

CCB Ethics and Governance Workshop - London 7 Jan 2009

Beyond 'fair access'

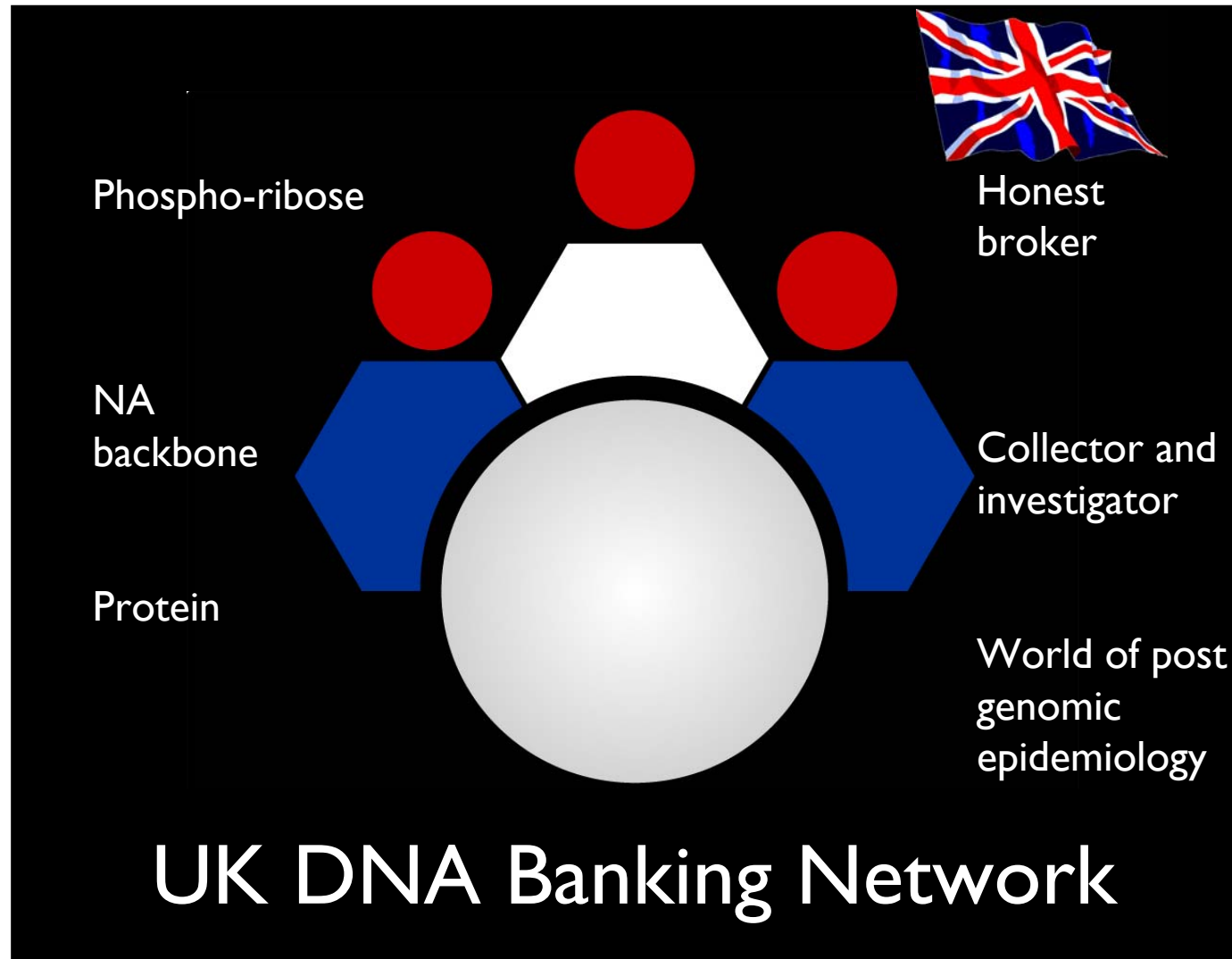
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Summary: access to human biomedical resources

- “Open access” is not an option
 - its denial of restrictions on use is incompatible with
 - privacy of data
 - non-renewable nature of sample
- “Fair access” seeks to respect interests of all stakeholders
 - subject; study-funded collector; investigator; funder and employer
- “Science-driven access” is fair access+
 - wider range of collectors

Experiences of a secondary biobank



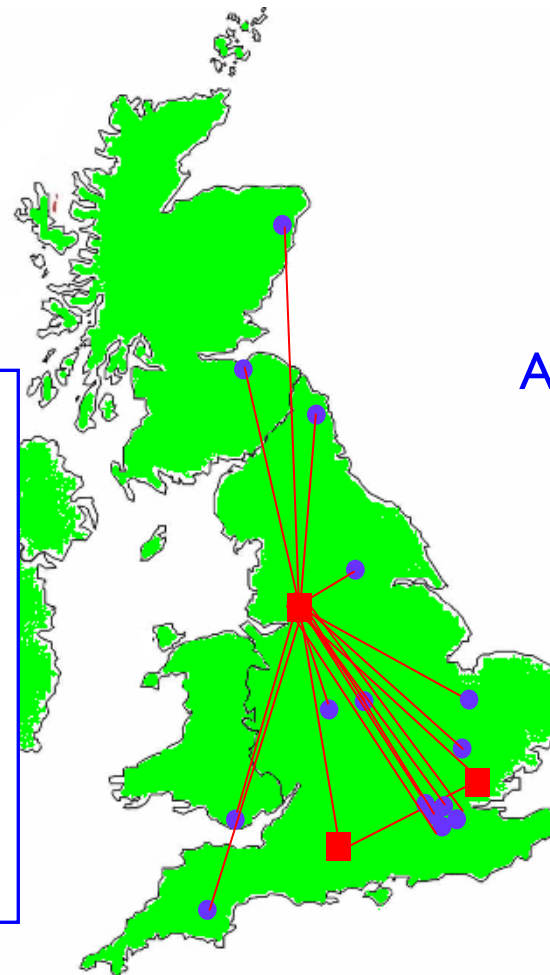
UDBN: preparatory phase

- Late 1990s
 - Government allocates funds for MRC to exploit the imminent human genome sequence
- 2000
 - MRC identifies genetic epidemiology as key
 - MRC issues Call for Proposals for large genetic collections. Grants had special conditions.
- 2002
 - MRC funds infrastructure
 - Mission: to store and distribute these collections

UDBN: construction

- DNA
- Cells and lines
- Website
- Collector PIs

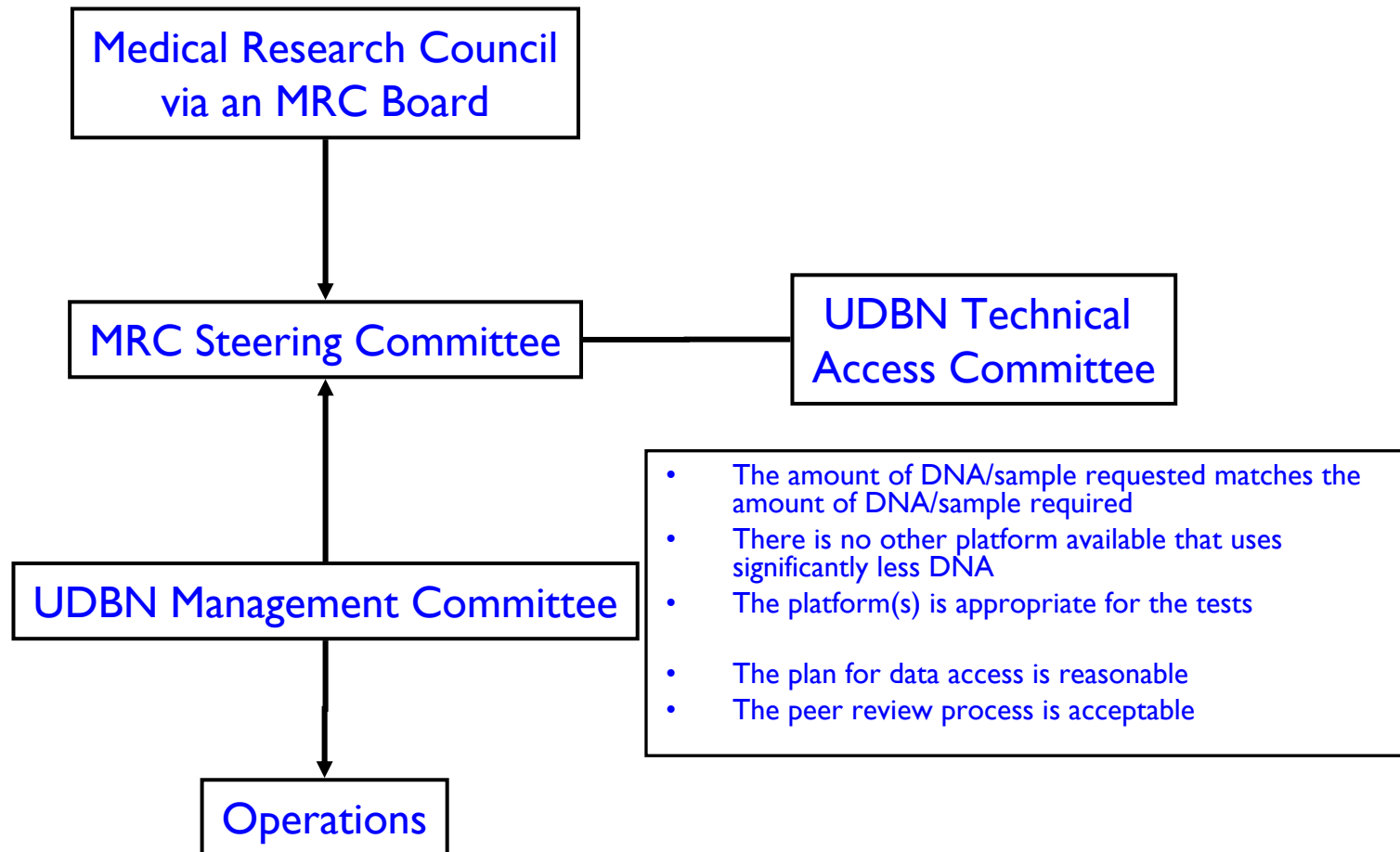
Alzheimer's Disease;
AML;
Asthma and Eczema;
Breast Cancer;
Colorectal cancer;
Coronary artery disease;
Glomerulonephritis;
Hypertension;
Macular Degeneration;
Malaria;
Multiple Sclerosis;
Parkinson's Disease;
Type 2 Diabetes;
Unipolar Depression



Aggregation network

Research infrastructure

UDBN organigram



Principles of access

- 2000: MRC told collectors
 - “All DNA collections in the Initiative are funded on the understanding that they are to be managed as **shared national resources**, and must be made **readily available to collaborators**. MRC (*and the joint funder, if appropriate*) retain(s) **formal** responsibility for the **custodianship** of sample collections funded under this initiative, but **day to day** responsibility for custodianship and management of the sample collection is delegated to the grant holders and the host institution”
- 2001: MRC told bankers
 - “Council now wishes to establish a network of centres with a remit to house large DNA collections. The network will be required to make these resources **available to the UK scientific community** and manage the associated databases”

Open access: disambiguation

- Wikipedia has disambiguated ‘open access’:
 - Open access is access to material via the Internet in such a way that the material is free for all users to read and use
 - Open access may also refer to:
 - Open Access publishing and pre-publishing
 - publication of material in such a way that it is available without barriers to all people
 - Open Access
 - a common database initiative in electronic design automation
 - Open Access Network
 - a horizontally layered network architecture and business model
 - Open Access Same-Time Information System
 - a policy for transmission service
 - Open access may also be used for:
 - Open access (infrastructure) such as railways
 - Right of public access to the wilderness
 - a legal right to travel through open countryside
 - Open Communication
 - open access to communications infrastructure and services
 - Wireless community network

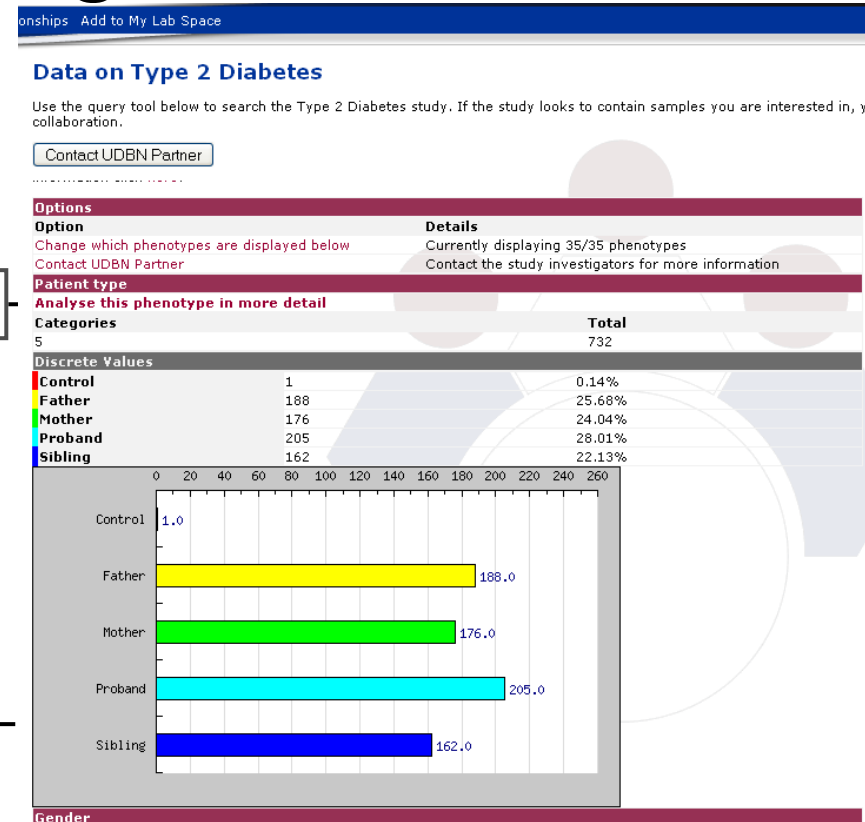
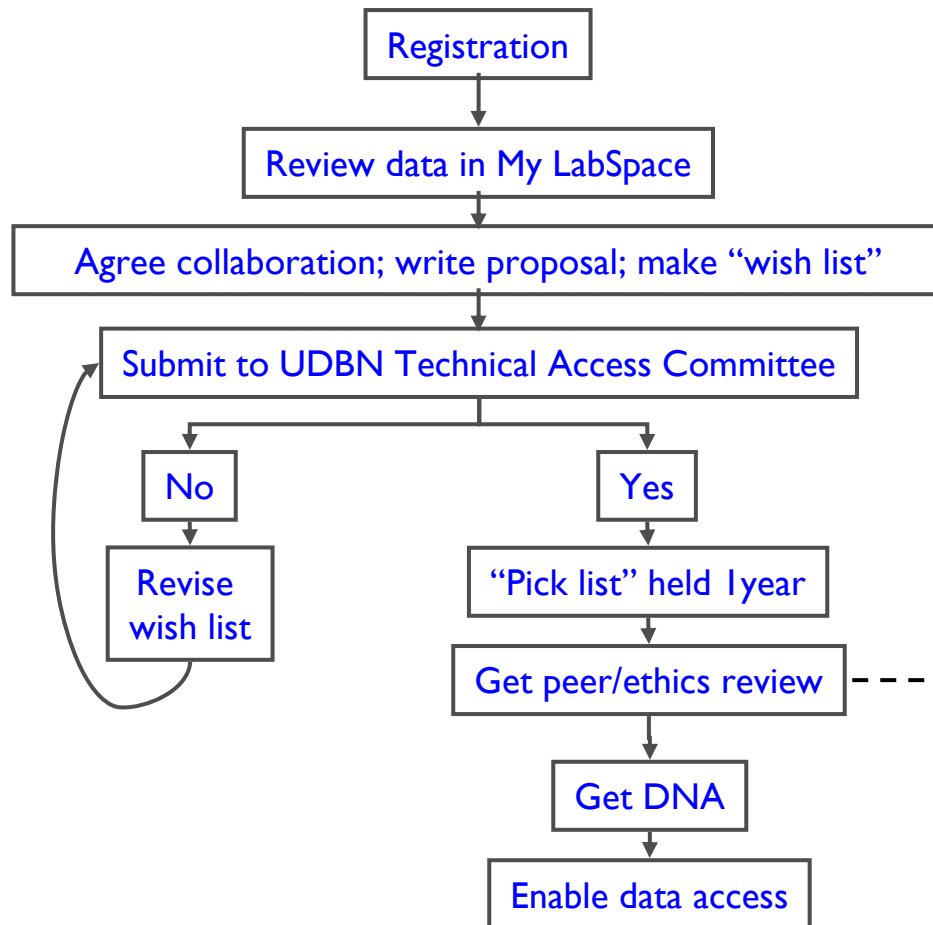
Organisation of access

- **March 2004 1st Steering Committee**
 - The Committee noted that each of the collections envisaged establishing “guardianship” committees (and some collections had already done so) to assess applications for access to a particular resource. It would be important to ensure that procedures were standardised across collections, and that equitable standards were being reached in terms of the decisions made.
 - The Steering Committee could act as a “Board of Appeal” should an applicant file a grievance about a decision made by a Guardianship committee.
- **October 2004 2nd Steering Committee**
 - Collection Guardianship Committees – The independent chair could be drawn from individuals involved in other collections. Funds for the DNA collectors meeting could be used to support the guardianship committees and working groups
- **April 2005 3rd Steering Committee**
 - Having 13 committees was unlikely to represent an efficient, effective and transparent mechanism for access via the bank, or a good use of people’s time. A generic access committee model was proposed which included an independent chair and members, collection representatives and the bank.

Organisation of access

- **October 2005 4th Steering Committee**
 - The model was based on the bank brokering a “collaboration” between a third-party user and the originator of the collection. **Where a collaboration could not be achieved then the Committee would be asked to help resolve this.** The bank suggested that one possible reward for sharing would be replenishment of the collection. The more an originator is happy to share/collaborate, the higher up the priority list the collection goes for replenishment.

Current access arrangements



The principle of 'fair access'

- UNESCO International Declaration on Human Genetic Data 2003
 - Article 18 : Circulation and International Cooperation
 - States should regulate the cross-border flow of data and samples “so as to foster international...cooperation and ensure fair access”
- UDBN principles
 - fair to subject
 - fair to collector
 - fair to investigator
 - fair to funder

Article 18 – Circulation and international cooperation

(a) States should regulate, in accordance with their domestic law and international agreements, the cross-border flow of human genetic data, human proteomic data and biological samples so as to foster international medical and scientific cooperation and ensure fair access to these data. Such a system should seek to ensure that the receiving party provides adequate protection in accordance with the principles set out in this Declaration.

(b) States should make every effort, with due and appropriate regard for the principles set

UDBN's 'fair access' practises

- Fair to the subject
 - Privacy and confidentiality
 - UDBN databases have alphanumeric IDs. Key held by PIs.
 - Access is restricted to *bona fide* investigators. UDBN defines who is *bona fide* (not the collector)
 - Ethical use of samples and data
 - All deposits and withdrawals must be backed with evidence of research ethics committee approval
 - Consent management: national open methods to permit effective withdrawal of consent
 - UDBN advocates a national regulatory agency that holds key.
 - Public engagement: understanding and goal-setting
 - Funding for public meetings, patient groups etc
 - Promotion of epidemiology that requires 'citizen scientists'
- Fair to the collector
 - Exploration rights
 - Right to sole access when a collection proposal includes an investigative proposal All UDBN collections have been funded with investigational goals (e.g. candidate gene studies).

UDBN's 'fair access' practises

- Fair to the investigator
 - Collaboration management: ensure transparency
 - UDBN tracks all website communications between collector group and collaborator group
 - Access to usable published / unpublished data
 - UDBN links sample data, phenotype data, genotype data
 - Long term availability of sample: stock control
 - Conserve native DNA
 - Use WGA DNA where possible
 - Minimum of administration
 - Online access form takes 5 mins
 - UDBN advocates that it commissions genotyping
- Fair to funder
 - IPR management: long term tracking of samples and data
 - UDBN keeps log of all aliquot movements

Science-driven access

- What exploration rights should collectors retain
 - when their intended investigation is overtaken by events?
 - when they are not funded for investigations?
 - when they are an institution, not a person?
- These circumstances have arisen:
 - UDBN's MRC collectors envisaged candidate gene investigations but opted for GWA studies
 - Creation of a resource - without any experimental investigation - is a recognised funding topic (e.g. UK BioBank)
 - Hospital-based accrual of research samples (e.g. BioBank Japan)

Science-driven access

- **Creation of a national resource is funded**
 - I have made an intellectual and/or operational contribution to the creation and management of a “national resource”. So
 - I am in the best position to get authorship of a paper describing the resource.
 - Failure to get published implies the resource is not as good as I proposed.
- **The resource can then be scientifically exploited**
 - I am in the best position to design the best means of exploiting the resource. I should write the best proposal. This will be judged by reviewers who may not fully understand the resource.
 - If I write the best proposal, then I get funding for the investigation and I get authorship.
 - If you write the best proposal, then I get nothing.
- **Is this fair?**
 - Maybe not: the fair access principle may be breached. But it ensures scientific excellence
- **Is this outcome likely?**
 - Probably not. Your proposal will be better than mine only if it combines your insight with my knowledge - i.e. if we collaborate on one proposal!
- **Conclusions**
 - Peer review is sufficient to ensure optimal exploitation of a national resource
 - A corollary may be that there should be no exploitation without peer review
 - A rider is that peer review should assess the impact of a proposal on sustainability of a national resource
 - Good management of a national resource should include promotion of collaboration
 - Does the culture of competition need replacing by a culture of collaboration?

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