Biobanks and informed consent

An anthropological contribution to medical ethics

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CHAPTER 1: INTRODUCTION

1.1 Entering the field: the case of UmanGenomics
This thesis provides an example of how anthropology could contribute to the field of medical ethics with respect to the issue of human biobanks. In 1999 it was announced that a new start-up biotech company, UmanGenomics, in Sweden in Västerbotten County would be granted what was called ‘all commercial rights’ to a large collection of blood samples and questionnaire data stored in Medical Biobank in the town of Umeå, Sweden. I first read about the company in an article which favourably compared its ethics policy with that of a more widely known Icelandic counterpart, deCODE Genetics (Abbott 1999). The article was followed by a debate about the respective merits of the two companies (Gulcher & Stefansson 1999; Hauksson 1999; Nilsson & Rose 1999; Rosell 1999; Sigurdsson 1999), and this sparked the thought that the circumstances surrounding this company signalled an interesting type of scientific, commercial and ethical innovation. I therefore decided to explore the case and conducted some interviews with donors of blood and biobank and company representatives in the year 2000. What seemed particularly interesting was the way in which ethics had apparently left the philosophical departments and had become part of public discourse. I wanted to find out how the advent of commercial genetic research would affect the community, and how ethical debate became entrenched in public life (Høyer 2001). The study I eventually carried out took a slightly different turn. Before I describe the study on which this thesis reports, I will run through the story of UmanGenomics and Medical Biobank. I begin with this background story for two reasons: because the entire study was stimulated by the advent of UmanGenomics, and because UmanGenomics, in many respects, holds a prominent position in Swedish tissue-based research.

1.1.1 Background
Medical Biobank is one of the few biobanks constructed for research purposes that are proven to be population based, i.e. comprising a representative sample of a whole population. The biobank contains more than 110,000 blood samples derived from most of the adult population of the 255,230 inhabitants of Västerbotten. The majority of the samples (78,000) stem from people participating in a preventive healthcare programme at public healthcare centres. The programme was initiated in the town of Norsjö in 1985. Initially, the samples were taken as part of quality assurance procedures
rather than with the intent of constructing a large-scale biobank. However, a group of researchers envisaged a prospective study of a whole population – a large-scale research biobank with both healthcare data and blood samples – and decided to store samples purely for research purposes. The preventive healthcare programme was extended progressively to the whole county over the following six years and the biobank ensued. People in the preventive healthcare programme were initially invited to participate at the age of 30, 40, 50, and 60 years, and in addition to a basic clinical check-up with some blood tests, they were also invited to complete an extensive questionnaire about their lifestyle and other healthcare related issues. The collection of samples and healthcare data in the questionnaires constituted a potential resource relevant to the county health authorities (for monitoring purposes) as well the university (for research purposes), and it became entrenched in the daily procedures at the healthcare centres.

At that time it was unusual to construct a prospective biobank for research purposes. Most biobanks emerge from clinical routines – some estimates suggest that approximately 60 million samples are stored in Swedish hospitals, i.e. as many as 7 samples per living Swede. When biobanks were initiated in the 1980s, they tended to focus on particular groups of individuals. Therefore, the group of researchers wishing to establish what was later to become Medical Biobank faced some problems in getting support for their plan of a large-scale prospective biobank. For example, the university and county council were both reluctant to bear any financial burden in relation to the unusual project, though they accepted being part of the infrastructure for the biobank collection. And, at that time, it was even illegal for the county to contribute to research endeavours. The group of researchers behind the biobank initiative procured external funding and gradually the biobank grew and research activities began, primarily by combining the accurate Swedish disease registers with samples taken prior to the outbreak of the respective diseases.

The management of the biobank was prompted to take some initiatives regarding research ethics. Whether this was due to the scale of the project or a desire to safeguard the work invested in the project is unclear. However, in the beginning of the 1990s, before this was in any manner routine in Sweden, donors were authorising their donation with their signature (see attachment 1), and the biobank had established a system of approval of use of the biobank material which included assessment by expert reference groups and applications to the regional Research Ethics Committee (REC). Initially, the REC had been doubtful as to the role it should play, as it usually confined its jurisdiction to research on living human beings, but in collaboration with the biobank a procedure was established. The role of RECs is traditionally aligned with ensuring
participants receive adequate information. The notion of informed consent had appeared inappropriate, however, because participants were transferring samples for unspecified future research rather than participating in research on their own bodies. It was postulated that it would be impossible to inform about the purposes of research in 50 years time. Instead, the authorization was termed a donation act (attachment 1).

During the 1990s, developments in genetic research, in particular PCR technology (Rabinow 1996a), together with the rising biotechnology industry rendered collections of human tissue objects of great scientific and commercial interest. The debate about deCODE Genetics, more than any other event, put this on the international agenda. Other biobanks, such as the one in Umeå, then changed appearance in the eyes of the medical research community from being potentially superficial resources for mainly epidemiological research to being scarce resources for genetic research. Simultaneously, they changed political status from being part of trivial routines into being topical ethico-political problems. In Sweden, this shift was most clearly illustrated by a brief series of articles in the popular tabloid newspaper Aftonbladet in April 1999. Aftonbladet claimed to reveal “Secret experiments on parts of your body” and though the series might not have had any significant influence on public attitudes to biobanks, it promptly spurred political initiatives. The journalists won the prestigious journalist award Stora journalistpriset for the series, and work on a law to regulate public Swedish biobanks was initiated.

In Umeå, by the turn of the mid-1990s, several actors had also realised both the scientific and the financial potential of Medical Biobank. The principal investigator had tried to establish contact with pharmaceutical companies and envisaged a marketing branch where findings of commercial interest would be offered for sale, while the money would be used for future research on the biobank material. The university management became involved and gradually took over the commercialisation process in collaboration with the county council. After having been virtually an entity for approximately 14 years, the biobank became part of the county administrative structure, and the university invited a researcher with corporate experience to help in developing a plan for efficient commercialisation. The researcher suggested establishing an independent company and granting it all commercial rights to the biobank, thus giving it a financial asset together with entrepreneurial autonomy. The company was UmanGenomics, and in the process Medical Biobank acquired its present name (having previously been known as first Blodbanken, then Medicinska Banken). Though both were affiliated with the university and the county, the company and the biobank were thus formally separated as two independent legal units. From the onset, other
researchers who had been using the biobank questioned what “all commercial rights” meant; it was only later, however, that the vagueness of this agreement became publicly debated. Start-up risk capital for UmanGenomics was ensured from a technology transfer agency, and from 1999 onwards approximately 15-20 staff were employed.

With the new millennium, however, the biotech investment bubble burst, and biobanks showed to be less profitable than first anticipated. This was not the only trouble that UmanGenomics was to encounter. A serious financial and political situation gradually impinged on the company. Not all the factors leading to this undesirable situation can be accounted for here, but it is important to note that it was gradually revealed that not all stakeholders were satisfied with the arrangements made for the biobank and the initiatives taken by the county and the university management. The principal investigator behind the biobank claimed to have dispositional rights in the biobank collection and an intense conflict evolved which has featured in the local and national newspapers since 2002. Employees in the biobank have submitted contracts between UmanGenomics, the county, and the university for legality testing, and even if most complaints have been overruled the working atmosphere has been severely tainted. Meanwhile, UmanGenomics has not signed contracts with investors and customers, and in early 2003 the research staff were made redundant. Initiatives have been taken to make a fresh start with a new business concept, a story which I shall not explore here. Likewise, I will omit the account of the conflict, as it appears elsewhere (Hoeyer 2004b; Laage-Hellman 2003; Lövtrup 2003; Rose 2003), and instead will return to the situation which spurred the research project on which this thesis reports.

In 2000 when UmanGenomics signed the first contracts with the county and the university, and as I was studying the social implications of this arrangement, the regional Research Ethics Committee (REC) took an interest in how the situation should be managed. The company and the biobank were developing new information sheets to accompany the consent forms for future donations (attachments 2 and 3), but expected the donation act previously used still to be valid for the use of samples already stored. However, several members of the REC speculated whether donors would prefer to give a renewed consent personally or whether they would prefer the REC to decide on their behalf. To comply with their institutional obligation towards securing the interests of the research participants, the REC wanted to initiate a survey of attitudes among donors. As a member of the committee and lecturer in medical ethics, Niels Lynøe asked me whether I would like to contribute to these efforts. In our exchanges on the subject he quickly acknowledged that
anthropology spurred types of queries and questions other than those usually posed in medical ethics, and further sensed that there might be grounds for a more encompassing project addressing wider issues than simply whether or not donors in the particular project would prefer renewed consent procedures or surrogate decision-making performed by the REC. With funds generously provided from the Swedish Ethics in Healthcare Programme I was charged with carrying out a doctoral study. Niels Lynoe had outlined a possible study with comparative surveys of three databases: one of which was never established; one which declined to cooperate; and the one in the custody of Medical Biobank, which was concomitantly becoming involved in severe public disputes over ownership issues. The original plan would not work, it seemed, but a new one was already emerging.

1.2 An anthropological contribution to medical ethics

Occasionally during the past 30 years medical ethics has travelled the same paths as anthropology, and lately some commentators have begun referring to an ‘ethnographic turn in bioethics’. Ethnography denotes the empirical description of ethnos, while anthropology is the adjoining theoretical project; therefore, it is noteworthy that it is an ethnographic rather than an anthropological turn: it is mainly ethnographic methods employed for ends defined by ethics, not the anthropological theory or way of posing questions, that has been welcomed (Haimes 2002; Zussman 2000). Further, it has been argued that the ethnographic turn seems to presuppose that by adding the right methods “a deeper truth might yet emerge… where philosophy failed” (Young 2002: 93). The latter form of logic has been part of spurring an antagonistic relation between some ethicists and the social scientists wanting to completely redefine the ethical enterprise. This I describe in more depth in chapter 2. It makes it important to consider whether there might be other ways of relating anthropology to more well-established contributions to the field of medical ethics.

Within the context of UmanGenomics and Medical Biobank, we therefore decided to explore the broader question: How might anthropology contribute to medical ethics? By emphasising anthropology, rather than ethnography, we wanted to take into account not only the different methods, but also the different ways of generating questions, the different theoretical genealogies. Focusing on the use of informed consent in relation to biobanks in general, and that used by UmanGenomics in particular, the study should contain two parallel parts: an
anthropological contribution to more conventional quantitative surveys well known in empirical medical ethics, and a qualitative project defined anthropologically. By conducting an anthropological project on the same subject approached in more conventional medical ethical terms, we wanted to refine our understanding of how the disciplines might compliment one another.

Anthropology and medical ethics are not homogenous traditions and the one’s contribution to the other cannot be explored en bloc. Types of anthropology other than the one presented here would probably have posed other questions. The following section describes the chosen anthropological perspective; presents the research questions; and describes how the data from the quantitative studies form part of the overall project.

1.2.1 The making of an anthropological study

In defining the anthropological study to be done, I decided to centre on the ethics policy of UmanGenomics (described in section 3.1). As mentioned, it was the international acclaim of the company’s ethics policy that sparked my initial interest, and the more I learned about it, the more this policy seemed to constitute an interesting form of innovation. On one hand it appeared to address key issues for medical ethics, and on the other it was presented in the form of a policy. It was both ethics and regulation: both morality and power. It appeared to me that despite ethicists having long argued that their moral insights must be embedded in law (Kemp, Lebech, & Rendtorff 1997; Rendtorff 1999), we are still inadequately theoretically attuned to the analysis of ethics as regulation, and a way of preparing for the task would be through engaging with a concrete example of ethics as policy work.

1.2.2 Research questions

With the overall purpose of exploring the anthropological contribution to medical ethics, I have asked: What does this form of regulation amount to in practice? This question concerns the social preconditions for, and implications of, the policy work and it is inspired by the anthropology of policy (Shore & Wright 1997). The overall question is addressed through the following sub-questions:

1) What prompted the making of the policy, who formulated it, and what form did it take?
2) Who was expected to implement it, what did they actually do, and what implications has it had for them and the policy?
3) Who was the policy targeting and what did it entail for them?
4) Do other people have concerns other than those addressed by the policy?

These questions have guided the empirical work and the data collected and constructed. The articles in the thesis, however, do not contain all the answers. They only constitute examples of the types of analysis done based on the material.

1.2.3 Why study the ethics policy?

There are several reasons for choosing to study the ethics policy, rather than, for example, delimit the study to the attitudes of donors to commercial genetic research. One of them is that the development of ethics as a regulatory form is clearly under-researched; another, that the ethics policy was used as a parameter in international commercial competition, which constitutes an interesting challenge to medical ethics traditionally seen as a safeguard against commercial exploitation of human subjects. Further, the fact that international comparisons are already being made implies interest in understanding what this form of ethics amounts to; what its social implications might be, and whether it is worth copying. The reason for choosing the specific research questions relates to what in Foucaultian terminology could be termed as searching for ‘the blind angle’ of other forms of knowledge.

The French historian and philosopher Michel Foucault (1926-1984) has served as an inspiration to the overall framework of the project. Foucault carried out several critical studies of medical history and is viewed by some as an outcast for having questioned the foundations of medical truth. However, he was not anti-realist, doubting the existence of the world, as some have taken him to be. He was merely sceptical about definite truth claims. Though the world does exist, and we can create knowledge about it, as he did himself with meticulous archival studies, he suggested that any form of knowledge will always leave something undisclosed and will never capture its object in its entirety. In this respect he differs little from any other social scientist (Bourdieu & Wacquant 1996; Geertz 1973; Taylor 1985; Winch 1995), or medical philosophy of science after Karl Popper and Thomas Kuhn (Johansson & Lynoe 1999; Kuhn 1995; Wulff, Pederson, & Rosenberg 1986). The way he differs is, perhaps, in the way he deliberately explores the shortcomings of other knowledge projects, rather than trying to contribute to a scientific
community’s shared attempts of establishing the most accurate knowledge. I will try to explain this position and how it has been inspiring for this particular project.

A few years before his death he reflected on how to choose what to study, and stated that: “The ethico-political choice we have to make every day is to determine which is the main danger” (Foucault 1997a: 256). By main danger he meant those features of the world which we can barely grasp within our present knowledge regimes, but which nevertheless have a power effect. The reason for him to suggest that they constitute dangers stems from a theme running throughout his work, though with different emphasis in different books, namely the interdependence of ethics (Foucault 1986; 1992; 1994), truth (Foucault 1999; 2000) and power (Foucault 2002). Claims to truth tend to serve particular interests and have political implications. So do moral propositions. Because they cannot encompass reality in its totality, statements which might at a first glance seem obviously true or ethical have different, sometimes unintended or at least unacknowledged, implications for different people: they embody a power effect. In my reading of Foucault the power effect is inevitably – it is not an error to be erased thus making a better world once and for all. There is no utopia on earth, where all problems are solved. Rather, the dangers surrounding us shift according to the contingent solutions we adapt. Accordingly, the task of the analyst is to keep moving in search of the current danger, i.e. the dominance, injustice and inequality passing unnoticed. Looking back at his own work he explains:

“You see, what I want to do is not the history of solutions (…) I would like to do genealogy of problems, of problématiques. My point is not that everything is bad, but that everything is dangerous, which is not exactly the same as bad. If everything is dangerous, then we have always something to do. So my position is not to apathy but to hyper- and pessimistic activism.” (Foucault 1997a: 256)

The ethics policy of UmanGenomics was presented as a solution to presumed ethical problems with commercialisation of Medical Biobank, and my contention is that this solution deserves particular scrutiny, not necessarily because it can be expected to be bad, but because any solution is potentially ‘dangerous’ in what it conceals, and it can be seen as the task of the analyst to disclose these ‘dangers’ and make them available for deliberation. In this particular case it seemed more pertinent to rediscover subjugated knowledge and moral positions than to contribute to an emerging consensus among policymakers about what the real moral problems and solutions are. The Foucaultian vocabulary of “danger”, “knowledge regimes” and “ethico-political” might seem provoking, which is exactly his intention: to display the hidden aspects of our ‘goodness’ and make
the familiar seem strange. However, the provocation should not deter us from appreciation of the results.

Considering the general agreement that definite truth claims (extending beyond fallibilism) are obsolete, it is somewhat surprising how provocative Foucault’s approach has been perceived to be. Throughout social science there is, however, a tension between acknowledgement of the inability to establish lasting truths on one hand, and on the other, fierce attempts to find the “right” method and the correct theory, as if they were to finally emerge from the haze of the present competing approaches (Rabinow 1996b). Paul Rabinow sees in Foucault a more radical solution to this tension: acknowledgement of the inevitability of multiple rationalities, i.e. method pluralism, multiple standards of evidence, types of argumentation, and objects of interest; namely *hetero-logoi* (Rabinow 2003: 4-5). This does not imply that all methods are equally suited for the same task. On the contrary, it poses a pertinent question as to whether the right method has been chosen for the question being pursued. Rather than presuming that success has finally been achieved, it might be preferable to acknowledge that no method, and no truth derived from it, will ever be universally recognised. Nor will it comprise an exhaustive understanding. Acceptance of hetero-logoi saves us time from science wars and mere polemics (Foucault 1997b), and allows us to focus on making the ethico-political choice: what do we want to know; what feature of the world currently needs exploring?

### 1.3 Structure of the thesis

The following chapter describes the debates in medical ethics about biobanks and seeks to place the present study in a wider framework of literature. Chapter 3 describes the methods used, while chapter 4 summarises the findings of the study. In chapter 5 these findings are discussed as anthropological contributions to medical ethics. Chapter 6 relates some research ethical reflections and chapter 7 provides a general conclusion.
CHAPTER 2: LITERATURE REVIEW AND THEORETICAL PERSPECTIVES

This chapter presents a literature review, and based on this an outline of the theoretical framework of the thesis. The literature review serves to position the study between the many different disciplinary and theoretical approaches to the study of biobanks and ethics. As the review straddles a number of disciplines and issues, it is relatively long. It constitutes an important part of the study, however, because a key element has been to find a way of embracing insights from studies rarely brought together, and to develop an anthropological perspective that might contribute something not usually seen as part of medical ethics.

The study is stimulated by an interest in the use of biobanks for commercial genetic research, and I begin with a brief overview of issues raised in normative medical ethics in Nordic and English-language journals. The study also delivers data of relevance to empirical medical ethics. These studies are briefly described in the subsequent section, followed by an outline of some qualitative social science findings concerning biobanks. As the present study looks at ethics as a regulatory form, however, it works from a different perspective than most empirical ethics. This perspective is influenced by Science and Technology Studies (STS): a cross-disciplinary field of social science perspectives on the introduction, regulation and implications of science and technology. Studying ethics as a regulatory form also necessitates a grip on moral issues. The second section of the chapter therefore describes the anthropological studies of ethics, morality and bioethics. It does so at some length, with the purpose of encircling the specificity of the perspective offered in this thesis. The third section outlines how the inspiration from these studies has been applied to the theoretical perspective of anthropology of policy, which was used to frame the project. Without attempting to exhaust the literature or number of approaches, through a generalised overview in the literature review I seek to provide a glimpse of the breadth of types of study, rather than the depth of their respective insights.
2.1 Studies of biobanks and genetic research

2.1.1 The normative medical ethical debate about biobanks

The mid-1990s saw a rise in debate in medical journals about storage, use, and re-use of human tissue for clinical and research purposes (Adams, Prentice, & Oki 1996; Knoppers & Laberge 1995; Korn 1996; LiVolsi 1996; Marshall 1998; McQueen 1998; Pentz et al. 1999). After samples had been routinely gathered with minimal ethical attention for more than 80 years in most countries with a modernised healthcare service (Lawrence 1998), biobanks and genetic databases – as some actors then began terming them – became object of a range of normative statements (for representative publications see (Ashburn, Wilson, & Eisenstein 2000; Beskow et al. 2001; Diest & Savulescu 2002; Hansson & Levin (eds.) 2003; Weir (ed.) 1998). Though it is often claimed by social scientists and critical medical ethicists that bioethical debate is largely shaped by normative moral philosophy (Hoffmaster 1994; Zussman 2000), this has not been the case with debates about biobanks: social scientists, medical researchers and practitioners have been just as much part of designating the debated issues and making the normative claims.

It is typically argued that biobanks become ethically problematic because stored samples can, today, be used for genetic research (Chadwick 2001; Greely 1998; 2001). The debates straddle such diverse issues as autonomy, confidentiality, and property rights, besides disagreement about definitions of and appropriate terms for biobanks. The issue that has received more attention than any other, however, is informed consent. In fact, consent is mentioned or discussed in virtually any normative statement about biobanks. It has been discussed how much information, number of pages, the donors should have; when they should have it, as samples are taken or when they are used for research; how it should be presented, written or orally; to whom it should be given, if the donor is dead, to the whole family or individuals; and what the information should be about, the disease studied, the methods, the funding, the location or the proposed research. The possible complications aligned with the introduction of informed consent have also received considerable attention, e.g. wastage, will certain research projects be impossible; psychological harm, how would it feel being asked when dying; and practical problems, how to contact donors years after the donation (Arnason 2004; Ashcroft 2000; Austin, Harding, & McElroy 2003; Barbour 2003; Dillner 2001; Hansson & Levin (eds.) 2003; Lo et al. 2003; Örn 2003; Swibel 1999; Woodward 1999).
Despite the intense disagreement about how strongly a demand for informed consent should by imposed, a general consensus seems to have emerged on the view that informed consent for research is indeed preferable; only the degree to which it should be allowed to hamper other goals is contested. The normative ethical statements thus seem to rest on a shared assumption about donors wanting to give informed consent (an implicit empirical claim) or, at least, that donors ought to want to give informed consent. This view also permeates the Swedish debate where the commentators have tended to see the ethical task as one of balancing societal interests against the integrity of donors (Hermerén 1997) – or as the Medical Research Council has termed it: to balance the knowledge requirement against the safeguard requirement (Swedish Medical Research Council 1999). Safeguarding has tended to be conflated with respect for patient autonomy in line with the convention of using the informed consent requirement for participation in medical research because it simultaneously allows participants to choose the risks they are willing to take and shows respect for them as human agents (Brody 2001; Faden & Beauchamp 1986). After biobanks had been launched as ethical problems, it was argued that samples are, all things considered, not the same as human beings and that too much emphasis on patient autonomy might undermine the notion of what constitutes a person (Knoppers & Laberge 1995). This type of reasoning has been used to propose presumed consent with the possibility of opt out (Dillner 2001) when assessing the use of stored tissue. Such arguments have been countered, however, by the claim that “research is research” irrespective of whether the person is present and that the very use of terms such as ‘participant’ and ‘source of genetic material’ obscures the status of research subjects as ‘real moral agents’ (Sade 2002).

With the focus on informed consent and the relationship between donor and research institution, very little attention has been paid to the organisational frameworks of biobanks, except perhaps in relation to the issue of confidentiality. As DNA is in principle always identifiable, total anonymity is impossible. The potential identification and leakage of information has been countered by requests for stronger consent requirements, though it has also been argued that confidentiality issues are better addressed through institutional safeguards than through informed consent (which, in fact, necessitates a more straightforward linkage to the donor’s identity) (Ashburn, Wilson, & Eisenstein 2000). It is striking, however, that even when organisational arrangements are deemed inadequate, the suggested solution is still to emphasise informed consent (Hoeyer & Lynøe 2004; Merz, McGee, & Sankar 2004; Potts 2002). Nevertheless, a few Kantian studies (O'Neill...
2002; Whong-Barr 2004) have challenged the notion of informed consent as the prime concern. These studies are discussed in paper V.

Closely related to the debate about confidentiality are debates about potential trade in genetic information derived from biobanks and the negotiation of entitlements in the stored tissue (Dahlquist 2002; Hellstadius, Wolk, & Wessman 2003; Nature 1996; Rogne 2003; Stigbrand 2003). Some commentators hypothesise that biobanks could potentially be used for screening for genetic disorders and in the event of insurance companies being in a position to buy information from biobanks, donors with high disease susceptibility might face problems in getting a health insurance (Juengst 1995; Stoddard et al. 1993). Considering the limited dependency on private health insurance in the European welfare states, the attention paid to the issue is surprising. Others have feared that genetic information retrieved for medical purposes could be used for forensic purposes (Barbour 2002). This indeed did become an issue in 2003 in Sweden after the murder of foreign minister Anna Lindh: a sample from a suspect was obtained from the Phenylketonuria (PKU) Registry at Huddinge Hospital with debatable legal basis. This made some Swedes demand their samples in the registry to be destroyed (Snaprud 2003a; 2003b). Also, the question of trade in tissue-based research is debated as part of contemplating whether the sort of entitlements donors might have in stored tissue should be conceptualised as property rights (Beyleveld & Brownsword 2000; Laurie 2002; Nelkin & Andrews 1998; O'Brien 1995; Skene 2002). Most attention is given to trade in tissue as such, rather than bio-information (Andrews & Nelkin 1998b; Holland 2001; Josefson 2000; Kovac 1998). Some see in property rights a better safeguard than informed consent, whereas others believe that property rights will imply a derision of human dignity. The assumptions about individual donors both needing and wanting safeguards against commercial and governmental exploitation are analogous to the general medical ethical debates about informed consent in biobank-based research.

The normative debate about biobanks is thus infused with assumptions of what donors want and the image of them posing themselves in opposition to other interests whether commercial, scientific or governmental. These claims are an implicit part of arguments rarely seen as needing empirical footing. The task of the present study, framed as it is from the perspective of anthropology as an empirical tradition, has been to confront and investigate these assumptions. In doing so the study contributes to the tradition of empirical medical ethics.
2.1.2 Empirical studies of biobank research in medical ethics

In line with the focus on donors’ autonomy and informed consent in the explicitly normative debates about biobanks, the studies of biobanks in the empirical tradition of medical ethics have concentrated on attitudes among donors to the use of tissue for various purposes with or without diverse forms of consent. Most of the studies focusing on biobank research within empirical medical ethics are quantitative studies and they partly share the assumption prevalent in the normative debates that informed consent is donors’ main interest. These studies seek empirical footing for this claim, however. Two such surveys have been undertaken as part of the present study.

At the inception of the present study there were only very few quantitative empirical ethical studies of attitudes towards tissue donation and they gave no coherent picture (a summary of the existing studies can be found in, Ring & Lindblad 2003). The heterogeneous results could be related to the fact that they concerned different forms of tissue, forms of donation, and different purposes. Since then several studies have been executed. The studies of greatest relevance to the surveys included in this thesis (Merz & Sankar 1998; Stegmayr & Asplund 2002; Wendler & Emanuel 2002) are discussed in papers III and IV. The picture remains more or less the same with little agreement between the various findings and difficulty in determining which factors affect reluctant or positive attitudes to the use of tissue.

The empirical medical literature on informed consent in general provides a characteristic picture: informed consent is inherently difficult to get. This is clearly illustrated in two meta-studies of empirical research on the consent requirement (Kaufmann 1983; Sugarman et al. 1999). Other empirical studies have partly confirmed the relevance of the assumption in normative ethical debates that donors resist commodification (Start et al. 1996), though one study finds that most donors seem to accept commercial purposes after 15-30 minutes of explanation (Jack & Womack 2003). Similarly, Stegmayr and Apslund (2002) found that people in Västerbotten had no objection to research cooperation with a private company. Other empirical studies on biobanks have been more policy oriented and sought to learn from the Icelandic experience (Kaye & Martin 2000; Martin 2001), or other biobank arrangements (Austin, Harding, & McElroy 2003; Laage-Hellman 2003). Some of these studies do not present themselves as medical ethics, in fact none of the qualitative studies on attitudes to tissue donation, to which we now turn, present themselves as medical ethics irrespective of how closely they are related to the issues debated here. Instead they are generally seen as part of Science and Technology Studies (STS). The
description of this type of empirical study of biobanks begins with studies with many empirical similarities to the work presented in papers I and II, followed, in more general terms, by a description of the social science work on the social implications of biobanking and genetic research.

2.1.3 STS: The regulation and public understanding of genetic research

Three studies conducted in the UK show many similarities to the findings presented in chapter 4 and paper I and II. The studies have been conducted by Erica Haimes & Michael Whong-Barr (2004), Helen Busby (2004), and Richard Tutton (2002). Based on qualitative interviews with donors to a biobank in Cumbria, UK, sociologist Haimes and ethicist Whong-Barr argue that the binary logic of informed consent which distinguishes between either participation or non-participation inadequately represents the way in which they found people to be relating to their participation. Donors tend not to have informed themselves about the specific research purpose, and they demonstrate various degrees and styles of participation that transgress the clear boundaries of a ‘yes’ or ‘no’ to participation. Busby shows how many donors do not share the notion of genetic exceptionalism characteristic of normative ethical debate about biobanks; and that donors tend to trust the authorities in the welfare states to safeguard the material they donate. This does not imply that people donate out of pure altruism: they tend to see the donation as part of an ongoing exchange relationship with the authorities. Similarly, Tutton has shown how people have various expectations to what they will gain from participation which do not fit the image of the purely altruist donor.

One of the most cited books in the social scientific literature on biobanks is Paul Rabinow’s *French DNA*, in which he analyses the event of (unsuccessful) commercialisation of a French biobank (Rabinow 1999). The book has been important in framing the analytical questions addressed by anthropologists. He describes how the biobank material became subject to a redefinition from mere tissue to “French” DNA, thus acquiring a national identity, and he situates conflicts over entitlements in the stored research material within a wider cultural and historical framework. Rabinow’s work has been essential to the framing of the present study, as it positions ethical debate over biobanks in both an historical and a political context and thus transfers the analytical gaze from the tissue to the socio-cultural institutions engaged in the negotiation of the entitlements in tissue. Only few other studies have so directly addressed the processes in which biobanks have become a new ethical problem (Lawrence 1998) and the negotiations of entitlements
in stored tissue as a particular form of social event (Anderson 2000). Discussions about entitlements have instead, as in the normative ethical debate, tended to focus on property issues in the form of intense debate about commodification of human tissue and health data (Andrews & Nelkin 1998a; Holland 2001; Lundin 2002; Morgan 2002; Rose 2001b; Weston 2001): a debate partly reflecting the greater amount of work on the trade in human organs (Das 1999; 2000; Lock 2003; Scheper-Hughes 2000b; 2001).

A great corpus of work revolves around the Icelandic company deCODE Genetics (Árnason & Simpson 2003; Fortun 2001; Pálsson 2002a; Pálsson & Hardardóttir 2002). These studies often support the notion in normative medical ethics that commercial biobanks and genetic research constitute ethical problems, though the normative positioning is often implicit, revealed in attitudes of opposition to the project (Rose 2001a; Sigurdsson 2001). Other cases having spurred social commentary are the Human Genome Project (HUGO) (Hellstein 2001) and the Human Genome Diversity Project (HGDP) (Greely 1998; Marks 2001).

Some of the most important insights generated in the social scientific studies of biobanks reflect attentiveness towards the interplay of power structures and the production of cultural significance. Anne Kerr thus situates the debate about biobanks in an historical context where notions of citizenship are being negotiated with allusion to a presumably eugenic past; the stored tissue (and the genetic research it accommodates) is ascribed new meanings in a process of defining the present rights and responsibilities of citizens in modernising welfare states (Kerr 2003). As pointed out by historian Lene Koch, the “reference to ‘eugenics’ with no further specification is (…) more often a function of our own projections and intentions than a reference to history” (Koch 2004). In a similar vein, Richard Tutton has shown how political negotiation of diverse interests is at play in seemingly ethical discourses about how to compensate citizens for their contribution of tissue to research. Based hereon he has shown the way authorities do ‘boundary work’ to distinguish between the substance donated (which is ascribed ethical significance) and the research results this substance is expected to generate (which can be sold on market terms) (Tutton 2004). Gisli Pálsson has shown how the project initiated by deCODE has implications for the sense of kinship (Pálsson 2002b), and he has elucidated the cultural production of moral claims, and their emergence in interplay with market interests (Pálsson 2002a; Pálsson & Rabinow 1999). He has also ventured to analyse the media debate about deCODE and found that though the venture has been intensely covered, very few actors have taken an interest in the matter, and these have mainly been general practitioners (GPs) who declined to give deCODE access to the medical records that they
produce (Pálsson & Hardardóttir 2002). Again the ethical debate is analysed as cultural politics, i.e. a matter of different stakeholders having different interests and ascribing different meanings to the object of strife, as in the case of French DNA. Similar approaches have been used for studying the establishment of exchange and storage systems for stem cells (Morgan 2002; 2003; Waldby 2002), and they all exemplify the fruitfulness of Rabinow’s inclination to situate current scientific conflicts in wider cultural and historical frameworks, which is a move typical of Science and Technology Studies (STS).

Other key issues for many STS scholars, which are relevant for the work contained in this thesis, are public attitudes to and social implications of genetic research. Studies directing attention to the social aspects of new medical technologies have been particularly important sources of inspiration (Brodwin 2003; Everett 2002; Finkler, Skrzynia, & Evans 2003; Franklin 1995; Lippman 1992; Novas & Rose 2000; Pfaffenberger 1988; Strand 2001; Traweek 1993). The Public Understanding of Science (PUS) tradition can be seen as a subpart of STS (Brown & Michael 2002; 2003; Elam & Bertilsson 2003; Holmberg 2003; Ideland 2002; Irwin 1999; 2004; Lundin & Åkesson 1997; 2000; Nielsen & Berg 2001; Nielsen, Jelsøe, & Øhman 2002), and it has been useful as background knowledge. However, with the focus on the ethics policy as a form of regulation, the exploration of perceptions of genetics has receded in favour of an understanding of ethics as a regulatory form.

A branch of STS concentrates on developing an interdisciplinary perspective on the regulation of new technologies. A study by Julia Black (1998) is very similar to the task set for this thesis, though she limits her interest to the policymaking level, whereas this study has embraced people working with the policy and also its target group. Black wants to understand the regulatory effect of ethics and she encircles three dimensions of the ethical policy work: a) a structural dimension (who has a speech position to influence policymaking), b) a cognitive dimension (which worldviews are in play), and c) a communicative dimension (what do they speak about). She concludes that the resulting “regulation” serves more as facilitation of research than as outright regulation (see also Koch & Zahle 1997). This resonates with the argument made by Susan Wright (1994) in her influential book on the regulation of genetics in the UK and the US, where she claims that administrative law is unable to regulate genetic research (see also Lindsey et al. 2001). Imposed bans are always lifted after a while. Herbert Gottweis (1998) modifies the claim that this implies that no regulation takes place thanks to his more elaborate theoretical framework: the power effect of the regulation is merely different from the political rhetoric of controlling research through
prohibition. Another viewpoint is suggested by Fleising and Smart (1993). They argue that the regulation of research is moving from administrative law to property law. This resonates with what seems to be Gottweiz’ contention that regulation is taking place: it merely takes on other forms than those we might be accustomed to look for. In a Scandinavian context, Thomas Achen (1997) has pioneered the study of the regulation of genetic research at the intersection of law, politics and ethics. He notes how Sweden, at an early stage, employed law to regulate gene technology with a type of risk assessment expounding explicit normative judgements (rather than claims a purely scientific basis).

Throughout these studies, however, the focus is on the regulation of research. But is it reasonable to assume that the ethics policy studied in this case primarily regulates research? Or could it be, for example, research participants? Also, it must be noted that these studies address issues of power, property and cultural perceptions, which all seem relevant, but insufficient when ethics is studied as a form of regulation. Naming the ethical inevitably invokes notions of morality, and social scientific grounding of a study of ethics as a social practice is found in the anthropological and social study of morality, which is therefore outlined in the following. The relatively extensive overview of social scientific approaches in this field provides the theoretical background of the concepts used in the respective papers. Also, the intention is to establish the necessity of having concepts that can communicate how something can be at stake for people which is not just their personal preference or influence. The overview thus contributes to the development of an analytical framework for the study of ethics as a form of regulation.

2.2 Ethics, morality and bioethics

2.2.1 Social science perspectives on ethics and morality

Generally, social scientists mean something different with the words moral, morality, and ethics than moral philosophers, and the terms are used in overlapping meanings even in social science debates. A concept such as moral, for example, is used both as an adjective and a noun. In the following overview of important trends in qualitative social science perspectives on ethics and morality, the use of the concepts therefore follows that of the respective authors rather than predefined categories.

At the inception of sociology, the study of moral was central to the discipline. Emile Durkheim deliberately wanted to reclaim moral from philosophy and repeatedly stated that moral is
a social fact (Durkheim 1957; 1979b). He believed to find in moral the glue of social structures (Durkheim 1973), and included it among the objects of a positivist sociology. However, with the hermeneutic turn in anthropology (from the study of facts to the study of people, their perceptions and experiences) his positivist image of moral became more of a bogey than an intellectual inspiration, and there have been only few attempts to revitalise the study of moral (Edel & Edel 1959; Jackson 1982a; 1982b; Read 1955).

Meanwhile the case for a descriptive study of ethics had been suggested by another strain of theory stimulated by the last essay of Durkheim’s nephew Marcel Mauss (1985). In this essay, Mauss ventured to understand the development of the western notion of self. Mauss showed the historical and cultural specificity of the concept of person, which is central to philosophical notions of autonomy. Clifford Geertz in his seminal book *The Interpretation of Cultures* (1973) made a synchronic analysis of the same topic, but it was with the work of Carrithers *et al.* that the study of the notion of personhood was successfully launched as an anthropological perspective on issues central to philosophical ethics (Carrithers, Collins, & Lukes 1985). Despite the increasing use of philosophical theory since the mid-1980s (see e.g. Jackson 1998; 2002b), the comparative impetus of anthropology remains at odds with dominant strains of moral philosophy, as the former rests on some version of relativism and the latter tend to transcend culture-based norms in search of moral truth (Geertz 2000; Rabinow 1983).

Signe Howell (1997) has suggested an ethnography of moralities, which renews Durkheim’s notion of moral as a social fact though challenging the image of ‘the glue of social structures’ both methodologically and theoretically. Whereas Jackson (1982a) and Bauman (1994) had already made ambiguity central to the anthropological understanding of moral, Howell suggests working explicitly with dilemmas: to study moral values through the moral reasoning in situations where values conflict, and choices have to be made. Theoretically, Howell challenges the positivist structural framework embedded in the Durkheimian tradition by talking of moralities as constantly emerging. There is a tendency, however, to be unfair in the description of Durkheim as structurally static. Although emphasising a structural level, he did not see moral as a static phenomenon. On the contrary, he stated that “the moral ideal…is alive, constantly changing and evolving. The future will have a different ideal from that which obtains now” (Durkheim 1979a: 81). These debates reflect divergent understandings of the relationship between structure and agency where some theorists argue that moral capability emanates from societal structures (as Durkheim held), while others claim that it resides in individuals (Rapport 1997).
This relates to the notion of choice, which is central to James Laidlaw’s (2002) contribution to the social study of ethics. Laidlaw draws on the work of Nietzsche and Foucault and makes a distinction between moral as social norm, and ethics as the practice of self, i.e. the ways a person uses his or her freedom to choose. Based on this he seeks to denaturalise our understanding of what is ‘moral’ in the evaluative sense and (re-)establish ethics as a more neutral comparative field of study. He suggests following Foucault who lays out four aspects of our practices of self which deserve attention in the comparative study of ethics (Foucault 1986; 1992; 1997a): 1) Ethical substance, how and why does something become an ethical problem? 2) mode of subjection, which form does the discursive environment for the ethical substance take, is it e.g. religious, scientific or aesthetic? 3) self-forming activity, what can an individual do to act ethically, e.g. pray or work hard? 4) teleology, what does the subject aspire to, e.g. an afterlife or a grand career? This understanding has become an important, though mainly implicit part of the present study because biobanks constitute a new ethical problem, something beginning to gain ‘ethical substance’. Foucault, however, concentrates on a different level of transformation where practices of self change only slowly over centuries.

Despite Foucault working within an explicitly anti-essentialist tradition, and despite having distanced himself from any theorising on the ‘human condition’ (a term he argues is an historical product (Dreyfus & Rabinow 1983; Foucault 1999)), here in some of his last work gets as close as ever to say something about a basic human condition: the freedom to choose. The point is, however, that what is made object of choice is never voluntarily decided; every choice is presupposed by other choices and facilitates yet other choices, and, as such, the practice of self is constantly emerging and not a self-generating basic unity from which structures emanate. Foucault does not presuppose a doer behind the doing; a chooser behind the choice. There is no truly transcendental ego in the sense implied by Sartre (1984). The notion of historically situated choices is pertinent to attune the analytical gaze towards what is at stake for people in different situations as it directs attention to the choices made without presuming that the involved agents have generated these choices themselves.

Understood in this way, Foucault and Laidlaw have ethics as an object of study and employ the concept in an almost ontological sense, i.e. as the name of something they want to know more about as explained below (though in general belonging to a nominalist tradition). However, there is an important difference between their approach and Durkheim’s because Foucault and Laidlaw study the contingent social conditions of choices, whereas Durkheim studies moral norms
presumed to reside in the social. To amount to a moral, norms must stem from the social, according to Durkheim.

2.2.2 Moral economies and exchange studies

Durkheim’s contemporary Max Weber also worked on moral issues, but whereas Durkheim used the concept of moral primarily in the ontological sense (as the name of something to be investigated), Weber used the concept in an epistemological sense (i.e. as an aid in the interpretation of other social phenomena). I take the distinction between ontological and epistemological concepts from Kirsten Hastrup (2002). Weber’s well-known and influential book on the protestant ethic demonstrated how a concern with how one ought to act could influence the emergence of certain types of economic systems (Weber 1992). Over the years, this approach to ethics has proven itself immensely influential in the social sciences. Ethics, ethos, moral, morality, and value have become concepts that are primarily used to understand a specific aspect of something else, and not the object of study as such.

Of particular importance has been the anthropological study of exchange systems. Economic anthropology can be said to be founded on the assumption that there is a continuum between gift and market economies: what can be analysed is the exchange of goods in different ways which are all culturally embedded. A central essay is *The Gift* by Marcel Mauss (2000) which laid out a mode of analysis for studies of exchange systems which emphasised the pre-existence of relations between exchanging parties: nobody exchanges anything without a pre-existing idea about the sort of obligations it will incur on the respective parties (Frow 1997). *The Gift* was interpreted by Mauss’ contemporaries as a study of primitive law (the establishment of duties) rather than exchange (Sigaud 2002). Since the 1960s, however, it has primarily inspired substantialists who have argued that economies are structured by culture and moral values (Sahlin 1972) as in the so-called ‘moral economy studies’ (Scott 1976). More actor-oriented theorists (the so-called formalists) have argued that economies emanate from self-maximising, rational individuals (Barth 1967). Later Appadurai and Kopytoff transgressed the divide between substantialism and formalism by looking at the meanings produced in specific culturally construed forms of exchange (Appadurai 1986; Ferguson 1988; Kopytoff 1986). Based on their approach, Pálsson developed the concept of moral landscapes to describe the complex webs of interaction between cognitive, moral and economic exchanges (Pálsson 2002a). Mauss has also inspired social policy studies, in particular
Richard Titmuss’ famous argument for a gift relationship in systems for blood donation (Titmuss 1997).

What unites all these studies is the analysis of moral value as an aspect of economic life; to use it to understand concrete arrangements of exchanges; and to reinstate culture in economics. They provide an important background to an understanding of the exchange of blood samples because they facilitate an understanding of the interrelatedness of moral, cognitive and economic value: the exchanged blood samples can be analysed as objects of a negotiation of meaning (cognitive value), as well as importance (moral value) and property rights (economic value). The concept of value has been re-conceptualised by David Graeber (2001) with the aim of integrating these diverse meanings of the word ‘value’ as interdependent aspects of any action by motivated agents (see also Waldby 2000). Graeber argues that value is what we desire and work for and that it is revealed in action, not through ethical deliberation. Barth (1993) follows Graeber in his attempt to attune the analyst to tacit human practices embodying moral worth, while adding a methodological challenge. If we observe only what people aspire to with their acts, we do not capture their own understanding of what constitutes moral concerns. Conversely, we cannot rely on people’s own articulation of values because the values informing their conduct of life tend to be so much taken for granted that they would not be considered as worth mentioning. Societies where, for example, sharing is embedded in social practice, do not discuss this as an ideal, whereas societies with strong regimes for private property tend to do so (Barth 1993).

Both Graeber and Barth look at value as an object of knowledge and thereby work with ontological concepts of value. In a sense, however, both their approaches make everything into value, which makes it very difficult to argue that something for some reason is without moral value. It deflates the particular meaning of the word moral that relates to the notion of ‘ought’, and if value is simply what we pursue it can be replaced by preference (as also admitted by Barth 1993:36).

The different positions have been organised in figure 2.1 to facilitate an overview. Category A comprises the studies seeking to develop ways of analysing ethics and morality as objects of study in their own right. Category B comprises the studies where ethics and morality are merely concepts that should help us understand something else (e.g. exchange systems). Category C comprises studies inspired by discourse and power analytics: they are more recent and will be described below. The arrangement in categories illuminates how studies presumably dealing with the same subject, namely ethics and morality, have different objects of analysis, and employ the same words with different understandings.
2.2.3 Social science perspectives on bioethics

Strangely, the studies of moralities described above have had only marginal influence on the social study of normative medical ethics, here referred to in short as bioethics. Recent studies assessing the contributions from the social sciences to bioethics do not even mention Durkheim (Hedgecoe 2004; Muller 1994; Spallone et al. 2000; Zussman 2000), even when setting out to give a general review of the sociology of ethical issues (Haimes 2002). This can probably be related to the ways in which these scholars have come to address bioethical issues. The social scientific commentary on bioethics falls in two main corpuses of work, which will be described in the following: (1) one emanating from medical anthropology and sociology, and (2) another emanating from studies of power. None of them is particularly closely affiliated with the classical approaches.

(1) In the studies emanating from medical anthropology and sociology, the social scientists typically take the normative point of departure in the assumption that patients constitute a
weak, vulnerable and varied group in relation to medical professionals, who are powerful, active and homogenous (Gabe, Calnan, & Bury 1991). Accordingly, many anthropologist and sociologists frame their contribution to bioethics along to the dichotomy prevalent in medical anthropology of patients’ complex and ambiguous emotional experience of illness versus unequivocal biomedical disease definitions (Kleinman 1995; 1999): the illness/disease distinction is used to oppose patients’ complex moral worlds to bioethical pretensions of universal clarity (see e.g. Gammeltoft 2001; Kaufert & O'Neil 1991; Nelson 2000b). The most compelling studies identify in mainstream bioethics a reduction of moral complexity and an inability to address the actual social contexts in which moral choices have to be made (most forcefully argued in Alderson 1993; Anspach 1993; Bosk 1992; 1999; Gorden & Paci 1997; Kaufman 1997; Zussman 1992). Some medical ethicists have identified similar shortcomings with respect to social context in medical ethics (Hoffmaster 1992; 1994; Holm 1996). This has spurred studies which not only comment on bioethics, but aspire to a new way of doing ethics (see e.g. Beeson & Doksum 2001; Borneman 2001; Joralemon 2000; Kaufman 2001). Indeed some sociologists commenting on the relationship between bioethics and sociology claim that their contribution should not be regarded as simply “adding the facts to normative judgement”, but must also be acknowledged as a more fruitful, theoretically informed approach to bioethical issues as such (Haimes 2002; Nelson 2000a).

The previous section introduced a distinction between ontological (type A) and epistemological (type B) concepts, but many of the studies of bio-ethics cannot be put in either concept type. Instead they use the concept of ethics in what is here termed a discursive sense. When used as a discursive concept, ‘ethics’ is not taken to mean anything; rather it is the implications of ‘ethics talk’ that are the objects of analysis. In particular, this seems to be the approach when the analyst focuses on the introduction of bioethical regulation. If we relate the studies critiquing bioethics from the perspective of medical anthropology or sociology, some of them can be said to employ an epistemological concept of moral because they primarily analyse the social structure of the clinical setting or the doctor/patient interaction and take up moral aspects of this interaction. Most of the studies modelled on the illness/disease distinction, however, more or less intentionally combine an ontological (or epistemological) sense of the concept with a discursive sense in as far as they seem to work with ontological notions of patients’ local moral worlds, while using the concept of ethics in the discursive sense.

(2) A purely discursive concept of ethics is employed in that corpus of work taking its inspiration mainly in political anthropology and sociology. Here, ethics is seen primarily as a
political technology and the focus is on the political implications of bioethical discourse and institutions. The proliferation of ethics is viewed as an expression of particular interests, and analysed as negotiations between unequal actors (Corrigan 2003; Fortun 2001; Lund & Horst 1999; Lundin 2002; Novas & Rose 2004; Pálsson 2002a; Pálsson & Hardardóttir 2002; Pálsson & Rabinow 2004; Scocozza 1994; Whitt 1999). Important insights into the power effect of phenomena referred to as ‘ethical’ have been disclosed by these scholars; not least Nikolas Rose who with inspiration from Foucault talks of a “new game of power [that] operates in a field one could term ethico-politics” (Rose 1999: 188). This field introduces “technologies of responsibilization” (ibid:74), and Rose argues that what might be presented as increased freedom of choice is also a way of enrolling citizens in government through an obligation to make choices which will have to be informed by experts (ibid:83). This perspective has direct relevance for an analysis of informed consent as a regulatory practice. Also, some of the studies emanating from medical anthropology have come to view ethics as a technology of power which serves unjust systems of exchange, in particular in the case of organ transplantations (Scheper-Hughes 2000b; 2001; Sharp 2000). Here, it has been shown how discourses of autonomy have been used to further the rights of wealthy healthcare consumers at the expense of marginalised groups who come to view their bodies as resources for the family economy (Das 2000).

Studies in this tradition, however, tend to see in morality nothing but personal or institutional interests and could be described from a philosophical perspective as a form of inadequately argued emotivism. Like Graeber, they reduce the scope of the moral to personal preferences. Though pretending to take a merely descriptive stance, these scholars thus, in fact, advance a moral philosophical position without realising the need to justify it. Hence, while accusing moral philosophy of unjustified universal pretensions, they endorse a position in the philosophical framework which does not acknowledge any other form of moral reasoning, and they imbue the concept of moral with one specific meaning (preference) that rules out other understandings. Existentialist philosophers have taken the argument further and suggested that this type of position where everything is just preferences (a position they term aesthetic (Beauvoir 1997: 73-77) is fundamentally lacking a sense of responsibility. However, this need not be an argument against this type of study per se because this approach to ethical discourse can be a methodological necessity in studies that have generated important insights. Nevertheless, this criticism provides reason for not letting such studies stand alone.
By invoking the anthropological studies of morality from Durkheim and onwards I wanted to find a way integrating into a social science framework respect for the normative aspect of human action which transcends individual preference. It is indeed possible to imagine an ‘ought’ which transcends the interest of the ego, and feelings about what one ought to do are in fact central to an understanding of the type of negotiations that an ethics policy produces. The practices of self in the Foucualtian sense are directed by notions about the good beyond ‘good-for-me’, and make it apposite to employ a theoretical framework which does not reduce moral to power.

Neither the work from medical nor political anthropology has really succeeded in engaging in dialogue with people identifying themselves as bioethicists. This probably relates to the fact that they mostly embody either a deficit model (social science perspectives have the sense of context that bioethics lacks), a replacement model (social scientists finally found the “right way” of doing ethics), or a dismissal model (ethics should be abandoned all together as a misconstrued veil of power); see Figure 2.2. Their work has been a criticism of ethics rather than a contribution to ethics. Furthermore, they have mostly work with a black-box notion of bioethics as a monolithic, homogenous fait accompli striking down on local moral worlds. There has been little awareness of feminist ethics (Walker 1998), pragmatic ethics (Fesmire 2003; McGee 2003b), neo-virtue ethics (Castoradis 1997; MacIntyre 1984) contextualist ethics (Hoffmaster 1994; 2001) and other ethical traditions that work with understandings of moral problem in ways much closer affiliated with their own social scientific approaches. It is hardly surprising if philosophical bioethicists have paid little attention to such claims, especially when made by people unaware of the philosophical implications of their own endeavour. If bioethicists from a social science perspective lack empirical footing for some of the claims they make, as argued in the first section, social scientists often present normative criticism with only limited awareness of the values on which it rests.

<table>
<thead>
<tr>
<th>Type of study</th>
<th>Position implied in argument</th>
<th>Examples</th>
</tr>
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<tbody>
<tr>
<td>A deficit model</td>
<td>Social science perspectives have the sense of context that bioethics lacks</td>
<td>(Alderson 1993; Anspach 1993; Bosk 1992; 1999; Csordas 2000; Gorden &amp; Paci 1997; Kaufman 1997; Nelson 2000b; Wexler 2000)</td>
</tr>
<tr>
<td>A replacement model</td>
<td>Social scientists have finally found the “right way” of doing ethics</td>
<td>(Beeson &amp; Doksum 2001; Borneman 2001; Joralemon 2000; Kaufman 2001)</td>
</tr>
<tr>
<td>A dismissal model</td>
<td>Ethics is a misconstrued veil of power and should be abandoned</td>
<td>(Amit 2000; Bourgois 1991; Harrison 1991; Nader 1976; Schep-Hughes 2001)</td>
</tr>
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Figure 2.2: Dominant trends in sociological and anthropological contributions to bioethics
Some studies, of course, transgress these tendencies and avoid succumbing to a ‘moral only’ or a ‘power only’ mode of analysis (Franklin 2003; Lock 2001; 2002; Rapp 2003). It is with them that I wish to see this thesis most closely affiliated because they embrace the understandings of morality generated in the tradition of type A and B studies, while belonging to category C inasmuch as they investigate ethics, not as a defined analytical object, but as an emerging social phenomenon carrying different meanings for different people. This approach aims at carving out an object of study rather than a target of criticism.

This theoretical genealogy was presented to situate the present study in its broader theoretical context and to clarify the nature of the contribution made by this study as a transgression of various traditions in the study of ethics. For the purpose of studying the ethics model of UmanGenomics, I have combined insights from the morality studies with the anthropology of policy in ways that I will briefly outline in the following section. An analytical understanding of policies is a precondition for developing a methodological approach. Without some notion of what is being studied the project cannot commence, and to facilitate a reflective research practice the notions should be made explicit.

2.3 The theoretical framework: key concepts

2.3.1 The perspective from policy studies

In the anthropological studies of policy, an important inspiration is again found in Foucault (Ferguson 1990; 1994; Shore & Wright 1999; 2001; Weiss 1986; Wright 1998). The self-image of policymaking as a linear process of identifying first problems, then solutions, and finally means of implementation has been dismantled, and policymaking revealed as a muddy process (Shore & Wright 1997). A precondition for studying the muddiness is the realisation that problems do not come in pre-packaged form, neat and ready to be solved. They emerge out of particular ways of engaging with a world that is open to multiple, sometimes conflicting, interpretations (Rabinow 2003).

Foucault suggested the term problematization for the process in which a range of nebulous issues becomes moulded into distinct problems (Foucault 1992). Problematization implies a particular gaze: rather than defining problems, it is asked how and why something at certain times comes to be viewed as a problem. Rather than asking whether something is more or less ethical, it is
asked how one thing and not another becomes object for ethical consideration. The Foucaultian notion of ‘danger’ described in chapter one is important in directing the attention of the analyst. Problems are not self-evident. The blind spots of specific problematizations constitute potential dangers. Hence, when looking at problematizations, a game of power is studied where different actors have different understandings of what needs to be worked upon and where the crystallisation of key problems has different implications to different people. A particular naming and framing in a policy serves both to get things done, and to close other discussions.

The concept of policy is at once empirical and analytical, or emic and etic as anthropologists would usually phrase it. Empirically speaking UmanGenomics has made a policy and given it a name, the Uman-model. The policy is a discussed object, i.e. an empirical concept. But what is a policy analytically speaking? How do we delineate the analytical object of the academic study? Shore and Wright (1997) suggest thinking of policies as social institutions, in the same sense as kinship. Social institutions structure our lives; or we structure our lives through social institutions. Policies constitute a way of thinking about political action, a way of shaping relations between people in public space. Policies are the prime means of expressing commitment to particular actions: they work, not as pieces of paper, but by framing and naming certain topics as objects to be acted on and engrossing them in existing power structures and networks of obligations. In this analytical sense a policy is what people say and do rather than what might have been the intentions of a particular group of policymakers, or what they, at some point, thought they decided. The very notion of decision-making as an event at a single point in time which can be captured in a document or verbal agreement (“this will be our policy”) is an image of policies, which is a feature of how they work as social institutions. It is not how policies, in the analytical sense of the word, actually operate. They are constantly open for change, never truly fixed. On the contrary, it is a trait of any communicated decision that it co-signals its own instability because there would be no reason to communicate a policy if everybody already followed its recommendations or wanted to do so (Knudsen 2004).

One of the key contributions of anthropology to the study of policy has been the emphasis on going beyond scrutiny of the written policies to explore what they amount to in practice. In a move typical of anthropology, it has been about setting what people say (or write) in relation to what they actually do. Whereas important work has focused on the moves to de-politicise and de-moralise policy initiatives and present them as neutral and knowledge-based (Ferguson 1994; Moore 1993), the case of ethical regulation is somewhat different. To be included in an ethics policy,
issues need to acquire what Foucault calls ‘ethical substance’ (Foucault 1992; 1997a): an important part of the policy work is actually about managing to present certain issues as important moral concerns. Therefore the study of UmanGenomics’s ethical model must move beyond the anthropology of policy with its emphasis on power and politics and recognise morality as part of the object of study.

2.3.2 Integrating the social study of morality into the policy approach

Just as there can be no sharp distinctions between the empirical and the analytical concept of policy, there can be no sharp distinction between empirical and analytical concepts of moral and ethics in a study of this type. This study operates with a discursive concept of ethics (type C in figure 2.1), and does not define what is truly ethical (and what is not). However, when my informants talk about ethics, moral and values, they usually tend to evoke a particular reaction or sentiment, which is anything but relativist or indifferent. Therefore it can be helpful in thinking about these issues to draw upon the insights generated in type A studies, where the concept has been employed to invoke a sense of contingent patterns in normative attitudes concerning how things ought to be, and particular forms of positioning that evoke a sense of responsibility or obligation. In line with these insights, respect for a person’s sense of agency and self can be seen as a moral issue because it comprises both this person’s sense of responsibility as well as notions about how the person ought to be treated. Debates about the boundaries of humanness can also be termed moral, as they tend to embody normative positions concerning responsibility and obligation. Accordingly, I use ‘moral’ as an adjective when wanting to communicate such meanings and ‘morality’ when referring to a pattern in moral positioning in a particular type of interaction. The point is having words to describe that something is at stake for people that is not just their ‘power’, ‘preference’ or ‘influence’.

The understanding of the words ethics, moral and morality is shaped by informants using them in an ontological sense. However, even if the feeling of an ‘ought’ is a very real part of the world, there is no agreement on what that ‘real thing’ is. As moral means different thing to various actors, this study cannot adhere to a strict definition of moral, ethics or values as if they were the names of delineated objects (the position is inspired by the late work of Ludwig Wittgenstein (Wittgenstein 2001)). Rather, the concept of moral travels from the informants’ discourse into the anthropological account while typically changing meaning from being used by informants with a direct normative intent (designating something as [a]moral) to a more descriptive meaning in the
Paraphrasing Margaret Lock as she describes her approach to the study of menopause, I would say that *ethics* –

“... is not ‘a fact’, and hence it cannot be neatly packaged or contained in a single precise term that transcends time and space, history and culture. On the contrary, it is a concept with boundaries and meanings that shift depending upon the viewpoint and interest of speaker and listener. Such variations interest me, most particularly the way in which, even as we strive to produce clarity in a few points, we descend deeper and deeper into an abyss of contradictions.”

(LOCK 1993: xviii)

In the policy process that I have studied, it is exactly the way the concepts such as ethics and informed consent travel and take on new meanings in new situations that is striking, and they cannot be pinpointed by a definition. They can be understood, however, by moving between different actors while staying alert to the way they single out different issues as worthy of attention; use different languages for creating that sort of attention; and in the process occasionally change the meaning of the words. Like menopause meaning something different to women around the world and their doctors, while still being used to refer to something very real and even physical, this approach to the study of ethics employs concepts such as moral, morality and ethics in epistemological senses to compare what is at stake for people in different subject positions without reducing this 'being at stake' to personal preference.

A study of potentially divergent moral problematizations cannot limit itself to what is expressed in the idiom of ethics. Donors of blood, for example, clearly hold views about how research ought to be and how people should be treated, even when they do not talk of these positions as ‘ethics’. Also, their acts, as when donating blood, can be seen to embody certain values, as pointed out by Graeber and Barth. These positions and values are part of the studied negotiation as they express a moral positioning; they express something at stake for the involved actors. How then to study this moral positioning? As pointed out by Barth one must combine people’s own contemplations with analysis of their acts.

For an understanding of the contemplations, Signe Howell (1997) suggests focusing on people’s moral reasoning when they are confronted with dilemmas. Just as the meaning of the word moral is constantly emerging, so are moralities. Nobody reasons independent of context (Strathern 1997), and one should beware that people might hold different opinions depending on the context without necessarily seeing themselves as lying. Therefore, interviews must be analysed reflectively. Barth then warns that “the more one seeks to trace, uncover, and generalize the ‘hierarchy of’ values (...), the more obscure they become” (1993: 35). This has to do partly with the limitations of
language in representing moral positions, and partly with the contingency of moral reasoning. There is no way to positively establish knowledge about people’s moral worlds as fixed and testable statements about what matters. What we can get is a glimpse of the type of concerns that most urgently come to people’s minds in situations of a particular kind (concerns which must be analysed reflectively with consideration to the context in which they were uttered) and combine this with careful interpretation of their acts. The donation of blood is such an act, and following the work by Mauss it is necessary to situate the donation in a wider context that might inform the motivation to donate – or exchange as Mauss would have it. People do make a choice to donate, but this ‘choice’ must be approached as a choice in the Foucaultian sense of administering the personal freedom informed by the social context in which one lives.

When seeking to understand what people take to be morally important we must engage in interaction with them and it is in this very interaction that the object of study emerges – and potentially transforms. An interview is therefore more than a window to the moral life of the interviewee: it is a workshop of values and self-representation reflecting the interaction between the people talking and the institutional setting in which the interview takes place, as are the policy statements in letters, descriptions of and comments on the ethical model made by policymakers.

Finally, it is important to note that we cannot take for granted that we know the meaning of the donated object. The STS work on public understanding of science, and the social implications of genetics has taught us that DNA is ascribed a different meaning by different actors. The moral conflict is linked to an epistemological question about what genes and questionnaire data are.

Hence, the object of study is the ethics policy as a social institution engaging different people in its formulation and practice. The approach is to explore divergences in problematizations made by actors in different positions in relation to the ethics policy using the awareness that problematizations emerge in a triangulation of power, knowledge and morality. The problematizations are analysed as what is at stake for the respective actors and revealed in a combination of verbal and non-verbal communication. The following chapter elaborates on how this task was undertaken.
CHAPTER 3: METHODS

3.1 Turning theory into research practice: the actual ethics policy

The studies of policy processes and moral reasoning seemed a good starting point for analysis of the ethics policy of UmanGenomics. Each particular case, however, presents its own peculiar problems. The immediate, concrete challenge, here, in this study was to obtain a copy of the policy. A written copy of the ethics policy was never available when asked for. Descriptions of it were given, including written ones, but no official version. The policy existed in the networks discussing it and I was invited to become part of those networks, but an official version was unobtainable.

The policy was described orally and in different articles and leaflets as a ‘model’ focusing on public oversight and control at three levels: 1) public majority ownership of the company, 2) approval by regional research ethics committee (REC), 3) individual consent from all donors (paper I:229). Sometimes separation of company and biobank was also described as part of the ethical model (as a safeguard against commodification of human tissue); sometimes community benefit sharing (paper II:12). Establishing the company locally rather than allowing foreign companies profit from the efforts of people in Västerbotten was advanced as an important concern, but not explicitly fitted into the public descriptions of ‘the model’, unless the public majority ownership is seen as addressing this concern too. The individual consent was clearly ascribed the most importance.

In February 2003, I finally received conformation that the policy had never been in writing. At that stage, however, it had long been clear that it was another form of policy work that the study revolved around; namely, a prime example of the analytical anthropological understanding of policies as structuring institutions, rather than pieces of paper. To some informants, however, it did come as a surprise that a certified official version did not exist. While it had not taken on this certified form, the policy had taken on a social life through commitments to particular framings of areas of intervention.

With the object of study defined as a policy process, and an analytical interest specified through the research questions described in section 1.2.2, the methodological task has been to establish ways of answering these questions. The anthropological fieldwork tradition typically transgresses methodological toolboxes such as discourse analysis, hermeneutical analysis, phenomenological analysis and grounded theory, because of the very diverse forms of data it
generates. Hence, the anthropological methodological emphasis is on reflexivity about variances in data material rather than on uniformity in the way the material is analysed. Throughout the fieldwork, the various data have been recorded in what amounts to three books of field notes and a compilation of documents. The three books were handwritten to facilitate immediate updating independent of computer access. Jottings were transferred from notebooks to the field notes, often several times a day. The field notes, which have been roughly indexed, serve to keep track of all fieldwork undertakings.

It was an important task to develop a fieldwork approach that could match the object of study. The research questions concern the social implications of a policy process. The theoretical pre-understanding of the object draws attention to the ways in which policies typically serve as both ways of getting things done, and of closing other discussions. Therefore, a fieldwork approach has been developed to address the implications of the policy in both positive and negative terms, i.e. concerning what the policy has actually amounted to in practice (question 1-3, see page 9-10) and the type of issues that it has managed to marginalise from policy attention (question 4). The fieldwork was in relation to three analytically defined levels of policy work respectively reflected in the first three research questions (as outlined in Figure 3.1). This is an operationalisation of Reinhold’s concept of ‘studying through’ (in Shore & Wright 1997).

<table>
<thead>
<tr>
<th>Level</th>
<th>Research questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policymakers</td>
<td>What prompted the making of the policy, who formulated it, and what form did it take?</td>
</tr>
<tr>
<td>Policy workers</td>
<td>Who was expected to implement it, what did they actually do, and what implications has it had for them and the policy?</td>
</tr>
<tr>
<td>Target group</td>
<td>Who was the policy targeting and what did it entail for them?</td>
</tr>
</tbody>
</table>

Figure 3.1 Research questions in relation to analytically defined levels of the policy process

The fourth research question about concerns other than those addressed by the policy has relevance to all three levels, though in particular for the target group as the members have had the least chance of influencing the policy framing.

The ambition of identifying “boundaries and meanings that shift depending upon the viewpoint and interest of speaker and listener”, described in the preceding section, provoked a guiding methodological principle, and this principle is outlined at first. Secondly, the type of activities undertaken and the diverse types of data that these activities generated are described,
before the practical conduct is elaborated with special emphasis on the qualitative methods. Subsequently, the quantitative methods are outlined, and then the approach taken in analysis of the material is explained. Finally, the last section presents reflections on some methodological problems.

### 3.2 Methodological principle

The overall idea has been to move between the three levels, 1) policymakers, 2) those implementing the policy (termed policy workers), and 3) the policy’s target group, in order to look for discrepancies in the ways problems are defined and to establish knowledge about what are the actual implications of the policy. This implies mirroring different understandings of ethical problems in one another, rather than trying to establish what the real problems are by reference to ethical principles or basic value judgements. The intention is to explore how issues might feature differently in the awareness of people in different speech positions and retrieve views (subjugated knowledge and moral positions) which have not been articulated in the policy process. The comparison could be regarded as unequal: at the level of policy workers and target group, the analytical interest has been centred on what is at stake for the respective actors. At the level of policymakers it would not have made the same sense to identify what is at stake for them as moral agents, because the policy is a conglomerate of many people’s intentions, and the analysis seeks to compare the reasoning represented in the policymaking with the moral problematizations of other actors. Therefore the policy has been identified as a ‘product’ devoid of personal moral interest, albeit representative of various forms of moral reasoning.

This principle of comparison led to a series of activities summarised in figure 3.2. Policymakers were identified through snowballing: informants were asked who they saw as key actors in the policy execution and who they thought took important decisions of relevance to UmanGenomics and Medical Biobank. Subsequently, these persons were contacted, and in turn asked the same question. a method taking the anthropologist around to many different organisational sites (including a visit to Stockholm). The regional Research Ethics Committee (REC) holds a double position as it has been regarded by some informants as part of the policymaking network (i.e. its members have been identified as key actors by some policymakers), while analytically speaking, its members are also policy workers because the REC is responsible for oversight at the regional level (reflecting what was, in fact, already common practice with academic
research proposals using material from Medical Biobank). This designated a particular space of action for the REC, and I studied how the REC administered this task. As other policymakers paid attention to the way the REC reacted, the committee is generally described as part of the policymaking level.

In 2002, the requirement of public majority ownership of the company was abandoned after being intensely negotiated among policymakers. Staff members at Medical Biobank submitted the amended contract between the county, the university and UmanGenomics to the appeal court for legality testing and in this way a new set of actors became involved in deciding which features of the policy were suitable for long-term survival. The policy as such had no legal standing and was not legality tested, but it was during this process that the durability of public majority ownership stood its test. As any policy must become entrenched in surrounding networks and power structures to survive (Koch & Stemerding 1994), the task has been to study how the different features of the policy made alliances with other policies and institutions and the court rulings were particularly important in this respect.

The data generating activities at the three levels: Policymakers, policy workers, target group

1. Identifying the policy networks: Snowballing
   - Interviews
   - Informal conversations and social interaction
   - Reading correspondence and documents
   - Attending conferences where the key actors speak or participate

2. Contacting those supposed to work with the policy issues
   - Interviews with 6 members of the REC
   - Interviews individually and in groups with nurses at 5 healthcare centres
   - Reading documents
   - Conversations, participation in nurse training, observation, focus groups, social interaction (nurses)

3. Contacting the policy’s target group (potential donors)
   - Observations during donations
   - 57 open-ended, semi-structured interviews at 5 locations during 3 time periods.
   - Two surveys:
     o The general public
     o Donors to Medical Biobank
   - Reading public debate and following the discussion on the local newspaper VK’s homepage (www.vk.se) etc.
   - General participant observations in the community, reading newspapers etc.

Figure 3.2: The activities at the three levels approached in the study
The research efforts have concentrated on informed consent as emphasis in the policy is on this point. Here publicly employed nurses hold the position as policy workers as they are supposed to ensure informed consent from all donors. As it was studied how the REC administered the mandate they were given in the policy, so it was studied how the nurses implemented the consent requirement. This was done by observing them with patients and talking with them individually and in groups. Finally, at the level of the target group it was studied what a consent process implies for donors.

The activities at the three levels produced very different types of data. Figure 3.3 shows an overview of these data. This figure can be read as a continuation of figure 3.2 as it outlines the type of data emanating from the activities at each level.

<table>
<thead>
<tr>
<th>The type of data produced at the three levels</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. The policymakers</strong></td>
</tr>
<tr>
<td>• Interview transcripts</td>
</tr>
<tr>
<td>• Field notes (including notes from conversations and unrecorded interviews)</td>
</tr>
<tr>
<td>• Letters and emails (publicly available through registries)</td>
</tr>
<tr>
<td>• Informed consent forms</td>
</tr>
<tr>
<td>• Homepages and public relations material</td>
</tr>
<tr>
<td>• Unpublished surveys</td>
</tr>
<tr>
<td>• Newsletters, academic debate and letters in local newspaper with comments from key actors</td>
</tr>
<tr>
<td>• Laws</td>
</tr>
<tr>
<td>• Appeal court proceedings</td>
</tr>
<tr>
<td>• Parliamentary debate transcripts</td>
</tr>
<tr>
<td>• Academic texts given to me by key informants who considered the texts as particularly relevant</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>2. The policy workers (REC and nurses)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Field notes from interviews, conversations and observation</td>
</tr>
<tr>
<td>• Figures on case management provided by REC</td>
</tr>
<tr>
<td>• Correspondence of REC</td>
</tr>
<tr>
<td>• Manual with instructions for nurses</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>3. The policy’s target group (potential donors)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Field notes from observations during preventive medical examination, and general participation in the community</td>
</tr>
<tr>
<td>• Transcripts from interviews with donors</td>
</tr>
<tr>
<td>• Survey data</td>
</tr>
<tr>
<td>• Newspaper articles and letters to the editor</td>
</tr>
<tr>
<td>• Prints from local newspaper discussion forum (<a href="http://www.vk.se">www.vk.se</a>)</td>
</tr>
</tbody>
</table>

*Figure 3.3: The data at the three levels*
3.3 Practical conduct

The practical conduct has revolved around the positioning of the anthropologist, and therefore the remaining part of the chapter is written primarily from the first person perspective. I conducted fieldwork, intermittently for 12 months, from June 2000 to February 2004, mainly in Umeå situated in the coastal region, but also in two field sites in the interior. Figure 3.4 shows a condensed timetable for selected activities.

<table>
<thead>
<tr>
<th>Date</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2000</td>
<td>Fieldwork commenced</td>
</tr>
<tr>
<td>Oct-Nov 2000</td>
<td>First set of interviews with donors at healthcare centres</td>
</tr>
<tr>
<td>Spring of 2001</td>
<td>Sabbatical leave</td>
</tr>
<tr>
<td>Feb-Mar 2002</td>
<td>Second set of interviews with donors at healthcare centres</td>
</tr>
<tr>
<td>Mar-Jun 2002</td>
<td>Survey based on questionnaire to the general population</td>
</tr>
<tr>
<td>Aug-Nov 2002</td>
<td>Survey based on questionnaire to the donors</td>
</tr>
<tr>
<td>Feb-Apr 2003</td>
<td>Third set of interviews with donors at healthcare centres</td>
</tr>
<tr>
<td>Feb 2004</td>
<td>Last interview at the policymaking level. Fieldwork concluded</td>
</tr>
</tbody>
</table>

Some visits were no more than a week; the longest five months. During short visits I focused mainly on prearranged interviews with the policymaker group, and during longer stays I also had periods at healthcare centres where I talked to nurses and donors. I stayed in student accommodation most of the time and occasionally in healthcare-staff housing and hotels when travelling around the country. I had access to an office at the University of Umeå during the second half of the project. Figure 3.5 shows a map of the region.

Figure 3.4: Timetable

Figure 3.5: Map of Västerbotten County
The following section elaborates on my practical conduct according the activities performed at the three levels: policymakers, policy workers and target group. Different types of information were searched for at the various levels. With policymakers, for example, I was particularly concerned with reconstructing the story of what had happened and who had decided to do what. With donors I was interested in understanding what was at stake for them. Policymakers were usually much more watchful and conscious about my use of what they said than were the donors. I weighed the pros and cons of taped interviews accordingly, and recorded fewer interviews with policymakers. Besides, I did not plan to quote policymakers verbatim as their identity would be difficult to protect.

3.3.1 Practical conduct at the level of policymakers

UmanGenomics and Medical Biobank constitute the two central organisations; I visit them frequently and keep email contact when not in Västerbotten. Contacts with other actors are more sporadic. For the sake of confidentiality it cannot be stated who was interviewed. Instead, figure 3.6 contains an outline of the institutions and the types of representative within these institutions with whom I spoke. Only three people declined my request for a meeting. One declined stating that is was due to lack of time; however, we had previously had an informative chat.

The way I approached people varied slightly. Initially, I simply phoned or emailed asking for an interview. I realised that I had to make a more informed agreement about their participation in the study as explained in section 6.2.1 on ethical reflections. The type of contact varied from very informal gatherings at people’s homes or over lunch or coffee, to formal interviews with prepared questions and audio-recording equipment. When I knew that I would have only one chance of an interview, the interview was more formal. I made notes after each interview about the atmosphere and what was said before and after. During transcription of recorded interviews I made notes about laughing, joking gestures and other features which were not captured in words. I did so because I wanted to ensure that I would not take the verbatim transcription too literally when at later stages I might have forgotten that the informant was only joking or clearly showing his or her ambiguity concerning the subject. The management of specific healthcare centres was contacted mainly to obtain their acceptance of the study, but I also used the meetings to discuss their personal views on UmanGenomics, Medical Biobank, and their own role concerning the biobank research project.
In many interviews I was given a range of documents and told about other documents that I could later request from public registries. The Swedish law on public records makes practically all written documents in public institutions available. During the conflict over entitlements in material stored in Medical Biobank, an enormous number of papers went into circulation. I read these partly to understand the factual events; partly to understand the reason why these papers are considered important by the actors referring to them; and partly to identify the particular framings of problems that these papers represent. I did not conduct discourse analysis in any strict sense of the word. Overall, I sought to understand what policymakers singled out as having particular importance in order to compare this with the concerns of those the ethics policy presumably targets and to identify the course of action it has effected.

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Subgroups represented</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Biobank</td>
<td>• Management</td>
</tr>
<tr>
<td></td>
<td>• Staff</td>
</tr>
<tr>
<td>UmanGenomics</td>
<td>• Management</td>
</tr>
<tr>
<td></td>
<td>• Staff</td>
</tr>
<tr>
<td>Västerbotten County</td>
<td>• Political management</td>
</tr>
<tr>
<td></td>
<td>• Political opposition</td>
</tr>
<tr>
<td></td>
<td>• Administrative staff</td>
</tr>
<tr>
<td></td>
<td>• Healthcare centre management</td>
</tr>
<tr>
<td>University of Umeå</td>
<td>• Management</td>
</tr>
<tr>
<td></td>
<td>• Selected academics</td>
</tr>
<tr>
<td>Regional Research Ethics Committee (REC)</td>
<td>• Lay representatives</td>
</tr>
<tr>
<td></td>
<td>• Scientific representatives</td>
</tr>
<tr>
<td>Technology Transfer Agency (venture capital)</td>
<td>• Senior staff</td>
</tr>
<tr>
<td>National Board of Health and Welfare</td>
<td>• Management</td>
</tr>
<tr>
<td>Parliamentary Committee for law proposal</td>
<td>• Observer</td>
</tr>
</tbody>
</table>

Figure 3.6: Types of informant at the level of policymakers

3.3.2 Practical conduct at the level of policy workers

As I have described the nature of my contacts with the REC in the preceding section, the focus in this section is on the nurses expected to procure informed consent. I chose the healthcare centres in collaboration with Medical Biobank; however, initially, I visited all centres in Umeå to make my own arrangements, but some centres were not doing the medical examinations because of staff shortage and I had to be certain I in places actually conducting the activity I wanted to study. Therefore, in collaboration we selected two centres in the scarcely populated interior of Västerbotten County, and three centres in and Umeå on its outskirts where approximately 40% of
the county’s inhabitants live. I also tried to arrange visits to centres in Skellefteå, the second largest
town in Västerbotten, but the staff there stated that they were too busy for visitors. I first contacted
the management of the centres and then spoke to the nurse responsible for the daily coordination of
the medical examination. At some centres I was invited first to present my project to the group of
nurses doing the examinations before they accepted my presence; at other places I spoke to the
nurses collectively at later stages. I gave the nurse responsible a letter for the participants in the
medical examinations informing them about my project and their right to decline participation (see
attachment 5). At two healthcare centres this was sent out together with the invitation to the medical
examination. However, this procedure was not absolutely consistent and I arrived before each
examination in time to talk to the nurse about how I would prefer to be introduced to the participant
and to ensure the participant received a copy of the letter. During the brief discussion with the
nurses I stressed that I was not evaluating their professional performance. I said I was interested in
the participant’s impression of the medical examination as a context for donation. I did not mention
informed consent per se. I also asked whether the nurses had any questions for me. A few nurses
were concern about my presence and were slightly anxious that I would criticise them for the way
they performed the medical examinations (nobody mentioned the consent requirement).

All nurses who I observed executing examinations were women and older than me. I
occasionally wondered whether a sort of maternal care affected their kindness towards me. Patients
irrespective of age and sex were embraced with similar kindness, however, and I found no
systematic differences concerning the implementation of the policy of informed consent. The nurses
were all thoroughly professional.

I spoke with the nurses (except when they were too busy) either during a break in the
examination when the participant was watching a video about healthy diet, or after the examination.
I would usually ask them to share their experiences with me about the normal reactions of
participants. During the later stages of the project I would share my own experiences with them and
ask them whether they recognised that image. I usually joined the coffee break of the group of
nurses conducting examinations and discussed various issues with them informally without taking
any notes. I could sometimes transcribe notes from my notebook to my field notes during short
breaks, but otherwise I did it immediately after leaving the healthcare centre always beginning with
the conversations that I had no notes on. I also became familiar with the task performed by nurses
by participating in a training course instructing new nurses (at a less advanced educational level) on
how to perform the examinations. Finally, I took notes on the interaction between nurse and participant during the examination where blood is collected.

3.3.3 Practical conduct at the level of the policy target group

My main access to the target group of the policy – the potential donors – was during the examinations. I spoke to 57 participants. They were selected by a simple process: the first participant to arrive and to agree to my presence. Two thirds of the interviewees were women, and I have not been able to determine the reason for this overrepresentation. I would typically wait outside the examination room until the nurse had asked permission on my behalf and informed the participants about their right to withdraw their consent at any point. In a few cases the nurse had also asked the donor for blood samples to the biobank. I then asked the nurse to recount the donor’s reactions at some later stage.

When I entered the room I shook hands with the participants and thanked them for letting me observe the examination. I then sat in a corner with a notebook and did not enter the conversation. I would occasionally help by stirring a glucose solution that the participant was to drink as part of measuring susceptibility to diabetes. This was a way of helping the nurse at a point when she usually needed to take the blood samples to the laboratory or do the lab tests herself, depending on the healthcare centre. Some participants would make remarks to me, usually jokingly, about something to do with Denmark and alcohol (apparently Denmark has quite a reputation in Västerbotten in this respect) or ask whether we had this type of medical examination where I came from. I always answered and tried to ensure a comfortable atmosphere, though I did not actively prolong our exchanges at this stage. Many commented on the taste of the glucose solution and asked if I had tasted it. I had undergone the medical examination myself in order to experience the physiological and psychological feelings that can arise (and to the horror of most participants I actually liked the glucose solution!).

This first part of the medical examination usually took about half an hour. I would then follow the participant out to a waiting room where he or she watched the dietary video while I transcribed notes. If the nurses had several participants on the same day, I asked them to request an interview with everybody who declined to donate; however, those who declined to donate usually decline to participate in my research. The typical reason given to the nurse was “I do this examination for my own sake”. I interviewed participants during a break in their examination. The
shortest interview took 10 minutes and seemed to be a mistake. It was a person who declined to
donate, and I had the impression that he had not understood that the interview was supposed to be
voluntary before I told him. Most interviews took 30-45 minutes, some an hour. The interviews
were recorded (except a few where the recording equipment failed and I had to take notes, and one
person who did not want to be recorded, thinking that I “would have to listen to a lot of stupid
talk”).

I used a small tape recorder for the first interviews and then changed to an MD
recorder with much better recording ability while being so small that interviewees could easily
forget it. We would sit alone in an isolated room, usually in armchairs, and with no papers or
notebooks. I would always begin by explaining that I was not affiliated with the biobank, company
or healthcare centre and that their confidentiality would be protected. I had memorised a prepared
questionnaire (a revised version in 2002 and 2003), and took out a copy of the questions only at the
end of the interview explaining that I needed to check if I had remembered all my questions. In
those cases where I had forgotten a question, it was then asked. The questions did not run in a
particular order: I tried to follow the reasoning of the informants, first prompting with open
questions prepared in line with Spradlye’s recommendations (Spradley 1979), then encouraging
further elaboration by e.g. repeating the last word of the informant, and then occasionally
confronting them with dilemmas (cf. Howell 1997). I used two types of dilemma: a mild version
used in all interviews about whether there was any difference between two options (e.g. between
donating a questionnaire and a blood sample); and occasionally a stronger version. The strong
dilemmas were not part of the prepared questions. They would be presented if an informant made a
clear-cut statement about what was right or wrong. I would then ask the informant to contemplate
what some people would consider the other side of the coin, the opposite view. In the few cases
where I sensed that this made them uneasy, I swiftly related to them that all answers were correct
and explained my way of asking questions, while returning to a more conventional form of
interviewing. More often than not the questions would fall naturally in conjunction with the points
the informant was already talking about.

At the closing stages of each interview I would ask the participants whether they had
any questions for me. I did this for two reasons. On one hand I wanted to give the informants the
chance of clearing their minds of whatever they might have considered during the interview; on the
other, it was an important way of assessing their perception of me and thus how I should assess
their answers. A few informants apparently had the impression that I was a medical researcher, and
this piece of information was used in the analysis to reflect on whether positive images of medical science could be related to this misunderstanding.

During the transcription of the interview I recorded non-verbal aspects as I did in the interviews at the policymaking level, and I wrote a code where the standard questions came in. This allowed me later to search quickly for all responses to a particular question and thus cut across the different interviews and get an impression of the patterns in responses, rather than the individual reasons of particular informants. Again, my interest lies more with the type of reasoning appearing among the donating public in general, and less with the deep emotional positioning of particular individuals (in which case I should have lived with them rather than interview them at a public healthcare centre).

I got an impression of the healthcare centre as being a culturally dense site: full of meanings to people visiting them at important stages of their lives. In seeking to understand these meanings, I also used general participant observation in the community – i.e. I took notes on conversations at parties, with local friends, housemates, etc., when I thought something significant about Västerbotten was illustrated. I also used the literature to make this type of contextualisation and I continuously discussed these ideas with friends, local colleagues and others. It could be said that I used my surroundings as a sounding board for ethnography, rather than reserving the analytical phase for the writing desk. This choice reflects Charles Taylor’s (1985) argument that informants’ recognition validates ethnographic analysis.

### 3.4 Quantitative methods

#### 3.4.1 Generating the questions

Shortly before the quantitative part of the study we met a research group in Uppsala, who wanted to execute a similar survey. We decided to coordinate our questions to facilitate valid comparisons. The initial questions to be used in the respective questionnaires by both research groups, however, encountered a variety of problems in getting approval from the relevant bodies of authority. This delayed the respective surveys and prompted divergent changes in both questionnaires. The research design for the surveys was the result of solutions to these problems and rather than being seen as optimal questionnaires, they reflect what was possible to investigate. One questionnaire went to the general public, one to actual donors.
The surveys have been informed by the qualitative work. There are very few qualitatively validated questionnaires (Groenvold et al. 1997), and unfortunately the two reported on in this thesis are not among them. The relationship between the qualitative work and the quantitative was hampered by the practical problems and the political circumstances surrounding the surveys and is therefore limited to the identification of new categories of answers and attentiveness to particular areas of concern. As the qualitative interviews showed that few people had considered biobank issues in any detail, we wanted to allow for an assessment of arbitrariness of responses by triangulation, i.e. by approaching their attitudes to the use of informed consent from several angles (cf. paper III:225). Thus, we asked when they would like to provide a renewed informed consent, what they would think of providing repetitive consent, and how they assessed the importance of informed consent in relation to other ethical concerns raised in the interviews. Each questionnaire was tested twice on smaller subject groups.

3.4.2 Practicalities

The survey reported on in Paper III was done during the spring of 2002. A random non-stratified sample (n=1000) of the population of Västerbotten County (N=255,230) was selected amongst people aged between 18 and 85 years. The questionnaire contained some background questions concerning experiences with healthcare, age and sex, and questions concerning attitudes to the use of their tissue with and without their specified consent. One questionnaire and three reminders were distributed allowing us to distinguish four groups of respondents and thus to conduct a dropout analysis.

The survey reported on in Paper IV was done during the autumn of 2002. A questionnaire was sent to a random sample (n=1200) of people who had donated blood to Medical Biobank since its inception in 1985. The majority of respondents had signed either the brief consent form which was introduced in 1990 as the project was broadened from one municipality to cover the whole county (see attachment 1) or elaborated consent sheets (see attachments 2 and 3). It was not possible to exclude the very few who had not signed a consent sheet from our calculations without compromising confidentiality. The questionnaire was followed up by two reminders. This allowed us to distinguish between three groups of respondents for our dropout analysis. As background questions, we asked about experiences with healthcare, age and sex.
For both surveys, registration and analysis were conducted using the EPI-info software programme. The response alternatives were mostly yes/no or do not remember etc. The Chi-2 test was used when estimating differences of response.

3.4.3 Comparison between the surveys

There has been no comparison with the surveys carried out in Uppsala, because they have not yet been completed. In our own two surveys, we used the same background questions and the same questions where respondents were invited to evaluate the relative importance of various issues of relevance to biobank-based research and their personal interest in the survey. Granted that some donors in paper IV might have been unaware of their donation prior to receiving the questionnaire (which happened to be the case), the intention was to see if these unknowing donors would value information higher than respondents in paper III, who were confronted with a purely hypothetical question. This might indicate a hidden importance of informed consent.

3.5 Mode of analysis

When moving into the stage of analysis, it is important first to assess the respective validity of the very diverse sets of data described above. This issue is addressed first in general terms and then in more detail with respect to the interviews with donors, which is where quotations have been used the most. I then proceed to illustrate the way the material has been analysed.

3.5.1 Validity and reliability

The material comprises documentation of human agency in what could be termed four different modes of interaction: what they do, say, write and how they respond to questionnaires. The different modes of interaction create different types of fact that relate to people usually having differing motivations for the activity: they use it in different ways. In turn it implies that the data can be used in different ways: partly for research ethical reasons, partly because the validity of the data must be assessed in context and in relation to the intentions bringing it about.

There is something very factual about what people do: either they stand up or they sit down – it can be described at a behavioural level without hypothesizing too much about their intentions. Within this superficial meaning, I recorded events as accurately as possible: I
noticed whether or not people donate blood; whether or not they took time to read the consent sheet or asked questions before signing. The validity of data at this level is either self-evident or a debilitating philosophical obstacle of the type necessitating explanation of why I trust my eyes and whether it is reasonable to assume that the specific language in which I convey an observation is adequate considering that other languages have other verbs and nouns. I will not engage in the deeper philosophical discussion because it seems to me that although language (including the description of observations) does not accurately capture the world of human interaction, it nevertheless helps immensely in getting meanings across to one another (Wittgenstein 2001). The three other forms of fact (speech, written material and questionnaire data) are even more dependent on the mediation of language. The following outlines reflections on variances between these forms of fact which are summarised in a simplified scheme (figure 3.7).

<table>
<thead>
<tr>
<th>What people…</th>
<th>Type of fact</th>
<th>How they might use it</th>
<th>How I can use it</th>
</tr>
</thead>
<tbody>
<tr>
<td>…do</td>
<td>a) Record of event</td>
<td>a) Emerge as agents who can change or maintain things</td>
<td>a) See what matters to people</td>
</tr>
<tr>
<td></td>
<td>b) Conversations with me</td>
<td>a) Explain themselves</td>
<td>b) Validate my interpretation</td>
</tr>
<tr>
<td></td>
<td>c) Observed conversations</td>
<td>b) Influence my perception</td>
<td>c) Inform my interpretation</td>
</tr>
<tr>
<td>…say</td>
<td>a) Interviews</td>
<td>a) Negotiate valid arguments</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b) Conversations with me</td>
<td>a) Explain themselves</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c) Observed conversations</td>
<td>b) Influence my perception</td>
<td></td>
</tr>
<tr>
<td>…write</td>
<td>a) Official statutes</td>
<td>a) Regulate behaviour</td>
<td>a) Identify framings</td>
</tr>
<tr>
<td></td>
<td>b) Letters etc.</td>
<td>b) Negotiate valid arguments</td>
<td>b) Identify counter framings</td>
</tr>
<tr>
<td>…tag as response</td>
<td>a) Aggregate numbers</td>
<td>a) Seek to affect public opinion; relate an adequate representation of themselves; perform a duty</td>
<td>a) Extend the reliability of the framings identified qualitatively</td>
</tr>
<tr>
<td>(to survey questions)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Figure 3.7: The different types of data and their relation to my interpretation*

Conversations between informants that I eavesdrop on have a relatively high validity taken as representations of the type of framings that are important in the given relation, though people might lie to each other. For research ethical reasons there are limitations on the usage of that type of data. Conversations can be kept in mind, however, to ensure that later interpretations do not conflict with the information thus gained. Speeches at conferences and receptions can be quoted, but what they reveal is not necessarily what is at stake for the speakers (moral in the sense explicated in the previous chapter); instead, we witness the speaker’s understanding of what can be said in the given context. With written documents the function the document serves can be considered (a letter between friends or between official opponents), and attempts can be made to
assess the degree in which the document represents what people think or what they think would have an effect. There are no sharp distinctions, however. With written documents and survey data researchers have little possibility of influencing the data, but the data still need to be interpreted just as the respondents will have had to interpret the questionnaire. Given the fluid nature of the issue investigated with the surveys, there is reason to be reluctant to ascribe to them the ability to empirically support the validity of the qualitative findings (Altheide & Johnson 1994). They do, however, extend their reliability.

3.5.2 Interpreting interviews

Whereas the actual interview is a dialogical process where both parties affect the resulting data, the analysis of the interview – based as it is on either notes or transcripts – constitutes a monologue in which the researcher applies a systematic approach to the data (Fog 1994: 127-132). The monologue incurs a responsibility on the analyst, who must avoid making claims about what the interviewee thinks and feels going beyond the feeling of resonance during the interview (Wikan 1992). While I have avoided using some quotes when doubtful as to what people meant by them, the whole range of responses has always been reported.

When interviews are analysed only as examples of the discourse prevalent in this type of context, it can be acceptable to transgress the opinions the interviewee might have wanted to convey given more time, and simply make it clear that this was the type of response given. When interpreting the interviews with policymakers where I was preoccupied mainly with establishing an outline of events, the validity has been sought by cross-checking with other informants and by procuring the relevant documents. In this section, however, I wish to concentrate on my interviews with potential donors, and the way in which I have used quotations from them, primarily as discursive examples, while also seeking to understand what is at stake for the donors in the moral sense described in chapter 2. This discussion is intended to outline the epistemological status ascribed to a quote from an interview.

First it must be noted that informants had rarely thought extensively about genetic research on blood samples prior to the interview. Therefore, the interview does not elucidate pre-shaped opinions, rather it is a melting pot for such opinions. Accordingly, it is important to work reflectively with the validity of the opinions produced and the influence my questions may have had on them. I used the dilemmas to probe the depth of the opinions, i.e. whether an opinion was well
considered or had just sprung to mind. Also, I have taken great care not to read a response as a statement of truth without seeing its consistency with other statements. I asked, for example, whether people would want to be informed about what happens to their blood sample, while also probing whether they had read the information already conveyed to them. Whereas some analysts, e.g. (Kvale 1994), distinguish between direct and indirect interviewing as different activities (where the former means asking the informants for a stance on a particular issue where knowledge about their opinion is wanted, and the latter means asking questions which reveal the position of the interviewee by exposing e.g. inconsistencies), I reserve the distinction for the level of interpretation. My questions served both ends. When I asked all informants whether they had heard about the company UmanGenomics, I deliberately chose this phrasing to elucidate indirectly whether they had read the consent sheet; however, I also wanted to know what they had heard about the company. When I found that people who claimed to want information had not read their consent form, I inferred that more information appeared reasonable for the interviewees while it was not apparently their top-priority during the actual donation.

The interviews have been interpreted as part of a context which also consists of tacit knowledge: aspects of being at the healthcare centre which are not articulated because they are taken for granted. Understanding tacit knowledge is a process of cultural translation. Some aspects of tacit knowledge are also made available for reflection through literal translations. When I asked potential donors why they had chosen to attend the medical examination they would often answer that they were “kallad”. I intuitively understood, but a fully corresponding term does not exist in either Danish or English. It means something between being ordered/summoned or invited to/given the offer of an examination. The existence of a term conveying the sense of obligation so strongly, without implying any sense of coercion, was informative with respect to the relationship between participants and authorities.

3.5.3 Making an analysis

When moving into the stage of writing an article yet another selection is made. I have not made a final general coding of the material. While the material has been amassed according to the principle of moving between layers looking for discrepancies in framings, the articles have taken their point of departure in particular issues I found intriguing and for which I indexed my material (predominantly the field notes and interviews) as suggested by Davis (Davis 1984). I have gone
through the material three times with different defined search categories to illuminate different aspects of the policy. The two qualitative papers (I and II) included in this thesis both take their point of departure in empirical problems: things that appeared strange or inconsistent. The three other papers extend the analysis of these empirical problems, which are used as themes to structure the remaining chapters.

The empirical problem addressed in paper I concerned donors’ lack of use of the information offered. Policymakers assumed that people would only want to donate to research purposes that had their intentional support, and informed consent should ensure them information about the research purpose, as also described in the description of the normative ethical debate about biobanks (section 2.1.1). As people did not seem to have read the consent sheet, however, I wondered why they donated. The empirical problem addressed in paper II was that people donated both healthcare information and blood, though only blood was talked about as an ethical problem by policymakers. Was this problematization self-evident?

Both problems have been addressed through contextualisation. In paper I, I have begun by reviewing all the answers concerning why people donate. They all conveyed some mixture of altruism and duty, but it was difficult to unravel the motivation as people had rarely thought about their donation and made very general comments. Secondly, I reviewed all the answers to my question about whether there was anything that they would not like their blood to be used for, or if they had any ideas about what the blood was in fact going to be used for. Again, it was easy to see that people had not contemplated these aspects of the donation. As the donation seemed not to be a thoroughly planned decision, I decided to view the donation in the context of the medical examination. It seemed reasonable to begin there, because if people did not come to the examination, they could not donate, and most people attending the examination happened to donate. I then tried to categorise reasons for attending the examination (and for donating). While it was possible to identify some types of reasons, I got wide ‘grey zones’ of statements. Instead of presenting the identified types, I chose very clear statements from the different types to show the range of responses. I then moved beyond the interviews to a socio-historical contextualisation to make the interviews and observations comprehensible: why would people feel it as a sense of duty; why would they trust the staff at the healthcare centres; why would they not need to read the consent sheet? The task can be described as identifying the question for which the observed actions are the answer (Koch 2000: 17); that is, to interpret what is at stake for people in these situations.
The result is a tentative understanding of the patterns of motivation involved in the act of donating blood and healthcare information to a biobank.

In paper II, I have taken the point of departure in a review of the donors’ answers to my question about whether there was any difference between donating blood and a questionnaire. Some people saw no important difference, whereas others did. I looked into the reasons given for seeing a difference and two interrelated themes prevailed: the sense of control of the thing donated and the description of it as ‘part of oneself’. Here, I first made an analytical contextualisation concerning what ‘part of oneself’ might mean, namely with reference to the literature on personhood. Secondly, I contextualised attitudes to other issues concerning exchanges of things seen as ‘part of oneself’, an issue which is usually treated under the heading of commodification. Here it was obvious that the policymakers had wanted to safeguard against commodification of human tissue. I then mirrored the understandings of legitimate items of trade at the policymaking level in the understandings encountered among donors.

In paper III and IV, some tendencies elucidated in papers I and II have been taken and their reliability tested. First, people were asked to rate the importance of informed consent in relation to other concerns; secondly, the differences were tested in attitudes to donating blood for genetic research and to allowing researchers access other healthcare data, namely in the form of medical records. Paper V takes the form of theoretical analysis and philosophical contemplation and is a logical exercise serving as a reflection on the overall contribution of the four previous papers to the field of medical ethics.

3.6 Methodological problems

The methodological problem I feared the most before initiating the fieldwork was as a native Dane, to work in a part of Sweden where Danish is so rarely spoken. I did have language problems in the beginning until I learned to re-cast my tongue and Swedify my own langue while expanding my Swedish vocabulary. Sometimes being a foreigner was actually an advantage as in the translation of culturally dense expressions as “kallad”. Having interviews on tape, it was possible to discuss the meaning of particular passages with native speakers when in doubt. Concerning the interviews with notes, these tended to be supported by written documents inasmuch as the establishment of factual events concerns. Sometimes I would also use my lack of language skills to make people reflect on what they meant by a given expression. Nevertheless, I cannot guarantee that I have not missed
some nuances in people’s speech. The translation from Swedish into English added a new layer of problems, in particular in paper I where the derisory proof reading made amendments in particular quotes without my approval. Nevertheless, the overall messages should be intact.

Another significant problem concerns access to the policy process. I rely on interviews, surveys and observations, rather than participant observation in the community. I hardly ever made any real time observations and it is an anthropological truism that people never know exactly what they have done. The problem of relying on recounts of what people think they have done is problematic. However, for the purpose of comparing framings of problems it might still be satisfactory.

With the potential donors, it is obvious that I would have obtained a very different sort of material if I had followed people from their homes to the healthcare centre. But instead, I met them at the healthcare centre and thereby forfeited the possibility of finding out about the concerns dominating their everyday lives (Huniche 2002, see also paper I:240). Also, the interviews could have taken place in people’s homes and perhaps revealed a different perspective, less affiliated with the culturally dense healthcare centre. My choice, however, was to follow the policy as an emerging social institution and place myself where people would encounter it. This is also the reason I did not pursue interviews with people who never turned up at the healthcare centres: they would not encounter the policy, and whatever interesting reasons they might have had for not wanting a medical examination, they could not be part of the study.

It could be speculated whether my presence interfered with the consent process. It must have, but what I observed was people not being particular receptive towards the information they were offered, and it is unlikely that the presence of an anthropologist studying informed consent should have drawn attention away from this requirement as the nurses, at least, were aware they were supposed to ensure proper information levels. Therefore, my presence should not reduce the validity of observations of lack of interest in the information offered.

Finally, there are many regrets concerning the construction of the questionnaires for the two surveys. They became caught in a political process where many different actors had interests in them and the possibilities for planned correlations gradually dissolved. Additionally, the qualitative anthropological input diminished, and the result is more a statement about what could be accepted by a wide range of actors with interests in biobanking in Umeå. It does not make sense to sum up all shortcomings of the surveys; they pretend to be no more than indicative of how a representative sample of the population reacts when confronted with questions about biobanks.
CHAPTER 4: RESULTS

This chapter sketches the issues which were singled out in the policy process and sets them in relation to the findings described in more detail in the enclosed papers. The thesis focuses on the level of the policy’s target group, i.e. the potential donors, at the expense of a detailed empirical description of the policy process at the level of policymakers and policy workers. The policy process is elaborated in more depth elsewhere (Hoeyer 2004a; 2004b; 2004c). In this chapter I seek only to outline the rationality which prevails in the public statements made by policymakers in order to mirror this in the concerns of the potential donors, as these concerns are portrayed in the papers. Secondly, the chapter contains an outline of the actual practices installed through the way the policy has been entrenched by policy workers, and thirdly, it addresses the entrenchment and implications at the level of the target group; in particular with respect to the moral positions which are not addressed by the policy. The aim is to allow for an assessment – in the following chapter – of the social and ethical implications of the policy.

Throughout the chapter the focus is on the two themes emanating from the empirical problems outlined in section 3.5.3. These themes are informed consent, which is the focus of paper I, and the notion of blood being a particularly sensitive ethical issue, which is the focus of paper II. At the end of the chapter it is summarised how paper III and IV add to our understanding of these two themes. See figure 4.1 for a short summary of the findings in the respective papers.

4.1 Policymaking: The naming and framing of moral problems

The ethics policy presented to the public at the launch of UmanGenomics was outlined in section 3.1. as matter of oversight at three levels: the individual, the regional and the national level. In the analytical sense of the word, however, the ‘policy’ cannot be pinpointed in three bullet points. It has been the aim to identify the networks in which the policy has been negotiated, and to understand the interplay with the other policies (in particular laws) that have influenced the use of the samples in Medical Biobank. Some policy issues, e.g. informed consent, have received intensified attention over the past couple of years; others, e.g. public majority ownership, have been subject to dwindling attention; whereas the implications of yet other persistent concerns, e.g. commodification of blood, have come to be reinterpreted in various ways over time. This can be seen as a matter of
entrenchment (Koch & Stemerding 1994). The first of the two themes to be described is the instatement of informed consent procedures.

<table>
<thead>
<tr>
<th>Paper</th>
<th>Main results</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Thanks to the informed consent requirement donors are offered more information, but few donors read or remember the information. As they do not know what they donate to, their motivation for participation in research must rely on something else. The paper teases out the importance of the historical and cultural context for an understanding of donor behaviour.</td>
</tr>
<tr>
<td>II</td>
<td>Whereas the policy focuses on the uses of blood for genetic research, the object of concern varies among donors. Some see themselves more closely affiliated with phenotypic information, others with genotypic information. Intellectual property rights are used to demarcate a boundary between blood as an ethnically sensitive substance and a free market at the policymaking level, but this logic is dismissed by some donors.</td>
</tr>
<tr>
<td>III</td>
<td>Among the respondents to the survey conducted in the general public there was a general acceptance of genetic research based on biobank material (71%), while a majority (62%) would not allow researchers to examine their healthcare records without specific consent. A majority (66.8%) accepted surrogate decisions by Research Ethical Committees; 48% of the respondents estimated that they would feel respected if they were notified each time a sample was used. Informed consent was a principal concern to a small minority (4%). Should research efforts generate information on future health risks, a majority (55%) would want to be told, but only if treatment was available.</td>
</tr>
<tr>
<td>IV</td>
<td>Among the respondents to the survey conducted among donors, 65% of the respondents were aware that they had consented to donate a blood sample; 55% that they had consented to donate phenotypic information; and 32% that they could withdraw their consent. Informed consent was a principal concern to a small minority (4%), and 6% were dissatisfied with the information they had been given. There was 85% acceptance of surrogate decision-making by Research Ethics Committees.</td>
</tr>
<tr>
<td>V</td>
<td>Based on the findings in paper I, it is argued that donors’ motivation for donation is inconsistent with theoretical understandings in a particularly influential strain of medical ethics. The discussion of the findings suggests that some donors experience the offer of informed consent as a double bind, which replaces the trust-based obligations of the welfare state with contractual relationships.</td>
</tr>
</tbody>
</table>

4.1.1 The focus on informed consent

The naming and framing of informed consent as a key concern for tissue-based research has taken a complex route influenced by concurrent national and international developments. The claim here is that four forms of problematizations have emerged in the shaping of a problem which informed consent can be seen to solve; four particular ways of naming and framing issues relating to biobank-based research. These cognitive developments are not confined to the people working with the
ethics policy of UmanGenomics, though this is the context in which they have been identified. They are inferred from statements and interventions as the logic that would tie them together. It is not a rationality in the sense that it describes how all policymakers think at all times. On the contrary, this logic presents itself only in fragments; it is an abstraction. The four problematizations can be summarised as follows: (1) blood samples were presented as being similar to living persons; (2) the problem was construed as a conflict between the individual and society; (3) the provision of information to individuals was put forward as a solution; (4) more ethics was conflated with more information.

(1) In understanding the processes in which biobanks become debated as ethical problems, it is important to remember that the storage of tissue is not something new or previously secret. For more than 80 years, tissue samples have been stored as part of normal diagnostic routines without staff members having been told to maintain secrecy. Sometimes, such tissue collections have subsequently been used for research. Whereas the journalists who launched the popular tabloid paper Aftonbladet’s story may have been startled that previously, donors had not been informed, the anthropological question became another: why were biobanks suddenly problematised after being considered inconsequential for so many years? It appears that what is at stake is a changed understanding of what tissue samples are (Lawrence 1998).

Today, by way of new cultural understandings of DNA, a metonymical relationship can potentially be established between a frozen blood sample and the person originally donating it. The policymaking surrounding biobanks in Sweden in general and Medical Biobank in particular has used DNA as a metaphor for the living person. This metaphor affects how the paraffin cases and frozen test tubes in hospital basements, which had been otherwise forgotten, can be handled (Lakoff & Johnson 1980). Without a metaphoric understanding of DNA as part of the human person, even after it has left the human body, Aftonbladet’s headline, “Secret experiments on parts of your body”, would not make any sense. When politicians subsequently proposed a biobank law (passed May 16, 2002 and enacted from January 2003), it showed how the metaphor had gained political legitimacy. It had become what Shore and Wright (1997:20) call a mobilising metaphor. The mobilising impetus is related to moral sentiments of what constitutes a human person (even a blood sample is part of a person) and how a person ought to be treated (the person’s autonomy should be respected). The framing of research on tissue samples as a moral problem hinges on the naming of these samples as persons.
(2) The huge political impact of the popular tabloid series probably relied on the way in which the metaphor of samples as persons was combined with a particularly popular narrative of social critique: state abuse of power. Aftonbladet successfully used this form of narrative to frame its story as a breach of governmental obligations: public hospitals and university researchers secretly using samples taken from gullible people trusting the authorities. By directing blame to state authorities, it indirectly played on older ‘scandals’ such as the forced sterilisations during the eugenic movement (Lynöe 2000; Runcis 1998). Influential Swedish medical ethicists sustained this framing of a conflict between individual and society with an analytical model for medical ethical problems emphasising the balancing of societal and individual interests. It was more or less taken for granted that people would regard themselves as having opposing interests to society, also in the case of biobanks. Accordingly, the legal initiative following Aftonbladet’s story addressed only management of biobanks established in the public healthcare sector, not samples gathered, for example, by the pharmaceutical industry independently of public service institutions. The framing was sustained further by alliance with a dualism running through medical ethics, not only in Sweden: paternalism vs. patient rights (Anspach 1993; Bosk 1992; Gorden & Paci 1997; Zussman 1992), where paternalism is increasingly seen as a ghost from the past that we must seek to overcome in the ambition of more transparent and democratic health services. This framing meant that the ethical quandary came to revolve around governmental transparency rather than the introduction of private companies in a previously public domain. This mode of thought was imported into the ethics policy of UmanGenomics where the local authorities wanted to avoid being accused for not offering individual citizens appropriate safeguards.

(3) If individuals begin to be seen as having both a right to and need for protection, what would then count as a protective shield – and for what? Not surprisingly, informed consent has become named as the key instrument. It holds a paramount position in medical ethics. It is a maxim in medical ethics that providing individuals with information about research and the right to decline to participate is a way of respecting their sense of integrity and autonomy as well as ensuring their safety (Brody 2001). However, the living body does not run any risk (the person having donated a sample is most unlikely to be affected by the research carried out on the sample), so what is it that needs protection? When occasionally defined, risk has been presented as possible leakages of information, in particular of genetic information, which again resembles the international ethical debate on biobanks presented in chapter 2.
Finally, the fourth form of problematization taking place is the way in which ‘being more ethical’ comes to mean ‘providing more information’. This depends on the previous problematizations because once information in the form of a consent sheet is construed as a ‘solution’, quantification of it is straightforward. A battlefield has been framed, and the divergences can be narrowed down to the administration of informed consent procedures, as we saw also in the normative ethical debate on biobanks. Conferences have been held, papers published and meetings convened to determine how to manage informed consent procedures (Hansson & Levin (eds.) 2003). Some medical researchers have articulated disapproval of strengthening the informed consent requirement, but the point is that a successful framing has confined the issues that can be discussed. Giving more information, is now promoted as being more ethical and this cognitive development provides room for changed practices. This is what happened when the research ethics committee (REC) pointed out that though people had signed a paper (the donation act, attachment 1) while donating their blood samples to research, they were not informed of the type of research that was to be conducted and by whom it would be conducted. Accordingly, it was not perceived as an informed consent.

In the course of the conflict surrounding Medical Biobank concerning entitlements in the stored material (cf. Rose 2003), the understanding of informed consent seems to have become reconfigured again. As the conflict is primarily confined to the policymaking level, while this thesis focuses on the implications for the potential donors, only one aspect of the way the conflict has evolved is mentioned, namely the transformed use of informed consent. Whereas practically every source of entitlement in the stored tissue has been contested, one source of entitlement has consistently been confirmed by all parties, namely what Strathern has called genetic originatorship (Strathern 1999). This is the right granted the person who the stored genetic material originates from. Considering how donors were seen as having hardly any important interests in stored tissue prior to the naming and framing of biobanks as ethical problems in the late 1990s, it is striking how in the course of the conflict everybody has come to agree that the only inviolable rights rests with donors.

The assertion here is that the conflicting parties come to use informed consent procedures as leverage for their own entitlements while simultaneously circumscribing the entitlements of donors to the level of informed consent. As the conflict intensified, the conflicting parties began to produce their own consent sheets. This also reflected the decision of the REC to demand renewed consent prior to UmanGenomics’ use of old samples. The company introduced a
consent form where people could (re)confirm their willingness to participate in the company’s research projects, while also clarifying that all Intellectual Property Rights belonged to the company. The biobank staff, on the other hand, decided to produce a form to be filled in by those who after having heard about the conflict had contacted the biobank to withdraw their consent (attachment 5). The form gave donors the choice between a) destruction of their material b) storing the sample for use in treatment or diagnostics of the donor only, or c) academic research. If donors then chose option (c) their sample would be inaccessible to UmanGenomics, but still available to the biobank staff.

In these ways, ethics was construed both as a tool for relegating property rights and as an arena for moral competition. Besides being seen as a matter of showing respect for the wishes of the individual, the practice of informed consent procedures came to imply a clarification of entitlements. Donors were entitled to informed consent, but not money. From the perspective of the policymaking level, genetic originatorship not only gives the right to decline research participation, it obliges the donor to stay informed about the uses of stored samples and to delegate the dispositional right in tissue to competing private and public researchers.

4.1.2 The issue of commodification: distinguishing blood from information

Though informed consent has much dominated the agenda in relation to biobanks in Sweden, as elsewhere, it is in no way the only object of policymaking. In this section the theme of the discrepancy between the ethical attention provided by policymakers to healthcare data and blood as a substance is described. The debates about the consent requirement have been constricted to blood and other types of tissue, i.e. substances containing genes, while little attention has been paid to the handling of information from medical records, disease registries and questionnaires – though genetic research depends on access to these types of information. Also, moral concerns about trade in blood have gained particular prominence, while intellectual property rights in the information derived from blood has been promoted as not only ethically unproblematic, but even a desirable solution to the ethical problems with commercial interests in research using genetic material. What are the implications of the emphasis on blood? And do donors, presumably protected through the policies, agree with the implicit reasoning?

Paper II encircles a way of interpreting the work undertaken by policymakers to establish and communicate a borderline between human health and dignity, and business life. It is
argued that what is seen is the construction of a cultural biography for blood, i.e. the cultural production of a legitimate exchange system allowing monetary involvement in a potentially sensitive medical practice. The monetary aspect of different medical practices has been viewed with suspicion cross-culturally as well as historically (Kleinman 1995; Whyte, Van der Geest, & Hardon 2003). As the body is often “represented as ‘sacred space’ resisting invasion, extraction and commodification” (Pálsson 2002:23), most societies regard the potential transition from sacred space to object of ownership with some unease. Sweden is no exception: we are dealing with substantial issues relating morality in the sense explained in chapter 2.

In 1970 when Richard Titmuss published his seminal work on blood donation, *The Gift Relationship*, he briefly mentioned that Sweden, in contrast to his overall argument, had a relatively well-functioning transfusion system, which nevertheless relied 100% on monetary incentives (Titmuss 1997). Titmuss probably underestimated the socio-cultural context of monetary compensation in Sweden: the exchange did not rely on financial incentives alone. It was nevertheless correct that blood was exchanged for money and when the system was debated, focus was on the practical aspects of ensuring a sufficient supply (Gullbring 1952), safety of the supply, and questions concerning patient safety (Kungliga Medicinalstyrelsen 1956), rather than issues of commodification. With transplantation technology, trade in human body parts became coined as an ethical problem in its own right. Nevertheless, in the transplantation law from 1995 (SFS 1995:831) blood, hair, breast milk, and teeth were explicitly mentioned as exemptions from a commercial ban. It was not until it January 2003 when the Biobank Act (SFS 2001:297) was enacted by the government that it became illegal to sell blood in Sweden.

The traffic in blood has shifted from being a practical problem to be solved using e.g. financial incentives to ensure sufficient supplies, to being an ethical problem in its own right. Interestingly, this seems related to new meanings attributed to blood. Blood is now increasingly seen as part of the donating person, and this is probably related to the increasing attention paid to the genes in the blood. Thus, policymakers tend to embrace, albeit implicitly, a notion of genetic personhood, i.e. a notion of the person being more closely affiliated with blood and genes than with other sources of information about the individual. Accordingly, Swedish policymakers have deliberately sought ways of keeping bodily *substances* out of market exchange. Commodification has been a central concern of the policymakers, not a concealed process that the social scientist could claim to ‘reveal’, as often held by social commentators (see page 19). Rather, what passes unnoticed is the way in which notions of commodification have been confined to the handling of
blood as a substance, while the legitimacy of other forms of trade, namely in intellectual property, has been enhanced.

In Umeå, the establishment of a clear boundary between humanness and commercial involvement had implications for the role of public authorities in relation to commercialisation of biobanks. Initially, public majority ownership of UmanGenomics was launched as part of the oversight requirement of the ethics policy (cf. section 3.1), while in other presentations it was occasionally presented as part of benefit sharing. UmanGenomics was said to be established with the ambition of avoiding exploitation, referred to as “baggböleri” – a word with a particular local etymology. In the 19th century Baggböle manor house, 12 km west of Umeå, acquired an unsavoury reputation for buying up the main local resource, the forest wood, too cheaply and selling it off to companies abroad. The profit left the region (except for a few wealthy traders), and such callous exploitation of local resources came to be known as ‘baggböleri’ (see http://www.vasterbottensmuseum.se/virtmus/16a1b.htm). When presenting the establishment of UmanGenomics, the university, the county and the company made it clear that they wanted to avoid baggböleri and instead keep the jobs and profit in the region. Also, in return for granting UmanGenomics all commercial rights, the authorities were ensured a minimum payment or a percentage of the company’s income if this would become more than that minimum amount. Besides, the community could expect to benefit directly from commercial gain, as community institutions owned shares in UmanGenomics. It was stated that UmanGenomics should not own the blood. The biobank was in the custodianship of the university and the county, and all samples were to be returned following each research project.

In sum, the policymaking level has been particularly concerned with informed consent and with finding morally legitimate ways for public authorities to facilitate commercial exploitation of the biobank. Whereas trade in blood has become viewed as an ethical problem, trade in knowledge has been viewed by policymakers as fully legitimate. In fact, intellectual property rights have been used to facilitate a legitimate object of purely commercial exchange (Tutton 2004). Additionally, it has been taken for granted that most people want, and perhaps also need, more information about the type of research their samples are to be used for in order to protect their personal interests and sense of integrity. These considerations form what could be termed a pattern in moral reasoning. Though there is no consensus, this reasoning has gained dominance and framed the topics that are acted upon. Making a policy of informed consent is a way of effectuating the concerns embedded in this reasoning. The following section outlines how the policy has been
implemented in practice, before the moral reasoning of policymakers is mirrored in the diverse concerns articulated by the policy’s target group, the potential donors.

**4.2 Entrenchment of the policy**

**4.2.1 Keeping blood out of the market**

When studying the networks where a policy is supposed to turn into practice, there are features which become entrenched in enduring social practices, while others lack the robustness necessary for long-term survival. One of the features of the ethical ‘model’, which quickly succumbed, was public majority ownership. In informal exchanges with the anthropologist, the main funding body, the Foundation for Technology Transfer, expressed its ambivalence right from the beginning: potential investors would never accept public ownership, they assumed. When, in 2002, a new contract was signed about the terms and conditions for use of the biobank, public majority ownership was no longer mentioned. Furthermore, the Biobank Act had explicated that authorities, in their position as trustees, should not commodify tissue in their custody, and the biobank research staff raised a case at the appeals court where the ruling made it clear that charging a fee for access to the biobank could be considered commodification. Also, UmanGenomics pressured the county and the university to release them from public majority ownership because the public involvement was seen as a hindrance to both venture capital and some customers. Hence, little by little, public institutions lost the right to profit, and having blood in one’s custody was clearly separated from the prospects of financial gain, though initially it had been part of creating the enthusiasm surrounding Medical Biobank and UmanGenomics. The population-based blood collection is no longer a ‘gold mine’ for shared regional development. Instead, legitimate trade is becoming confined to Intellectual Property Rights (IPR) that only private investors are entitled to. The initial attempt to create a legitimate exchange system has developed beyond the embedded intentions and strengthened the distinction between trade in blood and trade in information or knowledge.

**4.2.2 Informed consent and divergent notions of responsibility**

Informed consent has more easily become entrenched in existing networks working with the collection and storage of blood and influenced daily practices. Above it has been described how the REC posed demands mainly to the information sheet. Their interpretation of their role in the ethics
policy led to much greater emphasis on the consent requirement than anticipated by UmanGenomics: the policy carved out a role for the REC, but did not determine how it was to be used. The REC’s emphasis on the information sheet makes it even more interesting to study what the strengthened demands for consent imply for the nurses expected to ensure the informed consent.

Generally speaking, the nurses were not aware that they were part of an ethics policy initiated by UmanGenomics. At the time of the fieldwork, they did know, however, that they were supposed to use new consent forms and that increased emphasis was to be put on the consent process. The policy had focused attention on the collection practices, and again carved out a space for action, so to speak, which was used by the nurses. Their actions, however, were not mere executions of a predetermined policy demand: the nurses handled the consent requirement according to their own agendas.

The examinations are a particular valued task among nurses, and the ways in which the nurses embraced the strengthened consent requirement reflect both their sense of responsibility and the importance they attribute to their work with the examinations. With the establishment of UmanGenomics, many nurses were worried that the commercial research aspirations would divert attention from the examinations. Furthermore, many nurses were very conscious that they were first and foremost taking care of patients who are often anxious about the risk profile they are about to be confronted with, as described in paper I. UmanGenomics was seen by some as an opportunity to increase county support for the examinations, but most saw it as introducing competition between the efforts of preventive healthcare and the ambitions of commercial research, as well as introducing new forms of uncertainty: What was the blood now going to be used for? Could it be sold to other parties? Might it be dispatched abroad? Was it really acceptably to make money on medical research? How should they tell their patients about this?

Nurses are the face-to-face recipients of blood and many conferred a feeling of personal responsibility towards the donors. A few nurses saw in the more elaborate information sheets emerging in the period, a way of transferring the responsibility away from them personally and towards the county officials or biobank with whom donors could now be seen as making a signed agreement. They said little about the samples but usually asked whether potential donors had read the information sheet. Others thought that the advent of UmanGenomics incurred on them an increased burden of personal responsibility hard to tackle because they felt unfamiliar with the actual uses of the blood. This position has led to some covert practices among practicing nurses. Already in 2000, I met two nurses who simply no longer asked their patients whether they would
like to donate a blood sample because, as they said, they would not put that form of responsibility on themselves (paper I:236). Later, as the conflict over entitlements in the biobank hit the newspapers and some nurses were extremely angry about what they now saw as financial greed imposing itself upon an otherwise well-established practice of blood collection, they simply reverted to using the original information sheet from the so-called donation act. This sheet was now interpreted as given consent only to academic research, and since this was what they would subscribe to, they arranged with the biobank staff that blood collected by them would be used according to the academic standards prior to the establishment of UmanGenomics.

The entrenchment of the policy of informed consent has not only interacted with and transformed the responsibilities felt by nurses, it has also sustained the emphasis on blood as an ethical problem. The nurses spoke about responsibilities in relation to the collection of samples; never did they mention such considerations with respect to the questionnaires (at least not in front of me). In this way, turning the policy into practice bolstered the process of decommodifying blood: singling out material containing genes as of particular ethical importance. Through various partly covert practices, the policy has acquired a life of its own. It slowly assumes an efficacy beyond the mixture of intentions bringing it about. This is now discussed in more depth in terms of the social implications of the policy at the level of its target group.

4.3 The target group: attitudes and policy implications

The positions taken among the potential donors in relation to these issues are elaborated in the enclosed papers. This section presents the findings of particular relevance to the two intertwined themes of informed consent and the special importance attributed to blood, beginning with the policymaking reasoning that ascribes personhood to genetic material.

4.3.1 Conflicting notions of personhood

Paper II demonstrates how the donors think about the blood and the donated questionnaire in a myriad of ways. Some do not find the blood particularly important, whereas others do. Some find the questionnaires much more sensitive than blood samples, while the questionnaires are perceived by others with relative indifference. In discussions with informants outside the clinic, I also encountered people expressing very strong personal associations with blood. For example, a man who was a molecular biologist said that there was no difference between him and his blood because
the blood (or rather the genes in blood) could potentially be used for generating another him (cf. Putnam 1999). Such references to cloning were common in explaining why blood was viewed as important.

This type of reasoning indicates that genes can be conceived as the very essence of the person. However, the imaginary is not always so, and it differs from person to person and from time to time. The molecular biologist, for example, sensed no problem when he was working with blood samples that were anonymized and encountered in test tubes. Apparently genes can become de-personalized, informatized, and thus lose their potential for ‘personhood’ (paperII:13). Also, donors who had very recently left a blood sample, seemingly with no major consideration, could, minutes later in an interview, talk about the blood as being an intimate part of their very person. It seems that blood can be object to multiple interpretations even by the same person.

These incidents are important because they show how the actual tissue, the millilitres of blood stored in the Biobank, is open for multiple interpretations: blood does not hold one specific meaning; it is both human and non-human, both living person and dead object. The reasoning implied in the policymaking which focuses on the uses of blood is thus not unequivocally mirrored in the reasoning among donors. The point is that people have various understandings of what the donated objects mean to them and these understandings might change depending on the situation. The policy, however, has to fixate meanings to facilitate a legitimate exchange system allowing commercial trade in health-related material. If donors do not unequivocally share the understanding of blood that informs the policymaking, the divergences are even more obvious with the use of IPR, in particular patents. The moral reasoning which separates the biobank and the company and restricts private property to the domain of research results stands in sharp contrast to the majority of the target group’s view of commercial involvement in medicine (paper II:12-13).

At one point, however, the policymaking and donors’ reasoning seemed to conflate. Donors rarely wanted to sell their blood or information. An argument typically suggested in explanation was that selling it would amount to giving the buyer right to do anything with it, which was perceived as corresponding to a loss of control (paper II:note 4). What is it that is perceived to be in need of control? Looking into their reasoning about genetic research is a way of approaching this subject, which simultaneously expands the understanding of donors’ perception of the genes they donate (the following paragraphs draw on material previously published in Hoeyer 2004d).
Amongst the many different worries expressed in relation to genetics, eugenics and cloning were the most common. Some of these came in response to a question put to all participants: Is there anything for which they would not like the researchers to use their blood sample? Usually this question was followed by a pause. One woman responded that: “Research that has anything to do with cloning… I don’t like that […] Actually, that whole issue of looking into and manipulating the genes – it sounds … unhealthy to me.” When asked whether she would accept gene therapy or attempts at “manipulating” genes with the intention of curing illness, she immediately responded: “Yes, of course, then it’s alright!” She explained that she did not like research that simply wanted to ‘normalize’ everybody.

Another woman also saw “manipulation of genes” as being related to cloning. In response to a question about uses of her blood that she would not accept, she said: “I don’t know….Well, of course, it might be that they can clone – that somebody can do a copy of me? No [timid laugh]… I guess I haven’t thought much about it… [but] I am a bit scared of this genetic manipulation.” Asked what she had in mind by the term ‘genetic manipulation’, she said that she was not really sure. One woman explained that she supported research “when it’s about human suffering […] or inherited defects, then it’s okay. But to talk about, for example, homosexuality as an inherited defect? I’m not ready for that!” Her fear was that genetic research would be used for ‘normalizing’ people. In response to a question as to whether she thought it would be acceptable to ‘normalize’ persons with schizophrenia with medicine based on genetic research, she was less certain.

One woman, previously diagnosed with depression, wondered whether, if geneticists had their way, she might not have been entitled to a life of her own. She had suffered from her depressions but she also felt that the disease had given her something: “one wants to live without depressions, without the angst, but I also know that it has developed me – it has contributed… [There] is [a] sensitivity that follows in its wake.” The thought of research into the genetic component of a central aspect of her life felt offensive and potentially stigmatizing: ‘modification’ of some of her genes would approximate to the ‘removal’ of an aspect of her personhood. As she was later asked, she revealed that she did not know whether her donated blood sample would be used for genetic research; she had not read the consent form: “No, I didn’t read it, I just signed and left a sample.” She expected that it would contribute to new knowledge, to medical progress.

These reflections on normalization can be seen as implicit references to eugenics, as examples from other informants illustrate: ‘I’m scared if we end up in a situation where you’ll only
accept – let’s say – elite-healthy people. That’s what I’m scared of, that […] you’ll only want perfect people.’ One woman said that it would be much better if research were focused on diseases rather than on genetic research, which she expected to deal with ‘producing perfect babies’. Most such anxious responses contained only very vague formulations. Significantly, it was not the Biobank or the researchers associated with the university or UmanGenomics, but some undefined ‘they’ who were supposed to desire a certain kind of society of ‘perfect babies’ and ‘elite-healthy people’. This resonates with the fact that the most common response to the question about the unacceptable uses of their donated blood was that patients/donors had simply never thought about it. Mostly, research – or at least the research they contributed to – was assumed to produce something benevolent. This is important. Whereas many donors could deliver narratives of fear in relation to the new technologies, they predominantly saw gene technology as an aid in the combat of disease. The fears were not related directly to their personal sample.

4.3.2 Informed consent procedures and the presumed lack of information

We now move on to the ways in which the thoughts on informed consent among the potential donors diverts from the policymaking logic described above in terms of four problematizations. It has already been shown how some people did not identify themselves anymore intimately with their blood samples than with personal information about their health derived from questionnaires and medical records. The notion of blood being special was not unequivocally reflected in the attitudes of potential donors.

Secondly, the notion of the individual citizen having opposing interests to the general society was shared only by an absolute minimum of donors. They generally talked about how ‘we need research’, and employed narratives of progress to explain the human dependency on science and technology when explaining why they were willing to participate in research (paper I:233-235). A few participants in the healthcare programme, some of whom declined donation, articulated strong scepticism towards the state as well as the pharmaceutical industry. However, they did not see in informed consent forms a guarantee of safety. Indeed, one man remarked that he thought he would be told only what the authorities wanted him to know, and that would never include those things he feared the most. Similarly, he did not trust confidentiality to be maintained. His experience told him that if people in power wanted a piece of information, they would find a way of getting it.
Thirdly, participant observation and interviews revealed how the clear majority of donors had paid only limited attention to the information sheet (paper I:230). Still, when asked whether they would like to know what happened to their sample, many donors expressed an interest. Often, this was put in enthusiastic terms, and understood as a matter of receiving information about research results, which several donors regarded as ‘only decent’ (they had not noticed that the consent form explicitly states that such information will not be provided). As I then clarified that we were talking about a renewed informed consent to future research projects, some became more reluctant, thinking it might turn out to be troublesome. Others thought that it might make them feel more confident: one woman, for example, expressed doubts about giving what she termed ‘carte blanche’. However, she had not studied the concrete information sheet before signing the form just prior to the interview. Apparently, the consent requirement does not serve the safeguarding function very well. That people apparently hold strong opinions about genetic research, but rarely use the information they are offered about the research in which they are involved constitutes an empirical problem, a paradox. Similarly, many expressed an interest in giving informed consent though neither donors nor those refusing to donate paid any particular attention to the information actually provided in the consent form. This paradox is elaborated in the following chapter.

Fourthly, some people regarded increased information, not as a safeguard, not even as a service, but as a tedious burden. One man who wanted to sign his consent sheet but had not cared to read it, said, when a nurse insisted a fourth time on informing him, “Are you going to force me [to read it]?” A woman explained that she had decided not to donate as one never knew if they would come back to her for more blood – or with more paperwork (paper I:240). These donors have other concerns in their daily lives that they deem in need of more immediate attention than biobank-based research (ibid.). More information is not always perceived as a good thing by the people supposed to read it. As Haines and Whong-Barr (2004) argued based on their study of donors to the North Cumbria Community Genetics Project: it is nice to donate and thus do a good deed, providing it does not involve too much hard work.

These findings, which constitute a mirroring of the policymaking logic in the reasoning encountered among potential donors, are summarised and simplified in figure 4.2. Again, it is important to note that the reasoning of the target group is not necessarily more valid, better, more correct or of greater moral validity than that summarised as the four problematizations that
make informed consent a solution to the ethical problems of biobank based research. It is the divergences between them that are interesting.

<table>
<thead>
<tr>
<th>Policymaking logic</th>
<th>Target group</th>
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| 1. Research on blood samples is similar to research on living persons | • Some do not find blood samples particularly important; they are much more concerned about access to their medical records or questionnaires, which are objects that the policy does not address.  
• Genetic research appears less controversial per se than use of medical records. |
| 2. The problem is a conflict between individual and society | • Most donors do not see their own interests as divergent from those of the surrounding society; in fact that is why they donate in the first place.  
• Some potential donors are sceptical towards all research activities as well as the healthcare system in general. They usually decline donation, even without reading the consent form. |
| 3. The provision of information to individuals is a solution which will protect the individuals | • Few donors actually read the information offered.  
• Most tend to request political control with research and resist taking personal responsibility for the oversight of research.  
• Some donors appreciate information.  
• A minority find information crucial. They tend, however, not to feel confident about participation despite the consent form – which is seen as just a piece of paper. In the event of a conspiracy, they do not expect important information to be passed on to them via the consent form. |
| 4. More information equals better ethics                | • Some appreciate the idea of receiving more information; others find the idea of more information tedious.  
• Approximately 4 % of the population find that the most important issue in relation to biobank-based research is that donors should be informed about the research purpose. |

![Figure 4.2: Mirroring the policymaking logic in the reactions among members of the target group](image)

### 4.3.3 Quantification of the qualitative findings

As the qualitative results above were generated on a limited sample size, two surveys were conducted. In conjunction with the theme of the special status granted blood and genetic research it is worth noting that 71% of the respondents in the population-based survey (paper III) would accept genetic research on their samples. In contrast, 62% would not accept usage of their medical records without prior consent. This indicates that the notions of integrity associated with phenotypic information can be at least as important to the donating public as that associated with genotypic information.
In conjunction with the theme of informed consent, it was found (in paper IV) that 65% of the actual donors were aware that they had donated a blood sample, and 55% that they had consented to donate phenotypic information. Whereas 55% of the donors were satisfied with the information they had been given, 37% could not remember whether they had received any information, and 6% were dissatisfied. The tables in paper III and IV illustrating the ranking of different issues made by the respondents provide support for the qualitative finding that donors attribute less importance to informed consent than most policymakers. Here approximately 4% of the respondents rank being informed about the research purpose as the most important issue. The similarity of the response patterns of the two surveys is striking and even those who were unaware of their donation found issues regarding regulation of research more important than their own information levels.

These findings sustain the interpretations of the qualitative findings that 1) on its own, the consent requirement will not be perceived by the donating public as an adequate solution to the concerns people have with respect to population-based genetic research (cf. paper I), and 2) that the genetic exceptionalism implied by the focus on the usage of blood and other substances containing genes is not shared by all members of the target group (cf. paper II).

**4.4 Summarising results**

This chapter has outlined some of the findings in the enclosed papers relating to two themes: informed consent and the use of blood as a particularly problematic ethical issue, and supplemented them with findings published elsewhere. A simplified version of the reasoning implied in the policymaking was outlined to allow a comparison with the reasoning of the target group. It has been shown how some policy issues, namely informed consent, have been fortified or entrenched in daily practices, while others, e.g. public majority ownership, have proven themselves less socially robust. While the four-step logic making informed consent a solution to the challenges of biobank research is coherent, the various steps in the reasoning are not simply agreed upon by the target group. In particular, there are discrepancies in the perception of informed consent and in the importance attributed the donation of blood versus other sources of information. Similarly, there are discrepancies with respect to the notion of what constitutes legitimate objects of sale.

These findings have been presented in journals representative of the disciplines outlined in chapter 2, namely a medical journal (paper IV), a public health journal (paper III), a
science and technology journal (paper I) and an anthropological journal (paper II). In the following chapter these findings are discussed and related to the overall question informing this thesis: how might anthropology contribute to medical ethics. Paper V addresses this question at a theoretical level, and drawing upon this argument the following chapter discusses the findings and their relevance for the medical ethical debates outlined in chapter 2.
CHAPTER 5: DISCUSSION

This chapter offers some reflections on the findings presented in the papers and the previous chapter. It begins by outlining what was described as a paradox: donors tend to hold strong views about research implications and claim an interest in their blood and questionnaires, while they pay only limited attention to the consent procedure designed to inform them about the research in which they participate. It is argued that when looking at what is at stake for donors, their behaviour is not so strange after all. A way to understanding the importance of moral positioning is to compare how selective issues are problematized differently from the perspectives of the three levels: policymakers, policy workers and target group. This task involves rethinking informed consent as a matter of trust and the trade in blood as a matter of integrity and fairness.

Throughout the chapter the validity of the findings is discussed. Validity alone, however, is insufficient to draw conclusions about what recommendations the findings might imply. First, the relationship between empirical findings and normative guidance warrants consideration – how is the move made from ‘is’ to ‘ought’? This is the topic of the second section. Based on this, the chapter presents recommendations to medical ethical debates about biobanks. Finally, this discussion is related to the overall task set for this thesis, namely to reflect upon the anthropological contribution to medical ethics.

5.1 Reflections on the findings

5.1.1 Sorting out a paradox

The paradox reflects a tension between the two themes from the papers and the previous chapter, i.e. the lack of interest in informed consent forms (cf. paper I) and the different meanings ascribed to blood and other sources of data. (cf. paper II). How can people describe blood and questionnaires as part of themselves and the research executed on these data sources as important, while hardly bothering to read the consent forms, i.e. the means by which they are supposed to protect themselves and influence the research for which they provide their support?

First, the behaviour seems more comprehensible if we accept, as noted in the previous chapter, that the meanings attributed to genes are contingent (section 4.3.1). The point is that people
might more easily dispense with a sample in a situation where it is possible to think of it as ‘only
blood’. Then, in a subsequent interview, they may feel concerned about the blood being used for
purposes they dislike because the interview reconnects them, their sense of personhood, with that
sample again. The articulation of questions concerning ‘your sample’ attributes significance to it.

This makes it interesting to explore which type of situation would incite donors to
think of the blood as ‘part of them’ and which situations would make such considerations irrelevant.
If the healthcare centres hosted a sense of trust resting partly in non-verbal practices as argued in
paper I, it would make donations a minor issue. Consent procedures, however, can be expected to
have an effect similar to the interview. They also connect donors to their samples. In fact, this
probably constitutes a significant methodological problem for empirical explorations of attitudes to
informed consent. In the very process of asking whether people would like to know about research
conducted on ‘their samples’, a relation of obligation and personal identity between them and the
samples is potentially established. This mechanism amplifies the methodological problem revealed
through triangulation in the two surveys.

Policies, in contrast, have to fixate meanings. From an anthropological perspective,
definitions are political acts. It has already been shown how the cultural transformations that ascribe
aspects of personhood to stored tissue have very real political implications. Obviously, these
understandings are not merely mis-understandings: they signify many people’s moral ideas about
themselves and others, and they are shared by many donors and most nurses. The fact that these
understandings need to be articulated, documents the conflict surrounding them – if everybody
agreed, articulation would be superfluous. The cultural transformation thus takes the form of a
discursive struggle reflecting power inequalities. The creation of genetic originatorship is morality
in the making. This morality marginalises other moral understandings which would have pushed for
other rights. It would make little sense to deplore the political struggle per se: it is the way of the
world – every issue cannot receive the same attention. Nevertheless, awareness of the power aspect
helps to de-naturalise the claims made and thus to reopen the debate. This issue is revisited in
section 5.3, but first there is more to say about the presumed paradox.

Deeper consideration should be given to the meaning of the ease with which people
hand over something which they claim to be part of themselves – whether questionnaires or blood
samples. This paradox embodies a more substantial issue than a methodological flaw: the debates
about stored tissue relate to governance issues, to notions of integrity, as well as a sense of risk
attached to the circulation of data (and sources of data) about an individual’s health and genetic
profile. The argument in paper I is one attempt of overcoming the paradox by highlighting the non-verbal practices of the medical examinations (page 239), and donors’ interest in keeping the attention focused on the examination rather than on discussions of biobank-based research (page 240). The donor typically has other more immediate concerns than the research issues academics find so important. Adding to this argument, the contention put forward in the following is that when taking a closer look at the issues at stake for donors (with the tools from the studies of morality outlined in chapter 2) in relation to the possibilities they have in the specific situation of affecting these issues, their behaviour makes sense. By donating in an exchange system of generalised reciprocity (rather than for money) they opt for the security of state responsibility, rather than personal control over the scientific endeavour. They opt for a trust relationship.

5.1.2 Informed consent and the politics of ambiguity

In papers I and V, the values ascribed to the welfare state are described as resting on mutual obligations and trust. With the Swedish historical experience it is reasonable as a donor to expect that when performing one’s duty as a citizen, the authorities will assume responsibility for proper safeguards etc. Nevertheless, responsible citizens are expected first and foremost to take care of themselves: “to know how to behave” (paper I:236-237) and to employ rational judgment in doing so (ibid.:236, 239; paper V:14). When people willingly donate and request information that they do not use, it may reflect a perception of what it means to be a responsible citizen. A parallel argument could be developed in relation to people abstaining from active engagement with biobank-based research. In paper III (pages 228-229) and paper IV (page 7) it is shown how there is a correlation between people who do not wish to participate in research; who do not wish to delegate a decision to the REC; who do not find it worthwhile to express their opinion in a survey; and who describe their experiences with the healthcare system as generally negative. There is an overrepresentation of younger persons and men in this group. It would be interesting to investigate whether these individuals have special reasons for more negative experiences of the healthcare system than other population groups, but until that is established it seems safer to interpret these figures as expressions of a generally reluctant and negative positioning. This would indicate that the consent requirement interacts with people’s predefined perceptions of the health services and medical research (besides their feeling of obligation towards the authorities). The observed behaviour as people donate or abstain from donation without consulting the information sheet of the consent
form appears paradoxical if people are expected to use the offered information to control the research process, but not if it is seen as a reflection of their sense of self as proper citizens.

In light of the overrepresentation in the interviews of women in the middle-aged group which, according to the quantitative findings, was more positive towards surrogate decisions, the healthcare services and medical research, than younger persons and men tended to be, it is worth contemplating whether the findings represent a distorted picture of the moral positioning among potential Swedish donors in general. As representatives of a subjugated moral position, the findings nevertheless hold their validity.

A part of the trust most Swedes have in the authorities rests on the principle of public transparency ("offentlighetsprincipen"). Practically all administrative records are publicly available. However, if all citizens were to exploit this right, the system would break down; and the citizens would not get around to anything else. The practice of scrutinizing public governance is more random. The trust expressed by donors might reflect this sense of a potential oversight more than implementation of actual oversight. The concerns about misuse of research show that the trust is not naïve: abuse of power or other types of breaches of trust are expected to be revealed – not by the individual citizen/donor, but by journalists, non-governmental organisations or independent researchers.

It is worth relating these reflections on the trust relationship to the quantitative findings, particularly those in paper IV. We found that 446 respondents would appreciate further information about the research purpose, while only 33 donors (4% of respondents) found that the most important issue in this type of research was that donors were informed about the research purpose. This suggests that information may be perceived more as a service than as an essential ethical safeguard.

### Textbox 5.1: Other representations of the consent requirement

- As a *service* (instead of a means of protection)
- As a *potential* source of information, should interest arise (instead of an actualised object of scrutiny)
- As an expression of *polite* respect for the citizen (instead of an instrument to control research)

Textbox 5.1 summarises some of these other ways in which donors might view informed consent procedures, other than as respect for their autonomy. These other views reflect a
much longer exchange relationship with the health authorities than the relation established with the concrete donation. The question is whether informed consent procedures sustain or undermine this long-term trust-based exchange relationship, and in paper V it is argued that it potentially undermines it by replacing the trust relationship with a contractual relationship. The way the consent requirement potentially interacts with notions of responsibility at the level of the individual donor thus signals a shift in the governmental form. It is this shift that the rest of this section expands upon and discusses.

What type of political tool does the consent requirement represent for the individual donor? It is said among medical ethicists and policymakers that it transfers the power from the authorities to the individual citizen to choose to participate and to choose the level of risk each donor is willing to accept. However, the risks that the informants associate with genetic research would be unlikely to feature in an information sheet: how should an information sheet contain estimations of the likeliness that all population groups get equal access to research results, or that the circulation of knowledge about genetic predispositions will not have eugenic implications? The risks that the donors articulate relate to political action by national and supranational governments, if, in fact, the risks they articulate are at all possible to address. This might very well be the reason people who express doubts about particular research purposes do not read the consent forms before signing. They do not act from a subject position associated with the possibility to affect societal change: “I guess we just have to trust them”, as one man put it (paper I:238).

If this awareness of the values at stake for people seen in relation to the subject positions as responsible citizens from which they act resolves the paradoxical behaviour, it also directs attention to another level of ambiguity: a level of more central importance for our understanding of policymaking in this field than the ambiguous status of the donated blood. This is the ambiguity of concepts such as governance, ethics and informed consent. Everybody seems to agree that the whole field of research is in need of governance, hence the fabrication of policies. In principle, governance could address thousands of issues from forms of taxation, oversight procedures, data security measures, to organisational structures with adequate checks and balances, regulation of the incentives for research programmes and definitions of property rights and other entitlements. In this field, however, debates about ‘governance’ have focused on informed consent. Even careful studies of structural, legal, and organisational aspects of biobank research, which identifies organisational hazards or flaws, end up suggesting strengthened informed consent procedures as the preferred governmental tool (Merz, McGee, & Sankar 2004; Potts 2002). This
indicates that the ambiguity of concepts such as governance, ethics and informed consent makes it possible to present informed consent requirements as an answer to the general request for governance. As is obvious from the previous chapter, however, there is little reason to believe that a strict consent requirement serves to ‘govern’ the scientific process. Donors do not execute choices about the types of research they support or do not wish to support. Consent procedures might reduce the number of donors (which hardly embodies the values expressed concerning medical progress), but it does not positively guide research towards (or away from) particular outcomes. In short, the politics of ambiguity dissolves the object of regulation from the gaze of academic commentators and policymakers: it gives a situation where governance equals ethics, and ethics equals consent. The consent procedures diffuse the responsibility for research thereby making everybody, and thus nobody, responsible for research outcomes. The societal choices regarding the new technologies transform accordingly into procedures where nobody can meaningfully discuss why certain types of research should (or should not) be executed, who it should benefit, and which outcomes should be avoided or ensured.

Of course, it might very well be an illusion that anybody anywhere really has a choice to make. It is often claimed that if Sweden does not execute certain types of research or offer particular forms of treatment, other nations or corporations elsewhere will. Perhaps the notion of public control is first and foremost a rhetorical device, or a fantasy, which has little to do with the actual possibilities of directing the development and use of new technologies. In Science and Technology Studies (STS) it has long been claimed that “Modern “technics” […] is never really at the disposal of the “Man”, but sets Man up and replaces and displaces him in dynamic ways” (Waldby 2000: 42; cf. Heidegger 1999). Furthermore, if the studies of the regulation of science mentioned in chapter 2 (page 20) are considered, it can be seen how governance in the sense of prohibiting particular types of research has consistently failed (Black 1998; Gottweis 1998; Wright 1994). This makes it worth contemplating to what extent a ‘regulation-fatigue’ gradually contributes to a reconceptualization of the very concept of governance thereby making it feasible to talk of policies for offering individuals choices as the essence of good governance. This development resonates with what some sociologists have discussed in terms of governmentality (governance through the individual’s freedom) (Novas & Rose 2000; Rose 1999), others as privatized risk management (Green 1997). The question is whether a neo-liberal deregulation and diffusion of responsibility might be appropriating a language of governance hitherto associated with the welfare state, and by doing so infuse a concept known from the mutually obliging trust
relationship of the welfare state with a meaning more suitable to a new type of contractual relationships (cf. paper V).

The point here is merely that the individual donor does not experience responsibility for societal change in the particular situation where a consent form has to be signed. Donors seem to request societal solutions to problems which cannot be effectively addressed by them as individuals. In this respect they are in line with philosopher Hans Jonas as he probes the notion of the responsible agent in relation to the new technologies and writes that it is: “Not you or I: it is the aggregate, not the individual doer or deed that matters here; and the infinite future, rather than the contemporary context of the action, constitutes the relevant horizon of responsibility” (Jonas 1984: 9). If the immediate paradoxical behaviour among donors now makes sense, it leaves a new and more demanding paradox of governance: the concept of governance implies a responsibility from someone, while that responsibility is hard to place in the hands of any individual or specific agency.

5.1.3 Divergent understandings of trust, infringement and fairness

If informed consent relates to understandings of trust, it is interesting to compare notions of trustworthiness at the three levels singled out for the purpose of the analysis: policymakers, policy workers and target group. Similarly, a comparison of such variances in moral understandings is interesting in relation to the other theme, namely the notion of blood being a particularly sensitive ethical issue. But what is most interesting to compare in relation this theme? The previous chapter argued that the sensitivity associated with blood and other sources of data could be related to an interest in demarcating humanness from mere market exchange: if persons are treated as commercial objects, their dignity is seen to be infringed. Irrespective of whether donors are most concerned about their blood or phenotypic sources of data, they seem to believe that something can be infringed. Therefore it is interesting to ask what it is at the three different levels that people want to protect from infringement: are all actors concerned about the same, or can divergent trends be detected in the problematizations made from the different subject positions? This relates to the issue of governance because it concerns what different actors want to ensure proper regulation of. The commercial involvement is also discussed with respect to issues of fairness. It has been mentioned how UmanGenomics was launched with the intention of avoiding unethical exploitation of the region, so-called ‘baggböleri’, and that the company was established in an atmosphere of positive expectations of regional development. Hence, the pursuit of a genomic adventure was enmeshed in
expectations of future benefits and ideas about how these economic benefits should be fairly shared. In the following it is shown how these issues of trust, infringement and fairness tend to be problematized differently at the three levels.

If trust was seen by policymakers to rest predominantly on the delivery of adequate information, how did the nurses then perceive the establishment of trust? In contrast to the policymaking logic where informed consent is a systemic requirement which establishes a relationship between the biobank research projects and the individual donor, nurses tended to think about trust from a more concrete and personal perspective reflecting their professional position. The nurses wanted the authorities to assume a clear responsibility. Some of them used the consent forms to confer that idea to donors, whereas others felt a sense of responsibility impinging on their own role as the face-to-face recipients of the gift of blood (cf. paper I:236). The point is that the provision of information is valued less than the notion of a responsible agent: somebody (themselves or the authorities) worthy of trust. Similarly, it has been shown how donors express a sense of trust through their donation. From the concerns they verbalise, it can be seen that the issues they deem most important concern the usefulness of research and that all populations groups have equal access to research. If donors are to uphold their trust it is probably essential that medical research delivers medical progress for those in need.

Similarly, the object to be protected from infringement differs among the levels. Again, the divergences are simplified at the expense of nuances and individual variance in order to facilitate a synthesis and an overview. In policymaking circles the individual was seen to be in need of protection, and the trade relating to the biological body parts was problematized. Many nurses dealing with blood samples in their daily work were also concerned about the blood. When identifying problems, however, they mostly focused on the structures expected to take responsibility for what happened to the blood. From the perspective of the nurse, these structures determine whether donors were right to donate a blood sample. Hence, nurses mentioned mostly the importance of institutional integrity and transparency as the main problem needing to be addressed. From the perspective of the donor, protection is needed for the values of solidarity (the sense of belonging to a community which motivates donations) and the integrity of research directed towards medical needs. It is, of course, difficult to define medical needs, as exemplified in the debates about life-style drugs versus treatment of serious illness, which have surrounded genetic medicine. The point is, however, that the majority of donors do it for the benefit of people in need, for ill people. They would feel infringed if research were planned solely according to what
constitutes a good market if the market demand should be at odds with medical needs. Along similar lines, it is reasonable to see the resentment expressed towards patenting of human genes as a manifestation of what is perceived as a breach of solidarity. In this view, genes should not be monopolised by individual property holders (not even knowledge about genes). Knowledge about genes should be developed to alleviate pain and suffering. While there is disagreement about the role of privately sponsored research (some find that private companies address the task of alleviating pain and suffering better than public institutions), it seems safe to conclude that the main problem for most donors is an infringement of the generosity they have shown towards those in need, as would be the case if research were completely directed away from medical needs, irrespective of whether it was by academic or private researchers.

This relates to the final issue, perceptions of fairness. Rather than presenting baggböleri as a matter of money leaving the county, and benefit-sharing as a matter of ensuring regional development as the policy did, most nurses were concerned with more specific ways of ensuring what they perceive to be fair. They scorn those grand people in the country capital, Umeå, who disrespect their work and interests. They dislike initiatives imposed on them without prior consultation. In particular, they fear that the interests surrounding UmanGenomics will deter the attention otherwise paid to the preventive healthcare programme. Many nurses wanted the company to return part of the profit to the programme and at least free the examination from the standard medical charge, and perhaps offer participants a sandwich or a soft drink. Hence, when it comes to ideas about the sharing of profit, the nurses have much more concrete notions of fairness (e.g. the money returns to the preventive healthcare programme) than the model of broad community benefit-sharing through regional development expounded by key policymakers. It is important to note, however, that there is no consensus among policymakers either. Indeed the research group associated with Medical Biobank has strongly advocated a concrete return of profit, too; only, they believe the money should be used for a research foundation.

Donors often raise concerns about the rule of the Money-Devil, i.e. when profit overrules other considerations. Several donors associated the involvement of private companies with international capital and saw the problem of ‘baggböleri’ mainly as a question of lack of local control and of the rich deceiving the poor. Benefit-sharing, on the other hand, was articulated in various ways, some donors emphasising that research should be directed towards medical needs as already mentioned, others talking about local interests (where some donors from the interior region
found that Umeå had little to do with *their* local community), while yet others wanted profit to go to the authorities and the delivery of healthcare.

Bearing in mind that it adds to a gross simplification, figure 5.1 is presented to help illustrate these tendencies.

<table>
<thead>
<tr>
<th>Policymaking level</th>
<th>Policy workers (nurses)</th>
<th>Target group (potential donors)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trust</strong></td>
<td>Adequate information is essential</td>
<td>Responsibility is essential Usefulness for those in need is essential</td>
</tr>
<tr>
<td><strong>Infringement</strong></td>
<td>The individual’s biological body needs to be protected</td>
<td>Institutional integrity and transparency need to be protected Solidarity and sharing need to be protected</td>
</tr>
<tr>
<td><strong>Fairness</strong></td>
<td>- Baggböleri is when money leaves the county. - Benefit-sharing is regional development</td>
<td>- Baggböleri is when grand people in Umeå disrespects local work and interests. - Benefit-sharing is when profit returns to the preventive healthcare programme.</td>
</tr>
</tbody>
</table>

*Figure 5.1: Tendencies in different problematizations at the three analytical levels*

These reinterpretations are not and cannot be ‘proven’ to be right. They constitute alternative interpretations of the possible interests of the public, which could complement the assumptions informing normative ethical reasoning about biobanks in the academic and policymaking circles. This would destabilise the logic making the informed consent requirement an adequate response to people’s anxieties about population-based genetic research projects. To tease out how these interpretations and the findings they reflect could redirect our thinking, reflections on the relationship between ‘is’ and ‘ought’ are now needed. Based on this, some ways of addressing these issues with greater sensitivity towards donors’ expression of trust are put forward.
5.2 From ‘is’ to ‘ought’?

5.2.1 The naturalistic fallacy and its disputes

In a thesis of this type, bridging social science perspectives and medical ethics, a discussion about the path from ‘is’ to ‘ought’ will necessarily straddle diverse and multifaceted literature. It would be fallacious to expect philosophy to be prescriptive and social science to be descriptive. Both traditions make normative and epistemological claims, and both reflect on the relationship between them. In *Principia Ethica* (1903) G.E. Moore used the now conventional term naturalistic fallacy to denote the making of prescriptive conclusions based on descriptive findings. More than 160 years earlier, however, David Hume had written a passage which is now increasingly referred to when philosophers want to make the claim that an unjustified move from ‘is’ to ‘ought’ has taken place in a line of argumentation:

“In every system of morality, which I have hitherto met with, I have always remark’d, that the author proceeds for some time in the ordinary way of reasoning… when of a sudden I am surpris’d to find, that instead of the usual copulations of propositions, *is*, and *is not*, I meet with no proposition that is not connected with an *ought* or an *ought not*. This change is imperceptible, but is, however, of the last consequence. For as this ought or ought not, expresses some new relation or affirmation, ‘tis necessary that it shou’d be observed and explain’d; and at the same time that a reason should be given, for what seems altogether inconceivable, how this new relation can be a deduction from others, which are entirely different from it.”

(Hume, in Flew & Priest 2002: 274)

Hume thus emphasises the need to remain aware of the different forms of argumentation which are needed to make valid arguments for one or the other type of proposition.

To illustrate variance in forms of argumentation, which are relevant to the discussion of fairness above, it is worthwhile contemplating John Rawls’ (1999) work on the concept of ‘justice as fairness’. Rawls presents a theory of justice which contains elements of description. Rather than merely describing justice, however, Rawls endeavours to construct a line of argument that can serve as a corrective to the notions of justice already circulating (ibid.:45). He suggests an exercise of imagining an ideal society. This would be encapsulated in an agreement made between parties isolated behind “a veil of ignorance” of their own attributes, social position, and moral convictions. Since they would not know what their own advantage would be, people in such a situation could not try simply to maximise it at the expense of the welfare of others. Rawls imagines that they would agree on two principles. First, each person must have the maximum amount of freedom; second the socially and economically disadvantaged must have the opportunity to make
progress. While building his argument on an assumption about a basically egoistic human nature, Rawls describes his theory as “highly Kantian in nature” (ibid.:xviii) stipulating the sense of duty as the basis of moral thought. One of the concepts for which he has become known is “free riders” (ibid.:237-237), i.e. people who enjoy privileges without contributing to the welfare of others thus violating what Rawls expects people would define as just behind the veil of ignorance.

Rawls’ type of argument is based on thought experiment and has been criticised for resting on an unachievable situation: nobody can reason out of context. Hume was more concerned with empirical matters than thought experiments and wanted the analyst to study that which is. It is an intrinsic part of the enlightenment project, of course, to emphasise a distinction between ‘is’ and ‘ought’. In mediaeval thought the good and the correct were combined in a sacred unity installed by God. Catholic theologians have for example held that the Good is present in the world which is God’s creation. Casuistry emanates from this tradition and in recent years it has become more influential in medical ethics now increasingly detached from religion and instead promoted by advocates of a case-based approach to moral problems. This tradition highlights the context of the moral reasoning and questions whether the naturalistic fallacy really is a fallacy. Values are by these theorists perceived to be present in the world, in the context, and cannot be deduced as principles by way of thought experiments. Another very substantial challenge to the naturalistic fallacy stems from feminist ethics, notably the work of Margaret Urban Walker (1998).

Walker claims that moral philosophy has tended to evade the most important question: what is morality? It has taken for granted that this could be established through reasoning alone. She advances instead a notion of empirically informed critical reflection as the role of moral philosophy and will not acknowledge attempts of setting “morality’s terms and standards anterior or exterior to human life and human beings’ awareness and judgment” (Ibid.:5). In contrast to the emotivists, however, she does not “give up the right to talk about moral reality, because I think morality is a strikingly real dimension of every human group’s social life” (Ibid.). Morality should be studied in the interpersonal relations where it exists. Like Foucault (see page 23), she also points out how morality emerges in interplay with power and prevalent forms of knowledge. This is also the case for academic discourses: “Academic moral theories both mirror and reinforce publicly authoritative discourses of justice, rights, and obligations in Western countries” (ibid: 22).

Subsequently, she sees an empirical task in uncovering subjugated moral positions (ibid: 61). She wants to infuse the concept of morality with a particular meaning as she claims that “tracing distributions of responsibility yields the clearest picture of the structure of a form of moral life”
Walker’s project thus parallels many of the ideas on which the present thesis has been constructed: the search for subjugated moral positions; the notion of morality as a real dimension of people’s lives which can be studied in interpersonal relations; the interplay between morality, power and knowledge; and the interest in seeing how responsibilities are distributed.

Other recent contributions to moral philosophy share with Margaret Urban Walker the notion of an emergent morality, and they can similarly be seen as part of the trend of questioning whether the naturalistic fallacy really is a fallacy – or whether Moore simply made the fallacy of assuming that morality can be studied and discussed detached from human experience: that *ought* can be discussed separate from *is*. This trend includes pragmatic ethics (Fesmire 2003; McGee 2003a; Moreno 2003) and neo-virtue ethics (Castoradis 1997; MacIntyre 1984).

Wittgenstein (2001) also made the point that concepts, such as ‘morality’, ‘good’ and ‘justice’, were not the names of things existing independently of the human mind. Morality makes sense because we know particular situations in which it resonates with something we want to express. Therefore Wittgenstein disliked philosophers talking about moral laws detached from the actual subjects giving notions of good and evil meaning through their practices (Christensen 2003). Instead he suggested, much in line with Walker, tracing responsibilities and exploring the actual conscientiousness of people engaged in moral dilemmas (Skou 2003). Importantly, he states that ethics cannot be learned in the same sense as mathematics. A person has to embody values to make sense of a dialogue on ethics (Wittgenstein 1984: 117). He also claims that an ethical demand makes no sense as an abstract clause out of context, “Ein Soll an sich ist unsinnig” (Ibid.:118). In this sense he precedes MacIntyre’s proposition that normative claims only make sense in communities sharing the values that the claims embody. Moral cannot be inferred logically from metaphysical principles.

According to these philosophers the distinction between ‘is’ and ‘ought’ has to be rethought. Justice is not a concept which can be derived from carefully planned games: it is a concept that only makes sense in specific situations experienced by human beings embodying a particular, moral, capacity. Therefore they emphasise the empirical dimension of ethics. It should be noted however that Rawls consciously constructs a way of reasoning which can serve to *correct* what he sees as our otherwise somewhat selfish mode of thought, and it might be mistaken to criticise him for expounding an inadequate understanding of how we already think and makes sense of the word justice, granted that this is what he wants to change. If reading Rawls makes sense to us, we employ the moral capacities that Walker, Wittgenstein and others would like us to take as the
starting point for the investigation. Their approach is less apposite, however, when seeing one’s task as Rawls, namely to serve as a corrective to existing morality.

Perhaps the naturalistic fallacy, at least in the version of Hume, remains valid inasmuch as it serves to remind us of the difference between the variances in types of argument. There is a difference between identifying flaws in Rawls’ description of how justice works and expressing a dislike of his vision of how it ought to work. Moral claims, also those circulated by philosophers, are constructed as agents working in the world; they embody a power effect which can be studied independently of (dis-)agreement with the claims. Also, it could be agreed that it is necessary to share some values to agree with a particular vision. Therefore it can be useful to explicate the values informing one’s line of argument when moving from ‘is’ to ‘ought’. A similar conclusion can be drawn after consulting selected pieces of social science texts on the relationship between ‘is’ and ‘ought’.

5.2.2 Prescription vs. description in the social sciences

Social scientists would think of Max Weber rather than Moore and Hume when addressing the relationship between ‘is’ and ‘ought’. Weber imposed a strong distinction between empirical data and normative guidance for action. He makes the point that –

“– it is one thing to state facts, to determine mathematical or logical relations or the internal structure of cultural values, while it is another thing to answer questions of the value of culture and its individual contents and the question of how one should act in the cultural community and political associations”   (Weber 1947: 146)

In as far as this embodies a strong distinction between the descriptive and the prescriptive, Weber is the G.E. Moore of sociology. There has been intense critique of Weber, however, and the image of knowledge as residing in a realm of its own can be said to be at odds even with his own hermeneutical stance. An interpretation always employs a perspective from somewhere, and any interpretation can be challenged from other perspectives. It makes little sense in social science to imagine that any perspective is devoid of power relationships or moral propositions. Indeed this is the rationale behind the inspiration in Foucault for this thesis (see section 1.2.3) and the deliberate search for blind angles to other knowledge projects. Also, it was emphasised by Weber that science is useful to the surrounding society because it can give guidance of the type “if you want YY, then it is recommendable to do ZZ”. His point was that the first part of the argument (“If…”) could not be
established by reference to facts, not that the production of fact takes place in a void of power and value. The question then remains whether scientists are responsible for the purposes (the “ifs”) they decide to serve.

In relation to this question, it should be noted that Weber writes from a disenchanted position where no values are taken for granted. In this sense he can be read as an existentialist making the claim that meaning has to be produced by the meaning producing subject. The usefulness of a given activity cannot be deducted from first principles. In this perspective, Weber appears much like Walker, MacIntyre, Fesmire, and even Wittgenstein. Values are real, experienced by human agents and in a concrete sense guiding action (just as the protestant ethic has real effects). Even Foucault, with his emphasis on the practice of freedom, represents a sort of existentialist stance (though he explicitly distanced himself from existentialism) in that he sees values as emerging through choices. Only, it should be remembered that, for Foucault, there is no chooser behind the choice. Values as well as the people choosing them emanate from interaction. The point Weber makes is not about existentialism, however. It is that one should avoid claiming the authority of science (of facts) for personal values and political interests. The political usage of scientific authority was also a concern for Foucault. He deliberately sought to question the political aspect of knowledge production, but like Weber he did not take a specified political project as a valid starting point for scientific inquiry:

“I have never tried to analyze anything whatsoever from the point of view of politics, but always to ask politics what it had to say about the problems with which it was confronted. I question it about the positions it takes and the reasons it gives for this; I don’t ask it to determine the theory of what I do. (Foucault 1997b: 115)

This would lead us to conclude that Weber and Foucault – who at a first glance seem to advocate opposite positions in as far as Weber talks about a distinction between norms and knowledge while Foucault takes as his starting point the embeddedness of knowledge in politics and norms – share a particular concern; namely the (mis)use of scientific authority for political ends.

Thus, it seems feasible to create a tentative synthesis which would alert us to the dangers of claiming epistemological backing for prescriptive claims. If the recommendations are to be useful, there has to be agreement with the goal of the intervention, and that goal cannot be settled deductively or empirically. In brief, the fieldwork material of this thesis informs us merely that divergent notions of trust, infringement and fairness prevail among different groups, and that these notions emerge for real people in concrete situations. Walker would invite us to see these notions as
important reasons for critical reflection. It is nevertheless important to bear in mind that it cannot be decided from the facts only which notions of fairness are right.

In sum, it is tempting to say that at most, anthropological data serve a sort of fallibilistic function revealing which normative claims and assumptions do not work out in real life, and leave all formulation of guidelines to normative types of arguments while expecting them to make their own way around the naturalistic fallacy. Here another conclusion is drawn from the synthesis above. It is suggested that there is some guidance for action in the material, but that the guidance depends upon the values of the reader. For a recommendation to make sense, the reader will have to agree with the author or the quoted informant on particular propositions, and these propositions are better stated clearly. What the study can do is to deliver knowledge of the type “if you want…, then you should”. Of course the analysis of the material should make sense irrespective of the values of the reader.

5.3 Governance of biobanks in Sweden

5.3.1 Turning the analytical gaze to the structures of biobanking

As the argument now advances in a more prescriptive language, it is important to keep in mind that there is no solution which settles everybody’s needs. We should expect no agreement on the “ifs” of an argument: every option resonates more with some interests than others. Also, and equally important, this section makes the precarious step from a second order perspective describing the negotiation of moral values and systems of governance, to a first order perspective where the text is involved in that very negotiation. The safe terrain of observation is abandoned for the sake of partaking.

Rather than giving very concrete advice about how to run a biobank (a topic which has not been studied), this section is restricted to recommendations concerning the debates taken in medical ethics and among policymakers. The recommendations primarily concern issues which should be attended to, rather than descriptions of ways to attend to them. First I will elucidate the basic value premises on which the following argument is built, then proceed to recommendations for future objects for analysis, and, in the subsequent section, comment on possible ways of dealing with the issue of informed consent.
The values informing the following recommendations reflect solidarity with those least able to influence the course of events: donors. In line with the theoretical understanding of morality, the donation represents a moral act. The values expressed in this gesture are open to multiple interpretations besides undoubtedly having different meanings for different people. Nevertheless, there seems to be clusters of values around faith in medical progress and trust in public authorities. Therefore, the ethical analysis must centre on ensuring that the receiving structures prove themselves worthy of this trust. A consent form does little to ensure trust (O'Neill 2002; cf. paper V:17-18).

However, some participants in the examinations do not share these values. For example, the younger respondents and the male respondents to the surveys expressed a generally negative attitude to the health services, medical research as well as participation in surveys trying to reveal their position. As argued by Jackson (2002a) this type of positioning might appear uninformed and irrational, but from the given subject position it makes sense as a general expectation of being potentially exploited. In the argument I develop in the following, I wish to respect such divergent moral positions. It is important, however, to note that the discussion is about respecting people who do not care to know what the research is about and why they are asked; they do not feel it is part of their obligation because of an unspecified suspicion that this does not serve them. They might very well be right in this assessment; however, I am most inclined to side with those who feel as part of, and who want to confirm, the community, because these people support interests other than their own. These people express not only willingness to help, but also a general confidence in the authorities receiving their samples and questionnaires. If a society embodying these values should be advanced, it is these donors who should not be let down.

Therefore the central recommendation is to direct attention to the actual structures – and make them trustworthy (cf. Kaye 2004)). It is a matter of matching the trust expressed by donors, who are opening their veins and medical records for a medical gaze, as it were (Lindee, Goodman, & Heath 2003: 2-3). Structures is used to mean confidentiality and security issues; the forms of funding; the types of incentives which are installed; the approach taken with regard to benefit-sharing; democratic influence; the handling of risk and possible misuse of data; as well as dissemination of risk information derived from research. These issues are discussed in turn in the remaining part of this section.

It could be that most of these issues have been handled very well by Medical Biobank and UmanGenomics. Prompted by demands from UmanGenomics, the one responsible for quality
assurance in Medical Biobank, in cooperation with a consultant with experience from the pharmaceutical industry, has developed systems to enhance the safety of storage facilities, the confidentiality of donors, and control procedures for correct dispensing of samples. This work is being disseminated in Sweden through the coordinated effort of the collaborating county councils. It is not the task here to outline how biobanks should be administered, however, only to comment upon the ways in which an anthropological contribution to medical ethics might direct attention to new objects for policymaking and ethical debate. The work with security and confidentiality issues has been marginalised in ethical debate and been subject to only limited policy interests, and this implies that the proposed ideas have been subject to only limited international scrutiny and attention – in sharp contrast to the attention given to the consent requirement.

Also, the issue of funding structures has been inadequately addressed. If public trust is to be ensured by ensuring equal access for all population groups to research results, and that research is directed towards medical needs rather market shares, it is necessary to consider how funding is structured. Policies installed to ensure transfer of knowledge from university to industry and to facilitate better public-private collaborations are potentially in conflict with the public vision of medical progress for all population groups. These policies increasingly necessitate collaboration between private companies and university researchers to get public grants. The establishment of UmanGenomics is also part of attempts to attract money from industry to previously public research activities. The demand for industrial collaboration, however, implies that research projects have to have market relevance. The question is whether the definition of a public research agenda then, in effect, becomes guided by attempts to read market signs so that public funding is limited to areas defined by industry. These areas are subject to hype and contingent expectations and less concerned with medical needs than with the whims of venture capital. If the point of departure were taken in medical needs in policymaking, the logic would be reversed along the lines described in the section discussing the relationship between ‘is’ and ‘ought’: policymaking would be about determining which problems to solve (‘if…’). And rather than providing technical attempts of fortune telling by clarifying where the next ‘breakthrough’ was, the role of medical professionals would be to figure out the best means to achieve those ends (‘then…’). And this might not always be a technological breakthrough.

Clear statements should be demanded about the purposes informing the use of public expenditure. In the case of large trusts, such as UK Biobank, these purposes should feature prominently in the objects clause in order to oblige such trusts to commit themselves to well-
defined goals: to state the values guiding their work. In Västerbotten this topic has special relevance, as UmanGenomics was launched with mention of an intention to study some rare diseases endemic to the region. However, international pharmaceutical companies have limited interest in solving local problems affecting few people only, and no such research has been undertaken. This is not the fault of UmanGenomics; it is a problem of the funding structure. Hence, there might be a point in revitalising the vanishing distinction between public and private funding and reserve parts of the public funding for purposes for which no private funding can be found.

A related level of analysis, which has not been addressed in academic circles and by policymakers, is the incentive structure. Considering the company’s poor financial performance, it could be claimed that it is just stating the obvious when pointing out that UmanGenomics was given imperfect conditions. Some problems could hardly have been foreseen, however, and cannot be pinpointed as any specific structural problem as they relate to the ownership issue, which apparently could not be settled amicably. The adequacy of actual contracts to provide a laudable incentive structure has been analysed elsewhere (Hoeyer 2004b). Here, it is argued that attempts to secure UmanGenomics independence from local authorities, and to safeguard blood from commercial exploitation, and thus save the company from the hazards of the conflict, has resulted in a problematic incentive structure. Researchers no longer retain rights in material they collect, nor in their original intellectual contributions. Likewise the trustees of the biobank, the university and the county, hold no commercial rights to it. They can claim a minor fee to cover part of their expenses, but they have no rights to profit. UmanGenomics no longer initiates its own research, but basically exists to retain the so-called ‘exclusive commercial rights’ to research carried out by other researchers using Medical Biobank. When companies, funding agencies or universities are entitled by law to IPRs in the research projects they host (so-called background rights), generally, such entitlements are supposed to create a structure of incentives (Webster & Packer 1996). With UmanGenomics, however, those who execute or facilitate research no longer find themselves entitled to the IPRs stemming from it. If biobanks are to be designed to serve as broad resource bases for research and facilitate the medical progress hoped for by donors, there is a need to rethink how different companies, academic researchers and others could be given adequate incentives to use Medical Biobank (it is beyond the scope of this thesis to discuss the implications of the use of intellectual property rights in this field in general; however, for some interesting discussions, see (Bobrow & Thomas 2001; Faulkner, Geesink, Kent, & FitzPatrick 2003; Knoppers 1999).
The issue of benefit-sharing also relates to the funding structure. Helen Busby and Paul Martin have pointed out how articulation of the nation or the community is used to mobilise donors in population-wide biobank collections (Busby & Martin 2004). Granted that people donate because the research project is part of community efforts, it is crucial that the community also shares the benefits. The notion of individual risk has marginalised debates about benefit-sharing in bioethical debate about biobanks and population-based genetic research. Discussions should be started about the more political question concerning the implications of benefit-sharing. Another political question, which seems to have been marginalised in ethical debate, is the use of an intellectual property framework to allocate commercial entitlements in biobank-based research. Who should have these entitlements; are they fairly distributed; and with respect to the previous point: do they ensure a good incentive structure?

Concerning community participation, it has been argued that large biobank projects have a democratic deficit and that there is a need for community consultations (Weldon 2004) or community consent (Chadwick & Berg 2001; Greely 1998; 2001). This is part of a trend in Public Understanding of Science (PUS) studies to emphasise dialogue with the public and to ensure deliberative democracy as part of legitimising new biotechnology (Elam & Bertilsson 2003; Irwin 2004). Considering donors’ lack of interest in consent forms (cf. paper I) and surveys about biobanks (paper III:228-229), however, it is important to keep asking critical questions about why people should become scientifically literate and why it is particularly important to enhance democracy in this specific area. Is it paternalism in the disguise of ‘democracy’ to define the issues that the ‘public’ ought to be concerned about? Democracy has such a positive ring that it is practically impossible to question it without being aligned with dodgy paternalists, semi-fascists or just old-fashioned fools. However, there is something peculiar about the ways in which biobanks have become subject to ideas about consensus conferences, public hearings etc. (while foreign aid, EU agricultural support systems and Middle East politics have more easily avoid these drivers for democracy). Might it be that ‘public debate’ about new biotechnology serves purposes other than deliberative democracy? Is public consultation sometimes used as a sort of marketing? The crux of the matter with respect to public participation must be to make a structure that makes public influence possible though not obliging. This would accommodate the trust described as emanating from potential oversight (cf. textbox 5.1). In major biobank projects, as in the UK and Estonia, donors could have representatives on the board, there could be homepages with current information, and there could be rules of press access – all in order to ensure access for those interested.
Whereas there has been wide debate about the individual risks of being part of a genetic database, the link between forensic uses and medical uses was hardly discussed in Sweden prior to the case in relation to the murder of foreign minister Anna Lindh in 2003 (see page 16). One informant said in explanation for not wanting to donate that “One would never know if the blood were to turn up at the scene of a crime.” Granted that small samples of blood are located in various hospitals, the proof status of blood at a crime scene needs to be reconsidered. There is always the risk of planted forensic evidence; of false positive answers; of laboratory contamination or other mistakes. This might merely be fanciful assumptions of conspiracy; nevertheless, it is relevant to investigate whether it is actually possible to keep track of all samples and discover mistakes, just as it is relevant to investigate further the public attitudes to the use of medically derived samples for forensic purposes. It is essential to be able to protect people before imposing an obligation to help others (cf. Chadwick & Berg 2001).

A final question needing contemplation is how to administer knowledge about individual susceptibility to disease when this arises from biobank-based research. It is of potential value to donors, but it cannot be taken for granted that everybody will appreciate risk knowledge. The results in Paper III suggest that a majority would prefer to be informed only if well-established treatment exists – if the knowledge can lead to action.

These issues represent an attempt to replace the general and ambiguous call for ‘more governance’, with more focused questions on: what ought to be governed; what can be governed; and by whom? If the concept of ethics has increasingly been used as a means to ‘facilitate’ research by describing how research should be conducted (Black 1998), this thesis invites the reader to re-infuse the concept with meaning making it an idiom for the identification of ends. It is, in fact, striking how ethical debate about biobanks has focused on how to do it, at the expense of asking why! In line with Heidegger’s (1999) famous essay on technology we might say that the real danger of modern technology is not potential misuse, but the transformation of mind it induces which makes it impossible to appreciate the worth of anything in its own right: the technological reasoning makes everything into a resource, a means, for something else with no genuine purpose. What we need ethical analysis to do is to get debates back on the track of deliberating what we need; how and why we should use our resources for one purpose rather than another; and how structures can accommodate publicly legitimate purposes. Now the issue of informed consent will be treated, albeit briefly.
5.3.2 How to handle the issue of informed consent?

Though informed consent is a new problem in relation to stored tissue, the administration of the consent requirement is practically the only issue that policymakers have invited recommendations on when I have discussed my work with them. As the argument of this thesis is that more attention should be given to issues other than informed consent, a suggestion for how to handle the consent requirement is presented with the hope that this will not be the only part of the thesis that will be read and reflected on.

There are several concerns to take into consideration with respect to the handling of the consent issue. Some donors are very interested in giving individual consent, whereas others find it a burden – no matter which policy is adopted, somebody will be bothered. Also, some, who donate to what they perceive as a community project where everybody is obliged to contribute, will find in a system of informed consent a systematic production of free riders. As argued by Chatwick and Berg:

“It is considered a right of people participating in medical research to withdraw from a study at any time and to demand that one’s sample is given back, regardless of the damage to research or researchers. It is not obvious, however, why a right to refuse to participate in genetic research, when it could be of benefit of others, should be overriding. On the contrary, it could be argued that one has a duty to facilitate research progress and to provide knowledge that could be crucial to the health of others.”

(Chadwick & Berg 2001: 320)

Whereas several of the people abstaining from donations did in fact share the vision of medical progress and agreed with this notion of obligation, the position taken in this thesis is not in support of a universal obligation to participate with no possibility of opting out. One reason is pragmatic: a few furious involuntary donors could cause great harm to otherwise beneficial research. Another reason reflects the inevitable plurality of values and the ambiguity of research usefulness. The ‘uninformed’ decision of the people positioning themselves generally negatively towards the health services and medical knowledge must be respected as a valid choice (cf. Huniche 2002). There is no way to establish with certainty that biobank research is beneficial, and though donors rarely assess concrete research purposes in the informed consent situation before deciding whether they feel an obligation to support research, their general positioning towards the authorities, medical research and industry remains an expression of a particular set of experiences and expectations that we must respect (Jackson 2002a). We cannot put an obligation on people to deliberate biobank research according to specified standards of rational judgment (Brodwin 2003: 15), nor can we dismiss their right to decline participation without presenting a convincing argument for such an obligation to
participate. An argument in favour of obliging people would demand a demonstration of careful attention being paid to the research structures to ensure that they facilitate research for those in need, that the risk is minimal, and that the benefits are shared.

To strike the golden mean the following model could be suggested (inspired by the work of British lawyer Jane Kaye (2004: 134). When collecting samples for research purposes people should be given a brief information sheet inviting them to donate a sample for future medical research broadly defined together with a description of the procedures for approval of specific research projects; a clarification of the donors’ right at any time to withdraw their consent; and, if possible, guidance on where to learn more about the research project and its results. This is what Arnasson (2004) calls a written authorisation to distinguish it from informed consent. If controversial changes arise, a letter should be sent to the donor giving this person the chance to opt out, though not obliging the donor to return the letter signed. In Sweden, the problem of accurate updated addresses is minimal as the central registry facilitates a constant update. It can, of course, be asked what is controversial? There is little reason to believe that new medical uses are controversial according to this study, but an easy approach to the question would be simply to say that everything giving rise to intense debate in the organisations accountable for approval procedures is controversial: new partners, new techniques, new sources of funding, or new aims of research on the fringes of the medical realm.

Concerning the collection of samples for purposes other than research there is reason to entirely reconsider the consent requirement. Tissue is stored routinely for many reasons, one of them being to ensure that earlier diagnostics can be verified. This is crucial in establishing certainty in cases of accusations of medical mismanagement, and here the doctor is also entitled to preservation of the ‘proof’. Therefore it cannot be the decision of the patient alone. These routine collections must be ensured high standards of safety, and control systems should be in place to facilitate easy and safe procurement of relevant samples, which would also be of use to facilitate research on these samples. In this case, however, donors should be entitled to opt out after having been personally addressed with information about the reasons for using this tissue. The recent Swedish law on biobanks states that all tissue from routine collections should be destroyed after two months. This time limit could be expanded to one year, and providing that the tissue is deemed to be of potential scientific worth, it could be transferred to a research biobank after a consent procedure similar to that used for other research donations. Again the purpose is to facilitate medical progress
without incurring on donors a burden of responsibility, while simultaneously respecting those who position themselves in opposition to these ends.

Alternatively, the Danish authorities have decided to establish a tissue donation registry where anybody who is anxious about their tissue being used can register (Indenrigs- og Sundhedsministeriet 2002; Law 312, 05/05/2004). Prior to any usage of tissue this registry must be consulted and unless people have opted out, their sample can be used. This is feasible in the Nordic welfare states where all public records use the same personal ID number. This system gives those interested in opting out a chance to do so – once and for all – while those wanting to facilitate research with a minimum of personal discomfort and time wasted on keeping themselves informed are relieved of the consent burden. For major biobank projects where donors are specially invited there should, of course, still be an independent consent procedure. This system resonates with the inclination to respect the variances in interests among donors suggested here, but will only prove itself worthy of the trust expressed by donors if proper security structures are installed.

These suggestions will be deemed very ‘laissez-faire’ by proponents of strict informed consent procedures. The position taken here, however, is that it is a more dangerous relaxed attitude to rely on a consent requirement as the main control mechanism when donors pay such scanty attention to the information provided and seem to trust the public authorities, to whom they donate, to take care of their interests and protection.

5.4 The anthropological contribution

The overall purpose of the thesis has been to explore the anthropological contribution to medical ethics. Paper V responds to that task at a theoretical level, and part of the argument presented above is developed in that paper. In brief, the anthropological contribution has been to reintroduce political issues to ethical deliberation, and to redirect the ethical scrutiny of biobanks from informed consent and the autonomy of the individual to biobank structures and issues of fairness. The anthropological contribution has added empirical substance to debates thick with assumptions about donors’ interests, and some of the most prevalent claims are now harder to substantiate, namely the notion that all donors want to protect themselves and find informed consent procedures an adequate tool for that end. As also stated in paper V, there are theoretical contributions in anthropology of different relevance to different medical ethical traditions. Another finding from the crossing of the borderland of ethics and anthropology has been the potential for mutual inspiration between
anthropological studies of morality and feminist ethics, pragmatic ethics and other empirically grounded ethical schools.

This anthropological contribution offered to medical ethics is not a nicely planned, succinctly told narrative and it is poorly summed up in terms of a certain number of findings. Rather, it constitutes an attempt to find ways of doing anthropology in relation to the chosen topic. It is an attempt to merge social science and ethics. The route taken into this field has been directed by a search for blind angles to other knowledge projects starting with the conviction that blind angles constitute potential dangers worthwhile assessing. The result should not be seen as a dismissal of ethics, or as an attempt to replace it, or to complement it with context as a sort of spice (cf. Figure 2.2). It is an approach to making a situation accessible for reflection anew. For whoever holds an interest.
6.1 Between social science and medical ethics

This thesis traverses the borderland between social science and medical ethics, and this has stimulated an increased awareness of the divergent research ethical traditions of anthropology and medicine. In another paper, the differences have been described and used to analyse the types of conflict which occasionally arise when social scientists begin studying the health services (Hoeyer, Dahlager, & Lynöe 2004). This chapter draws on the discussions developed in that paper, but has another aim: to describe the research ethical considerations which have guided the project. But first, the type of differences that can be identified between medical and anthropological research ethics are briefly stated.

Whereas medicine has a series of key documents, the Nuremberg Code, the Helsinki Declarations, the Belmont report etc., which constitute a codified and established set of minimum standards for research ethics (Brody 2001; Rothman 1991), social scientists have not managed to agree on any such principal documents (Mills 2002; 2003). In fact, ethical codes are heavily criticised by many anthropologists for de-politicizing the research endeavour, for impeding activism and for allowing people in power hinder research that does not support their personal aims (Bourgois 1991; Pels 1999; Scheper-Hughes 1995; 2000a). Codes are even seen as un-ethical by some anthropologists (Amit 2000).

Anthropology and medicine have tended to find divergent solutions to comparable problems. Both traditions, for example, find it essential to avoid doing harm to the research participants. However, in medicine, informed consent has been launched as the paramount way of safeguarding participants, while simultaneously serving the purpose of showing respect for their autonomy. In anthropology, there has been a tradition of safeguarding through anonymised representations and careful consideration of which parts of the material should be published. Ethnographers have tended to invent false names for the villages they have studied, and as they began studying the health services they often masked the identity of the studied hospital. In anthropology, it is taken for granted that participant observation in a local community cannot be executed with informed consent from everybody. Furthermore, anthropologists typically study community interaction between parties with conflicting interests. Therefore, they do not expect everybody, who is enrolled in the study more or less passively (as they are talked about by other
informants), to arrive at a consensus about how the research should be executed. A hospital manager, for example, might not want to participate personally in the study, but if other informants continuously talk about the way this person executes his or her office, the anthropologist will have to find ways of conveying these views without allowing the manager simply censor the representation of the organisation. Hence, it has been argued that if particular, powerful informants are given such rights, social science will achieve nothing more than preservation of the ideologies that elite groups want to retain (Scheper-Hughes 2000a). Once a person holds an office which has important implications for others, it is asserted in the anthropological tradition that this person has to accept that the running of that office is commented upon and analysed. The medical tradition, however, advises the researcher to show respect for all participants. Therefore, each person has a right to request that only information already circulating in public is analysed. The point is, nevertheless, that office holders should not be in a position to completely bar commentary on their practice. It is not the persons as private individuals who are being studied: they are the path the researcher has to traverse to arrive at a general representation of the ways in which the setting works.

The approach taken in this project has been to seek a mediation of the two types of ethical reasoning and find ways of respecting all participating individuals while simultaneously retaining a room for critical analysis which can bring forward marginalised viewpoints.

6.2 Practical conduct

6.2.1 Issues of particular importance when studying policymakers

The anthropological inclination to protect via anonymised representations is problematic when small identifiable units are studied. Researchers studying UmanGenomics and other biobank projects have consistently revealed which biobank they have been studying, partly because it is important for providing useful input to policymaking in this field to know which biobanks are being managed in what ways, partly because it is simply impossible to anonymise.

When studying the policymaking level it has therefore been necessary to find ways of minimising the friction between the different interests in the field studied, and of respecting people’s privacy while retaining room for critical commentary on the administrative networks in which the ethics policy was developed. The tools employed to achieve this end can be summarised in relation to four points:
• clarification of the informants’ role as research participants
• communication of the difficulty of predicting results from explorative studies
• elucidation of the ownership of data
• retaining the right to make conclusions

Concerning the first point, throughout the project I have attempted to clarify its aims and that even those policymakers who are themselves researchers are research participants from my perspective. This has proved difficult, as I have repetitively heard my project described as one of studying ‘attitudes among donors’. In long-term relations, it has been a task to keep reminding the informants that they are also being studied and that the resulting thesis will describe what they say, rather than subscribe to it. Secondly, I have attempted to communicate the explorative character of the project. Unlike most biomedical trials, there has been no protocol, and it has been necessary to follow the acts and events as they unfolded. This approach brings new issues into focus and therefore it has been impossible to inform informants about the whole project beforehand. In particular, the evolving conflict (mentioned on page 7) has brought an element of flux into the research interests. In the beginning of the project, I was less aware of the need to convey this to interviewees. Thirdly, it was made clear that all field notes and interview transcripts would be in my custody with a strict confidentiality clause. Fourthly, key informants had the offer of reading manuscripts prior to publication, but they were informed that while I would be open to recommendations and dialogue, the decision on what to write rested with me alone.

People giving an isolated interview have been treated differently than people with whom there has been a continuous relationship. Prior to an isolated interview, an email was sent describing the project and why this person had been approached, and through this email it was also sought to clarify the issues outlined above with a formulation of the type reprinted in textbox 6.1.

Textbox 6.1: Information given to informants at the policymaking level during the latter part of fieldwork.

Participation in the interview is voluntary. You may also choose to have an informal chat only. You can decide to be anonymous (if it proves difficult to be fully unidentifiable, together, we can decide upon a form that you find acceptable). I do not know whether I will use specific quotes. If you wish to be quoted verbatim, I can offer you a viewing of the manuscript before publication, but will not censor my conclusions or interpretations.
A few informants expressed unease when talking about UmanGenomics and Medical Biobank, probably due to the development of the conflict. In these cases, I made no attempt to arrange additional interviews.

In the continuing relationships, several informants expressed their interest in talking about what had been happening and also that they found these talks consoling. I aim at keeping my intentions clear and at each meeting we have decided upon the terms of our interaction. It was also these informants who were invited to see papers prior to publication (when the respective papers drew on material generated in interaction with them).

6.2.2 Consent from nurses
The nurses’ participation in this study was negotiated slightly differently. Some of the managers of the healthcare centres claimed to provide consent on behalf of the nurses. Nevertheless, I insisted on informing them about the intentions of the project and what sort of cooperation would be needed from them. I also gave them the chance of declining to participate. A meeting was held at the larger healthcare centres where the nurses discussed whether they would accept my presence; others were informed in more informal exchanges and over email and telephone. After the individual interviews, the each nurse was invited to pose her own questions to me, and explain how she experienced having an observer in the room during the examination. As some nurses preferred to be alone with the person being examined during the last part of the examination, which focused on counselling, the observations of this part were discontinued after the first third of the interviews. Some nurses conveyed a sense of relief of finally being in a position to talk about what was happening and expressed satisfaction with their participation in the study.

6.2.3 Consent from potential donors
The consent procedures with the donors were described in the methods sections (page 44). A letter was given to them (see attachment 4) and they were informed about their right to decline my observations as well as the right to suspend an interview at any time. Though quoting these people verbatim they have not been invited to read transcripts or drafts of articles. This would have necessitated an exchange of addresses etc. and exposed their identity. Furthermore, it is most unlikely that they should be recognised in any way. The analytical interest has focused less on issues of personal sensitivity and more on identifying patterns in reactions and concerns.
6.3 Is it possible to inoculate a project against anger?

Though it has been one of the aims of these measures to avoid infringing the integrity of research participants, it might not be possible to inoculate a project such as this against people disliking its conclusions or the approach taken. For example, the distance implied in culture analytical discourse can be experienced as hostility and therefore infringing (Knudsen 1995: 20). Besides, the conflict which evolved during the project created much tension and made many people very alert to possible misrepresentations. However, it could be claimed that these people were already feeling infringed – it was not the project as such which created the tensions.

In one case, an informant expressed dislike of a paper sent with an invitation to give comments. The informant admitted not having read the whole manuscript but disliked the use of a particular quote, which was being explained and justified later in the manuscript. Arguably this informant felt misrepresented (though recognising the quote) and regretted having spent time with me. The reaction was very sad. Nevertheless, it is hard to say what should have been done differently. The quote was not used in the article submitted, but the conclusion remained the same – and in my view a favourable one for the position from which the informant was speaking. Only, this informant might never realise this because the communication was broken off following the first reaction to seeing the quote. If nothing else, this illustrates the need for mutual trust and that the researcher alone cannot ensure a fruitful dialogue.

In sum, the key concern informing the research ethics of this project has been to combine respect for the involved individuals with a dedication to remain free to make conclusions irrespective of the political interests of particular parties. Great attention has been paid to communicating the project intentions to, and engaging in a dialogue with, long-term key informants, while at the same time seeking to protect more peripheral informants through confidentiality.
CHAPTER 7: CONCLUSION

This chapter contains a summary of key findings and analytical points from the previous chapters and the enclosed papers. Secondly, it clarifies the type of recommendations made, and thirdly discusses the nature of the contribution made by this study. Prior to this, however, a short disclaimer might be needed. None of the findings presented here should be read as accusations; there has been identified no guilty party, nor any 'misdeeds'. There is a tendency in critical social science to look for the conspiracy or the malevolent (ab)use of power. It would be mistaken to read the account above in this manner. Indeed, there has been a use of power, and surely some things could have been handled differently, but it is utopian to imagine a situation where there would have been no use of power and where nobody would have found anything to criticise. No policy can be developed without representing some views more than others. Furthermore, the very point about unravelling the ways in which some issues have been included in the policy is that this process has a dynamic of its own: it is not the result of a conspiracy. At some point in any policy process it becomes immensely challenging to express an opinion other than that most commonly expressed, or even think differently. This is what happened with the consent issue and the Swedish biobank. UmanGenomics should not be blamed, nor the biobank, for emphasising one ethical issue at the expense of others. In a sense, the key policymakers have been pushed around by the policy discourses just as much as anyone else. The Research Ethics Committee (REC), for example, took the consent requirement to mean something else than the company and created a push for the more-information-equals-better-ethics doctrine, but the committee was simply using the space for action carved out by the policy and the policies guiding its work. Concerns about the commercial endeavour, for example, were much harder to articulate and beyond the REC’s mandate. Hence, it is important to read the account without looking for the crime or the criminal. The point about interrogating a policy process from the so-called ‘third position’ of anthropology is to make the situation available for reflection anew, for all parties. That is, to develop a critique rather than to criticise. This said, now comes the summary of the analytical findings.

7.1 Analytical findings

The analytical findings in the enclosed papers and the preceding chapters cluster around the divergent views of informed consent in relation to biobank-based research and the divergent
understandings of blood (versus phenotypic information) and its proper storage, utilisation and commercial uses.

Figure 7.1 sums up the main points with respect to informed consent. Policymaking and academic discourse have both attributed much more importance to the consent issue than those people for whom the consent is supposed to play a role, namely, the potential donors. It has been a widespread assumption in policymaking circles that people would request information; however, many do not, in fact, read the information they are offered. While some donors, in particular young men, are offended by the thought of not being offered information, information is viewed more as a service, or a right that can be left unused, than as the central control mechanism of science or an expression of autonomy. Also, it has been assumed that an informed consent requirement could be decided upon by the relevant bodies and then implemented by the staff responsible for the collection of samples at the practical level. However, the nurses have had their own views about the responsibility incurred on them as face-to-face recipients of blood for commercial genetic research. They administered the consent requirement in divergent ways.

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<tr>
<th>Prevalent ideas among policymakers and normative medical ethicists</th>
<th>Findings after study</th>
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<tr>
<td>Informed consent is seen as the most important issue</td>
<td>Only approximately 4% of donors regard being informed about the research purpose as the most important issue</td>
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<tr>
<td>People are expected to request information</td>
<td>Many people do not read the offered information</td>
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<tr>
<td>A policy is expected to be implemented by nurses</td>
<td>The practices installed through the policy emerged through series of contestations and alterations at all levels</td>
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The other theme running through this thesis concerns the meanings ascribed to blood. Distinctions can be identified at the policymaking level; distinctions that were less dominant among members of the target group and the nurses. These distinctions have had important implications for the entitlements in the stored material. They have facilitated a commercial domain from which donors are excluded; where university researchers have limited incentives; where the university and the county cannot get their biobank expenditure fully compensated. These distinctions operating at the policymaking level can be summarised in four bullet points:
• Genotypic information is fundamentally different from phenotypic information
• Blood as a substance is fundamentally different from knowledge derived from blood (the latter can be subject to trade, whereas the former cannot)
• The storage of blood is a fundamentally different task than the commercial exploitation of blood and the two should lie in the hands of separate organisations (Medical Biobank and UmanGenomics)
• The expenses relating to operating the biobank constitute a different sort of economy than the profit made from its exploitation, and the two types of money should not be mixed (the former will be paid for by the county and the university, the latter accrued by company stakeholders)

Finally, everybody has come to agree that biobanks are in need of governance, and that this is an ethical issue. However, because concepts such as governance and ethics hold countless meanings, the ambiguity of the terms facilitates important shifts in signification. This is what happens when governance comes to mean the same as ethics, and ethics the same as informed consent. Ambiguity can also be seen in the ways that blood is ascribed different meanings; the ways in which it moves between humanness and data source. While policymaking attempts to fixate meaning, the practices installed through the policy remain open for reinterpretations.

If this all revolves around ‘ethics’, what, then, is ethics in this analysis? It has been an open concept used for mirroring divergent moral understandings in each other. For the policymaking level, ethics has become closely associated with respect for autonomy and almost synonymous with the practical solution of the consent requirement. Another understanding of ethics running through the material is related to responsibility. Margaret Urban Walker (1998) sees in responsibility the very core of what she wants ethics to signify, and methodologically, she suggests tracking responsibilities to understand moralities. From the perspective of the donors there seems to be an expectation about the authorities assuming responsibility for the governance of research. Therefore, Walker’s notion of the ethical has a particular relevance for the moral positioning of donors. This makes it apposite to ask whether informed consent procedures alone are an appropriate response to the trust donors express through their donations. It is worth contemplating whether policymakers’ narrowing of ethics to autonomy at the expense of responsibility empties the word of some of the meanings giving it its public legitimacy. And whether a consent model building on
notions of autonomy facilitates a diffuse arrangement of responsibility for biobank research, which is at odds with the generosity of trustful donors.

In short, it has been elucidated in this thesis how a temporary fixation of debates about stored tissue has transformed the biobank routines through increased emphasis on informed consent, and it has been suggested that in the course of negotiating access to blood samples, political transformations take place relating to benefit sharing, solidarity, obligations and duties. The transformations are articulated in an ethical idiom, however, which acquires a symbolic power that tends to block off further debate.

7.2 Recommendations

The brief version of the recommendations made in section 5.3 is that ethical scrutiny should be broadened from the overriding emphasis on informed consent to issues concerning confidentiality and security; the forms of funding; the types of incentives which are installed; the approach taken with regard to benefit sharing; democratic influence and transparency; as well as the handling of risk and possible misuse. As informed consent has captured the ethical agenda in relation to biobanks, the debate has simultaneously carved out two possible speech positions: that of patients’ rights (seeing the competent individual as the appropriate decision-maker) or paternalism (as the negative label for everybody else). These positions seem to work along an inverse logic: if you do not support a strict informed consent requirement, you must support paternalism and vice versa. Ways of overcoming this divide must be found as must ways of showing respect for the donating public which do not dwindle into a ritualised consent requirement: an ‘empty ethics’ (Corrigan 2003). What is needed is a way of responding to and respecting those citizens who wish to help, but who do not care to exert personal judgement, in other words, a way of providing the active citizen with options for influence without obliging all to carry out the same task. It is a careless attitude to make superficially read information sheets the prime safeguard of people, when these people presuppose the protection of the authorities. The biobank structures must match the trust expressed in donations. And they must be designed to facilitate research for those in need.

7.3 The contribution made by this study

As a last point, it is important to consider how this type of anthropological empirical ethics has contributed to the more established forms of medical ethics. First of all, the anthropological
approach brings a political revitalisation to the ethical analysis that is absent in dominant strains of medical ethical theory. Secondly, it poses several theoretical challenges, in particular with respect to the understanding of human agency and autonomy. Thirdly, the chosen approach focusing on subjugated moral positions has contributed to raising new questions for what Margaret Urban Walker calls critical ethical reflection. There is reason to pursue this last point a little further as it also entails reason to reflect on the criteria for success for this type of study.

The act of posing new questions – or raise awareness of new areas of concern without defining how either the old or the new issues should be handled – can be seen as a very limited contribution. For the following reasons it is nevertheless the contention, on which this study rests, that this task is important in its own right. Policymaking is guided by a search for solutions. Therefore, solutions tend to precede problems. In their seminal article on informed consent Fox and Swazey write that the “advisory role to decision makers has reinforced the cognitive predisposition of bioethics to distil the complexity and uncertainty, the dilemmas and the tragedy out of the situation they analyze” (1984: 358). Consequently, it is important to create modes of probing the circulating solutions and their relationship to problems; modes which are not obliged to come up with yet another answer; yet another solution. If this study shows that the demands of policymaking limit the scope of ethical analysis to very manageable problems, such as the procurement of informed consent, then it is important to create a room for academic reflection which is not restricted by the same demands (cf. Weiss 1986).

The posing of new questions is useless, however, if nobody dares to answer them. Therefore, there is reason to embrace multi-disciplinarity and several forms of arguments (cf. section 5.2). The contribution of this study has been to pass on new problems to solutions-makers, whether they be policymakers or normative ethicists. In this respect, the point of doing the study builds on the notion of hetero-logoi as described in the introduction. It is not about replacing normative judgement with anthropological empirical ethics. It is about creating room for a dialogue where different people have different research interests and demands.

Finally, the promise of mutual inspiration may also serve as an enrichment to anthropology. The anthropological fieldwork has been developed to address an uncommon type of topic and this methodological challenge might prove useful in other studies. Also, the crossing into less known areas of medical ethics such as feminist ethics and pragmatic ethics has revealed sources of inspiration and areas of common ground which will be helpful in further exploration of issues relating to biopolitics and science studies. Finally, it is important to remember that every knowledge
project has its own blind angles and anthropology also needs watchdogs. Critical ethical reflection can serve to remind social scientists that power has no greater ontology than morality, and can even redirect attention to areas of respect for individuals in concrete social science research practices.

This study has sought to open new paths of inquiry rather than identifying the right paths for action. If it has served as an inspiration to engage with new questions or has added new approaches to familiar questions, it has fulfilled the intentions bringing it about.


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ABSTRACT

**Background:** In 1985 the first moves began towards establishing a population-based biobank in Västerbotten County, Sweden. In 1999, a start-up genomics company, UmanGenomics, was granted what was called ‘all commercial rights’ to the biobank. The company introduced an ethics policy focusing on public oversight and informed consent, and the policy was praised in prestigious journals, such as Nature and Science.

**Aims:** It has been the aim to expand the understanding of how social anthropology might contribute to the contemplation of the challenges posed by the new use of the biobank in Västerbotten and thus supplement more established traditions in the field of medical ethics. The means for doing this has been to execute an anthropological study of the ethics policy.

**Theoretical perspective:** With inspiration in the anthropology of policy and social science perspectives on ethics and morality, the policy has been studied at three analytical levels: policymakers (who formulate the policy), policy workers (people expected to implement the policy, primarily nurses expected to obtain informed consent) and target group (the people for whom and on whom the policy is expected to work, in this case the potential donors to the biobank).

**Methods:** The guiding methodological principle has been to mirror the moral problematizations made at the three levels in each other and to study the *practical* implications of the policy. A number of policymakers, nurses, and potential donors have been interviewed, and series of official documents analysed. To extend the reliability of the findings two surveys were executed: one in the general population, one among donors.

**Results:** The qualitative studies demonstrate how policymakers attribute greater attention to the issue of informed consent than potential donors, who often do not read the information sheet. Donors tend to be more concerned about political implications at a societal level than with being personally informed. Also, policymakers tend to distinguish between blood and data in ways that do not confer with the reasoning of the potential donors. Among the respondents from the survey conducted in the general public, a majority (66.8%) accepted surrogate decisions by Research Ethical Committees, and informed consent was a principal concern to a minority (4 %). There was general acceptance of genetic research based on biobank material (71%). Among the respondents to the survey conducted among donors, 65% were aware that they had consented to donate a blood sample, and 32% that they could withdraw their consent. Informed consent was a principal concern to a minority (4 %), and 6% were dissatisfied with the information they had been given. There was 85% acceptance of surrogate decision-making by Research Ethics Committees.

**Discussion:** The ethics policy seems to constitute a particular naming and framing of moral problems in biobank-based research which marginalises other concerns held by the potential donors, while overemphasising the need for informed consent. It can be seen as embodying a political transformation where access to stored blood and medical information is negotiated in ethical terms, while also having unacknowledged political implications. In particular, the relations between authorities and citizens in the Swedish welfare state seem to be undergoing a transformation from mutual obligation to individual contracts.

**Conclusion:** It is argued that anthropology contributes to medical ethics with increased awareness of the practical implications of particular research ethical initiatives. This awareness attunes the analyst to also appreciate the political implications of ethics policies and raises new issues for further consideration.

**Keywords:** [Medical ethics, empirical ethics, social anthropology, policy, informed consent, stored human tissue]
ACKNOWLEDGEMENTS

Looking back at the process of writing this thesis, I confess that it feels awkward placing only my own name on the front page. Even if writing is mostly a solitary task, thinking is not, and I have so many debts that cannot be settled by a brief mention of names. Special thanks are due to the many anonymous nurses, potential donors and various policymakers who used their time to convey to me their hopes and fears. In particular, I would like to thank the staff at Medical Biobank and UmanGenomics. Without your generosity this work would not have been possible. Also, I feel very privileged to have met people who allowed me to become part of their lives as a friend. Åsa, Lena, Leif and Helena: thank for all your patience with the anthropologist wanting to go native.

With respect to intellectual debts, my two supervisors, Niels Lynøe and Lene Koch, are of course the first to be thanked. Without Niels I would not have commenced this whole project. Thank you for your willingness to embrace this type of venture and for your patience with my sometimes stubborn insistence on a social science perspective. Your generosity has been a central component of this work. Lene is what one in lack of less emotional expressions might have to call the rare combination of intellectual lighthouse and guardian angel. Without your support and encouragement I might not have finalised this project and ignored the conflicts, which at times seemed insurpassable. Another person also stands out, namely Richard Tutton, who has not only read, commented on and improved several of my articles, but has also opened numerous doors and enlarged my network considerably. I hope we can continue the discussions in the future.

Most of the work has been undertaken as a visiting research fellow at the Department of Health Services Research (University of Copenhagen) and the Science and Technology Studies Unit (University of York). Both places provided stimulating academic environments and numerous important discussions, which feature in different ways in the thesis. Though I cannot thank all my colleagues here individually, I must mention Lisa Dahlager who has been an important discussant on research ethics and who gave useful comments on the manuscript in the final stages; Signild Vallgårda who has among many other things helped me with language queries; and Anette Sonne Nielsen and Tania Dræbel who have kept reminding me of the anthropological view on selected issues. In addition to these two departments, a discussion group with Maja Horst, Lotte Huniche, and Mette Nordahl Svendsen has given me ample chance of having a heated and stimulating exchange of ideas. At an early stage of the project, Gisli Pálsson invited me to be part of an international network on “Bodily Commodities”, and I owe him, and later Susanne Lundin, Lynn Åkesson, and Sarah Franklin thanks for taking me on board as a fellow academic in various ways. During the final stages, Tine Gammeltoft gave encouraging and useful comments on selected chapters and articles, and Sue Wright most generously took the time to discuss my project as a whole and helped clarify the issues I still had to address. As research assistant, Johan Gudmonson has done much of the tedious work with the surveys using great care and technical shrewdness. Carol Bang-Christensen did much more to the thesis text than could be expected from a language editorial, and Lennart Søgård-Høyer generously provided the pictures for Paper II.

I am indebted in numerous ways that I cannot account for here to my friends and family in Denmark. I need to mention two men of immense generosity and integrity who have passed away during the time I spent on this project: my father, Flemming Lindgaard Høyer, and a dear friend, Poul Aage Kjeltoft. I probably never would have dared enter a university in the first place, if it weren’t for you. Jesper Sørensen joined me on several occasions, even helping with some of the monotonous tasks of the survey work, and nevertheless it seems he came to enjoy Västerbotten’s many pleasures as much as I. You make travelling so much more fun!

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ATTACHMENTS
INFORMATION

VÄSTERSBOTTENS PROJEKTET
SPARPROV

Blodprovstagningen i dagens hälsoundersökning syftar i första hand till bestämning av kolesterol- och blodsockernivåerna. För framtida sjukdomsforebyggande forskning ber vi om ditt tillstånd att i sam-
band med hälsoundersökningen få ta och spara 20 ml blod.

Sparprovet doneras till Medicinska Banken vid Umeå Regionsjukhus,
vilken ägs gemensamt av Västerbottens Läns Landsting och Umeå
Universitet. Dessa har ansvaret för att provet – enligt gällande
lagar och efter prövning i forskningsetisk kommitté-inte används
på ett sätt som kränker Din integritet.

Du kommer inte att få något personligt besked om analysresultatet.

BEKRÄPTELSE.

Jag har tagit del av ovanstående information och lämnar ett blodprov,
att användas på sätt som ovan anges.

UMSÅ ............. ......

NAMNTECKNING ........................

NAMNFÖRTECKNINGSFÖLJENDE ........................
TILL Dig som är deltagare i Vårdetextens mäktensombesättningar

I mötet med den mäktensombesättningen för 2 april om 11:00, vilket med följer ett möte med medicinska studenter vid Örebro universitetslaboratorium, detta paper informerar de medarbetare om viktiga saker som har avseende på mäktensombesättningen. Detta paper innehåller viktiga meddelanden som har avseende på mäktensombesättningen.

MÖTE och förberedelse vilja vi förbereda att detta möte bli lyckligt och att det inte påverkas i någon mån av de mäktensombesättningen.

Vid detta möte omhandlar vi...

På detta möte ska vi förbereda deltagande för att vi ska ha ett bra förståelse av de viktiga steg som nu är pågående och att vi ska kunna ge det bästa Ava...
INFORMATION OM MEDICINSKA BIOBANKEN.


Vad ska forskningsproven användas till?

Provena ska användas för forskning kring förebyggande, diagnostering och behandling av sjukdomar, slegodfall och alzheimers sjukdom ombesända till att ge nya kunskaper om sjukdoms och andra sjukdomar, s.ex. cancer. Innan provena får användas granskar Medicinska Biobankens expertn för forskningsprojekten nyförd, att individers intresse skyddas och att sekretessens upprättståd är. Den forskningsetiska Kommissionen vid Umeå Universitet gör därefter en gränssnuten avverkning och avgör om forskningen är enligt regler, ett av saker, om avsikten för projektet väg med önsken mot verandera på bästa sätt.

Varför har landstinget och universitetet bildat ett nytt forskningsföretag?


Hur garanteras offentlig insyn?

Genom att landstinget och universitetet ligger Medicinska Biobanken och samtidigt har kontroll över aktörer i UmanGenomics AB, garanteras offentlig insyn och kontroll i verksamheten.

Har du frågor kring detta, vänligen skriv till Medicinska Biobanken, tel 090 – 785 29 90.

Umeå i oktober 2000

Göran Hallgren
Professior Verksamhetsansvarig
Medicinska Biobanken

Lars Varndahl
Chefarbetare, Medicinskoordinatorer,
Västerbottens Hälsoundersökning

Skriftlinjer

Jag har tagit del av ovanstående information och lämnar härmed blodprov för att användas på sådant som anges ovan.

Datum
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## Kvalitetsmanual

### Sveriges Ångarst deltagande

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Medicinska biobanken har mottagit din begäran om att sina bioprover inte får användas för kommersiellt forskningsändamål. Din förstahandsöverenskommelse kan emellertid sparas under försök:

- akademisk forskning (ej kommersiell)
- diagnostik och behandling (för dina och närbelägna ev. kommande behov)

För att undvika missförstånd börjar vi att gå kryssar passande ruta eller rutor nedan och ställer din bekännerskap till oss i närmast följande adressen knute.

Proven kommer att behandlas i enlighet med ditt önskemål. Du kommer att få en bevisfetelse när detta har skett. I avstånd på dina "afbönas" dina prover och kommer inte att användas.

### Mer viktigt hämtning

Lena Nilsson
Informationssamordnare
Medicinska biobanken
Nordiska universitetssjukhus
901 85 Umeå

Om du har ytterligare frågor, kontakta logistikchef Sören Holmgren tel: 090-735 29 90

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### Min prover:

- för användas till akademisk forskning: □ JA □ NEJ
- för sparsa för kommande behov av diagnostik eller behandling av mig eller näststående vid ev. framtidiga sjukdom
- ska företräda i sin helhet: □ JA □ NEJ

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Namnunderskrift: ____________________________
Personnummer: ____________________________

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Medicinska biobanken
C:\Sveriges Ångarst deltagande\Prover\Kvalitetsmanual 4.0 (kopia)
Vad anser Du om att ge blodprov till forskning?

I samband med hälsokontrollen står Karl Näslund, en dansk onkolog, att nåvärna. Han arbetar med en undersökning om vad i ett företagat Umeå-universitet betyder för vikarbeiterbostäders besvarelser att lämna blod för forskningsändamål. Han ställer samtal både med de deltagare i hälsoprojektet som vill lämna blodprov, samt även med dem som inte vill medverka. Nedan beskriver han forskningsprojektet:

För jag nåvärna under hälsokontrollen och därefter ställa några frågor?

Jag skulle vilja att nåvärna under hälsokontrollen för att förstå hur den genomför och ev. ställa några frågor i anslutning (1 ex om hur du upplevde undersökningen). Om du inte vill att jag ska vara med och ta del av hela undersökningen, men tycker det är bra att jag ställer frågor till dig efteråt, så kan du meddela vårdpersonalen, eller mig när du kommer. Om du inte vill enskilt min medverkan, så gör det bra att ta om detta i samband med det besök.

Intervjuerungen beror och är till sist från mina respektive omsorg och beroende vad som känts rätt för dig. Du kan begära att det deltagande när som helst under intervjun.

Sektionen

Samlade oförändrade har följdskilda anonymitet. Din intervju kommer inte att bli registrerad, inte heller i patientjournalen.

Min avsikt


Många hälsningar,

Klaus Höyer
This thesis is based on the following papers, referred to in the text by their Roman numerals.

I

II

III

IV

V
**Hoeyer, K. & N Lynöe.** Motivating tissue donors for genetic research: informed consent as a double bind? An anthropological contribution to medical ethics. (Submitted)