Trading in Cold Blood?

Trustworthiness in Face of Commercialized Biobank Infrastructures

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Abstract In this chapter I discuss trustworthiness as a quality of biobanks constructed and regulated in ways that make them serve the expectations donors have. Beginning with a short review of empirical studies of donor expectations and attitudes, I show that their concerns tend to revolve around issues of 1) personal control, 2) harmful uses of medical knowledge and 3) social fairness, in particular whether research is shaped by creed rather than medical need. I then rehearse the regulatory tendencies addressing these three issues, and identify an overall trend towards commercialization in particular in the areas of property law and research management. Then, the potential effects of this commercialization on the research agenda and research results are assessed based on available empirical studies. In conclusion, I point to the gap between donor expectations and the thrust of regulatory efforts. I argue that it is important that ethicists begin to address the wider innovation system surrounding biobanks if they wish that biobanks do not only preserve, but also deserve, the trust of the donating public.

1 Introduction

Public trust is a prerequisite for the viability of population-based biobanks. As such, it can be considered a valuable asset for the researchers and authorities responsible for the construction of large-scale biobanks. From the perspective of the research participant, however, trust in itself is not necessarily valuable; donors are typically more interested in the trustworthiness of the institutions handling their biological material and data. If trustworthiness in this context means that biobanks are capable of and committed to pursuing the goals that donors expect them to pursue, this chapter looks at the relationship between trustworthiness and research regulation: what do we know about donors’ concerns and expectations, on the one hand, and about regulatory trends and their implications for medical research, on the other hand.

Legislation that deals explicitly with biobank governance has mainly focused on informed consent – a requirement that is occasionally described as pivotal in
preserving donor trust (Clayton 2005, Sutrop 2007). In this chapter I claim that biobank governance must be understood in a wider context of innovation politics, including regulatory measures such as property law, research management and funding regimes. Current innovation politics stimulate what I call ‘commercialization’, a process that has potential for contradicting the interests expressed by donors. I argue that debates about ethics have been too narrowly focused on the level of information that are to be provided to donors and that donors’ real concerns, and thus the trustworthiness of biobank governance, require scrutiny of the overall regulatory frameworks for biobank research. The fact that people have signed a consent form, the content of which they might not have understood or remembered, is likely to be of little help if people gradually discover that their expectations are not met. If biobanks are not only to establish or preserve, but also deserve public trust, we must address the wider innovation system in which biobanks operate.

The chapter begins with a short rehearsal of the main insights generated by studies of the expectations and concerns of donors. The following section explores the policy areas that affect the ability to meet these expectations and concerns. It demonstrates that many features of the regulation of innovation point towards a commercialization process in the medical research field. The general implications of this tendency are assessed in the next section of the paper. It is argued that commercialization might effect negative changes of a type that concerns donors: decision-making that is increasingly based on assessments of commercial rather than medical need. Finally, in the conclusion, I point to the need to refocus biobank ethics to this wider set of issues and to move ethical debate beyond the consent issue.

A chapter seeking to deliver a broad outline of donor concerns, regulatory measures and implications of commercialization naturally cannot claim to exhaust the issues. Rather than attempting to deliver a comprehensive presentation, the chapter wishes to point to some important but under-explored regulatory contexts in urgent need of attention for the sake of continued donor trust.

2 What Are Donors Concerned About?

Qualitative empirical studies of donor expectations and concerns indicate that the majority of donors are positive, even if ambivalently so, towards medical research and its implications (Busby 2004, Weldon 2007, Hoeyer 2004). Although they are largely inclined to support medical research, they have concurrent worries about potential misuses and unwarranted effects. Studies have highlighted how people in the European welfare states see participation as a type of obligation connected with the benefits of universal healthcare (Busby 2004, Busby 2006, Hoeyer 2003, Skolbekken et al 2005, Svendsen 2007). In observation and interview studies the information provided to donors prior to research participation has been shown to