Ethical Issues of Human Genetic Databases: A Challenge to Classical Research Ethics?

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Scientific discovery fuels medical progress, and in this post-genomics era, most modern day breakthroughs of the biological sciences could not occur without access to unique repositories of healthy and diseased human tissue samples. Because ongoing access to fresh tissue is not practical in a research setting, these repositories are typically sequestered in carefully maintained and annotated biobanks.

Usually under the protective wing of forward-looking health research scientists and students, biobanks of specially characterised tissue are stored cumulatively, often in a frozen state or, in the case of archival pathological specimens, paraffin-embedded.

Worldwide, many existing biobanks were established decades ago. Now, through benefit of these early endeavours together with vigilant scientific oversight, uniquely comprehensive and valuable collections have emerged. In many cases, linked clinical, pathological and genetic or other data is available depending on the specialised academic interests of the principal investigators involved.

Present rapidly advancing biotechnologies mean that, for a given donor, genetic information entered into a database can range from the entire genomic sequence of healthy or diseased cells, to specific information on a gene locus obtained from a particular test or experiment. For this reason, and despite the ethical challenges they impose on society, biobanks are proving their value time and again for the identification of new genetically determined health conditions, improved biological understanding of known conditions, and better targeted treatments.

New Zealand is no different from Europe, US, Canada or other countries for its early ad hoc introduction and gradual consolidation of tissue biobanks with linked genetic data at different university hospital locations. For most, if not all of these biobanks, a continually fermenting Darwinian-style evolution of ethically and legally acceptable guidelines for operational oversight, access, donor rights, benefits and consenting privileges occurs over time.

This book addresses major controversies associated with human biobanks for medical research, specifically those with linked genetic data, and including underlying ethical positions and arguments. Practical guidance to deal with these controversies at a local level is provided, while also pitched internationally in search of consensus resolutions.
The book has 5 chapters. The first provides an insightful and sharply crafted introduction to the history and background of genetic biobanks for medical research.

Chapter 2 explores in detail four selected existing biobanks, providing a summary of the ethical problems and the public debate running parallel with or succeeding their establishment. The four banks include the Icelandic Health Sector Database, the UK National Biobank, the Estonian Gene Bank and the Swiss Paediatric Oncology Group Tumour Bank.

Chapter 3 addresses the ethical debate that has emerged more generally in response to existing biobanks, including an analysis of the classical principles of research ethics (respect for autonomy, beneficence, non-maleficence, justice) and the ability (or not) of those principles to resolve new ethical dilemmas confronting genetic biobanks in particular. Need for newly emerging ethical principles such as those associated with research freedom, respect for the human body, respect for populations, community values and democracy is considered, but largely rejected in favour of classical principles using logically reasoned philosophical arguments.

Chapter 4 examines more closely the most important issues of controversy, including general versus focussed models of informed consent, reversible versus irreversible anonymisation, confidentiality and access to genetic databases, the nature and extent of feedback to participants, and the extent to which participants can expect to benefit from use of their samples in research.

Finally, Chapter 5 provides a futuristic view of the ethical issues confronting human genetic biobanks and their possible resolution.

Clearly written and logically structured there are many strengths to this work, not least the author’s obviously comprehensive world view of current and past legislations, guidelines and opinions regarding genetic biobanks, her recognition of the crucial role of ethical review committees in biobanking processes, and of the importance of research outcomes as an endpoint for utilisation. Detailed footnotes and extensive tables summarising local interpretations of international/national medical research ethics guidelines are testimony to an intensive research effort. Reviewed across these guidelines are interpretations as to the place of respect, rights, benefit-harm considerations, justice, community, other cultural values and best interests for participating donors.

Weaknesses include some repetition of content. Whereas this could be viewed as useful reinforcement in a complex book of this nature, this repetition is at the expense of a final crisp summation of the key controversies and recommended mechanisms to resolve these at a local and international level. As it is, these gems of wisdom are unfortunately dispersed within the relevant chapters. A careful reader will find them.

Professor Bernice Elger is a teacher of ethics and health law at the University of Geneva, Switzerland, and is widely published and recognised for her work in medical ethics in genetics, ethical problems in clinical medicine and research involving biobanks. This book is one of two covering related topics by the same author, and it sits well in a field otherwise rather sparsely populated with well-informed global perspectives, and with recommendations to resolve many of the troubling ethical dilemmas that currently plague genetic biobanks.
This book would be of high interest to clinical and scientific leaders of genetic biobank initiatives, to biobank custodians, and to members of ethical review committees overseeing operational aspects. It is essential reading for any student, or donor for that matter, interested in the ethical challenges and dilemmas that have in the past, and will continue in future, to influence research patterns and progress using these valuable resources.

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