

## Chapter 13

# Human Biobanks: Selected Examples from and beyond Europe

**Brigitte Jansen**

*BioEthicsLaw e.V., Germany & University of Madras, India*

### ABSTRACT

*The chapter presents a careful comparative study on ethical and legal aspects of human biobanks both in Europe and elsewhere. The rapid expansion of human DNA sampling and data collection has taken place in the last few years, but the legal and ethical perception of this situation looks very different in European countries and beyond. The author focuses her attention on the European Union, especially in Estonia, where a population wide gene bank has been established; moreover, she also discusses what is happening in Macedonia, a relatively neglected country in Eastern Europe, as well as Australia, India and Israel.*

### INTRODUCTION

Traditionally, biobanks are defined as a systematic organized collection of cells, tissues or blood samples which are stored to be retrieved for analysis for a more or less long time. This definition includes the idea that universities, researchers etc. have their own working collections which are also increasing in the last time (Cambon-Thomsen et al., 2003, p. 145). Since large population biobanks were set up, this definition is not really broad enough as large population biobanks are a good

basis for health surveys, research etc. because this allows monitoring of the health status on a permanent basis.<sup>1</sup> So it seems helpful to make a distinction between<sup>2</sup>:

- **Diagnostic biobanks and treatment biobanks:** Collection of human biological material delivered for medical examination, diagnostics and treatment, and
- **Research biobanks:** Collection of human biological material and information directly deriving from analyses of this material for research purposes.

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The consequence of such working definition could change the understanding of our current biobanks<sup>3</sup> in a more practical way. It is obvious that for example for research in biobanks the physical sample itself may become less important, because more tests and analyses can be run automatically with the collection of samples. In particular genomic data could become more important (Mattick, 2003), and we shall concentrate on this aspect. Biobanks are increasingly viewed as an international resource; thus, standardization and collaboration between biobanks will become common practice (Hirtzlin et al., 2003).

The chapter will describe the situation in several countries where the discussion and development of DNA banks is especially advanced. Furthermore, indications will be given as to how the situation is developing, especially in European countries.

## COUNTRIES

### DNA Banks in Australia

In Australia there are a number of DNA banks for research and clinical use. Already at the end of the eighties, the “Human Genetics Society of Australasia” (HGSA) (1990), which represents both Australia and New Zealand, foresaw that the development of genetic tests would lead to an enormous growth of bio-banks. Therefore, the “Guidelines for Human DNA-Banking” were developed, to be presented in July 1990 to set standards in medical/legal and ethical areas.

These guidelines take stock of the differences between clinical services and research and require that the researchers have certain duties towards the families whom they are investigating. Part of this is that the responsible State office that is carrying out the clinical genetic support service makes this public, and engages in exact documentation which is to be made available to all health care givers of the family. Future services for the family

must be taken into consideration, even after the end of research. This aspect related to the care of the family in the Australian HGSA guidelines is stressed here as less emphasis is placed on this area in the other national guidelines.

According to the guidelines, the cases are carefully delineated as to when it is necessary or not to get consent for a blood probe and the retention thereof. In certain cases, formal consent is absolutely not necessary; in other cases, this depends on the situation. For example, the guidelines assume that the purpose of prenatal tests for recessive genetic disorders such as cystic fibrosis is generally known and that only parents and their children are affected by this (The Human Genetics Society of Australasia, 1990, p. 4). In this case, a formal agreement is not necessary. On the contrary, Huntington’s chorea requires samples from extended family members who may not be motivated enough to undergo tests nor even clearly understand the purpose of the tests. In this case, consent seems to be quite necessary.

The secrecy of test results is also held to be a high ideal by the HGSA. As such, no results should be passed on to third parties without written permission and this clearance is only allowed to a small number of exactly specified people (The Human Genetics Society of Australasia, 1990, p. 4).

In the same year, the Australian Health Ethics Committee (AHEC) that was set up by the National Health and Medical Research Council (NHMRC) published the *Guidelines for Genetic Registers and Associated Genetic Material* (1999). These guidelines, which came into power on January 1, 2000, are to take into consideration all aspects related to the establishment and the organization of a genetic register.<sup>4</sup> There are certain key characteristics that are to distinguish these genetic registers from other collections of data. The registers record genetic disorders where each register only should collect data relating to one disorder or a narrowly related group of disorders. At the same time, one should ascertain family members who have a higher health risk because of such abnormalities so that one can

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