reshaping Scientific Practice** *Nature Review Genetics*, 9,

•Heeney C., Hawkins N., de Vries J., Paula Boddington P., Kaye J. **Assessing the Privacy Risks of Data Sharing in Genomics** (submitted to Public Health Genomics)



Articles

- Hawkins N., de Vries J., Paula Boddington P., Kaye J., C.Heeney
Planning for Translational Research in Genomics *Genomic Medicine* 27th September 2009
- Kaye J, **Networking Biobanks –What are the Challenges?** In Principles and Practices for Biobanking Kaye J. and Stranger M.(Eds.) (Ashgate Nov 2009)



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Articles

- Heeney C., Hawkins N., de Vries J., Paula Boddington P., Kaye J. **The Changing Context of Data Sharing – Types of Identifiability in Genomic Data** *PLoS Genetics* (2nd October 2009)
- Kaye J., Boddington P., de Vries J., Hawkins N., and Melham K. **Ethical Implications of the Use of Whole Genome Methods in Medical Research** *European Journal of Human Genetics*



Further Papers

- Feedback of Incidental Findings
- Access Policies
- Tension between data sharing and IP protection



Conference

Data Sharing in Genomics What are the Challenges?

Oxford, September 2010



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Thank you P3G!



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