

KEY ISSUES IN GENETIC EPIDEMIOLOGY: LESSONS FROM A UK BASED EMPIRICAL STUDY

Erica Haimes¹, Michael Whong-Barr²

¹*Policy, Ethics, and Life Sciences Research Institute (PEALS),*

²*University of Newcastle upon Tyne*

Abstract. This paper addresses critical issues in DNA banking by using the UK-based North Cumbria Community Genetics Project (NCCGP) as a case study. The NCCGP collected blood and tissue samples from the umbilical cord of newborn babies, maternal blood samples and personal health information derived from questionnaires in order to conduct genetic epidemiological studies. Our paper, based on findings from a Wellcome Trust funded study, provides empirical data on the nature of participation and non-participation in genetic databases and addresses key issues such as informed consent, altruism, and notions of community. We argue for the need to problematise concepts of genetic donation and to investigate the particular social circumstances in which ethical issues arise. Only through empirical research can we provide much needed evidence to inform normative discussions and policy-making in the area of population genetics.

Keywords: biobanks; genetic epidemiology; donors; donation; empirical ethics; social sciences

1. Introduction

Population-based genetic research aims to study gene-disease associations and genetic polymorphisms. By combining genetic samples (taken from blood or tissue) with medical, genealogical and lifestyle information, researchers hope to better understand disease causation and to develop improved methods of diagnosis and treatment. Such studies are a growing area of international research (Austin, et al 2003). In 2004, the world's largest proposed gene bank, UK BioBank (UKBB), plans to start collecting DNA samples from 500,000 British men and women aged between 45 and 69. As one might expect, however, gene banks raise a number of ethical, legal, and social issues. A key question for policy-makers and practitioners is how to create a climate in which potential health benefits can be realized without harming the interests of donors. In order

to be successful, biobanks must achieve high rates of participation. Thus, a central question concerns the acceptability of databases to the public (Lowrance 2001).

This paper addresses critical issues in DNA banking by using the UK-based North Cumbria Community Genetics Project (NCCGP) as a case study. The NCCGP was a collaboration between the University of Newcastle and Westlakes Research Institute in north-west England. From January 1996 until April 2003, pregnant women in West Cumbria were informed of the project by their local community mid-wife and were asked to provide written consent prior to giving birth. The NCCGP collected blood and tissue samples from the umbilical cord of newborn babies, maternal blood samples (from 1999) and personal health information derived from questionnaires (Chase et al 1998). The samples were frozen and stored for future use, so that the NCCGP can provide a resource of DNA samples for other researchers to use in genetic epidemiological studies (which so far include investigations on heart disease, breast cancer, and neural tube defects)¹.

The NCCGP enjoyed a high response rate. Nearly ten thousand samples were collected, which means that nearly 90% of the pregnant women approached agreed to provide umbilical cord samples and maternal blood specimens (Chase et al 2000). However, only 60% of those approached completed the 'mother's questionnaire' (a health and lifestyle questionnaire for the woman and her partner) as well as donating samples. Such response rates could be thought as curious, given the ethical concerns often raised about DNA banking, such as informed consent, confidentiality and security of data, the potential for misuse and abuse of samples, third party access, feedback to donors (House of Lords 2001).

Our study, funded by the Wellcome Trust, sought to compare and contrast the perceptions and attitudes of those who have agreed to donate samples to the North Cumbria Community Genetics Project (NCCGP) with those who have declined. This has provided much needed empirical data to add to normative discussions of why people do and do not donate. It was based on the premise that we know little about the views of those who have actually been asked to donate to a genetic database and that policy-makers and researchers would benefit from an investigation that opened up the 'black box' of the social processes that lie between the request to donate and the collection of samples and information. As well as addressing original questions regarding donation and participation, our research enables us to address a wider set of issues including the nature of 'informed consent', 'altruism', and 'benefit-sharing'.

The fieldwork for our study involved semi-structured qualitative interviews with forty-three women who donated tissue samples to the NCCGP, seven who refused, seven NCCGP team members, two members of the NCCGP's Ethics

¹ Donors to the NCCGP will not receive individual feedback on results and women may withdraw at any point (their samples would then be destroyed). Children involved in the biobank will be asked to re-consent at the age of 16. At birth, the NCCGP also collected 'delivery details', i.e. the child's vital statistics. For more on the operating procedures of the database, see Chase et al 1998.

Advisory Group, two focus group discussions involving ten community midwives, and three members of local community groups that opposed the NCCGP when plans for it were first announced in the early 1990s. Interviews lasted one hour and began with discussions of the respondents' own experiences of, and relationship to, the NCCGP. In most cases, discussions of the NCCGP led to broader conversations about databases, genetics research in general, and the distinctive characteristics of Cumbria as a region of England.

2. Summary of empirical findings

This paper provides summary findings from our project. The themes raised here have been addressed in more detail elsewhere, but in this article we bring our arguments together for the first time (Haimes and Whong-Barr 2003, Whong-Barr and Haimes 2003, Haimes and Whong-Barr in press, Whong-Barr in press).

2.1. *Notions of participation*

It is clear from the data that there are varying levels of donation and non-donation and that there are different ways in which individuals donate or do not donate to such a database. Therefore, rather than use the terms 'donation' or 'non-donation' as descriptors which imply a single meaning attached to a simple, one-way act, we use the notion of 'participation' to begin to reflect what is in fact a highly varied social process, with multiple meanings. We took the notion of 'participation' as an essentially contested, and thus open ended, concept. In seeking to identify women's repertoire of considerations when deciding whether or not to donate we fully expected to find that those who did donate could nonetheless cite reasons for not donating and those who decided not to donate could cite reasons why donation was a reasonable action.

In terms of the design of the NCCGP as a database, 'full participation' would mean that a woman contributed umbilical cord samples from her baby, a blood sample from herself and health and lifestyle information from herself and her partner by completing a document known as the 'mother's questionnaire'. 'Partial participation' would mean a donation of any combination of cord samples, maternal blood, and lifestyle information, but not all three. 'Non-participation' would mean that nothing was given to the database at all. However, during our interviews with the various groups, these apparently clear distinctions became increasingly blurred as interviewees sought to explain how and why potential participants made their decisions over donation. In addition there were variations in the significance attributed to the differing levels of participation.

2.2. *Levels of participation*

Our study found that a simple two-way distinction between women who decide to donate and women who decide not to donate does not reflect the

complexities in the *levels* of participation, let alone in the reasons *why* some donate (even partially) and some do not. In our analysis, we compared views of the four main groups of interviewees (the NCCGP team, community mid-wives, women who were asked to donate, and opposition groups).

'Participation', in the minds of the NCCGP team, meant primarily giving blood and tissue samples. According to one team member, reasons for the near 90% rate of tissue collection was that, 'We are just taking samples that are normally thrown away and I feel that's a very strong reason why the NCCGP is so successful' (T351). The sentiment that there was 'nothing to lose' (T587) since 'all they are doing is giving samples that would otherwise not be used' (T177) was echoed by all members of the team.

In practice, 'partial' participation in the NCCGP meant donation of cord and maternal blood samples, but non-completion of the mother's questionnaire. The mother's questionnaire is a document printed on purple paper covering the woman's and her partner's socio-demographic profiles, their own health, their history of smoking, their employment history and their family histories of long term or serious illness. The NCCGP researchers' explanations for partial participation (that is, the non-completion of this questionnaire) were varied and ranged from 'apathy' (T033) to the sensitivity of providing personal information. They felt they could work with such participation rates, however.

Data from the donors illustrates that women were, perhaps surprisingly, very uncertain about the range of donations they were asked to give and just as unclear about what they did actually give. That is to say, most women who were interviewed as participants in the NCCGP were themselves not clear about whether they had in fact given all the samples and information that would constitute full participation. This is partly attributable to not remembering what they had been asked to give and partly to not being able to distinguish between the information and blood samples they were asked to give as part of routine antenatal care and those requested specifically for the NCCGP.

Despite the purple colour of the mother's questionnaire, many women said they did not remember ever seeing it, let alone completing it: 'No, I can't remember seeing one of those' (M007); 'I don't think so...certainly don't remember any purple paper (laughs)' (M070). One woman said about the questionnaire,

'Well, it's difficult to say because I filled that in at the same time as I filled in my medical notes...I had to fill that in as well and I think they were both the same kind of questions...so I have trouble thinking which one...I think maybe I did fill something in' (M024).

The difficulty many women had distinguishing between that which they were asked to provide for routine antenatal care and that asked for the NCCGP database applied to both the mother's questionnaire and to the maternal blood samples. Amongst donors there was a high level of uncertainty as to whether they were asked to provide blood samples for the NCCGP, let alone whether they consented to doing so: 'No, I don't think so, I don't think I was asked to'

(M002); 'I honestly don't know' (M044); 'I've no idea if they took one or not' (M049); 'If they'd wanted one I would have, but I can't remember' (M0101); 'No, I just think it was from the umbilical cord' (M046). Another said about the blood test,

'I don't know whether I did or not...they're taking test tubes off you for this, that and the other, it may well have been one or the other. I don't know. I'm sorry I don't recall, no' (M003).

There was even a small element of uncertainty amongst the non-participants as to whether a maternal blood sample had been taken for the NCCGP. One said that she had not given a sample, at least, 'not knowingly...they took a lot of blood at my antenatal' (M060). Another said, 'They might have taken one doing [sic] some of the antenatal stuff but I don't remember it. They took so much blood that they could have' (M067). This is not meant to imply that non-participants were suggesting that the NCCGP research team took illicit samples from them. Rather, it simply indicates just how difficult it is for any woman to be absolutely clear about who takes what samples, and for what purposes, during antenatal care.

Both these elements (that of memory and that of distinguishing the provenance of requests) could be explained in terms of their failings as individuals (for example, their poor memory and poor understandings because perhaps of poor concentration) but are, it would appear from the data, much more likely to be attributable to the fact that they were asked for this information and blood sample during antenatal care. Women were interviewed for our study within one month of giving birth so memory attrition alone cannot be the sole cause of their confusion regarding what they had agreed to donate.

2.3. *Styles of participation*

Our analysis of the participating mothers' interviews reveals two very strong strands: the wish to help and the sense that not very much was involved in providing that help. The wish to help was expressed in a number of ways with different views as to who it was they wanted to help. Some felt their donation was helping the future in some unspecified way, others that it would help their own children's generation, others that it would help babies and children in general, or simply 'other people' in the future, including local Cumbrians.

Several were aware that they themselves had benefited from research done previously and this influenced their own decisions:

'...because we had had the IVF treatment, you think, "well, if they hadn't done a lot of research about that then", you know...I think that was the main reason why we agreed that we would donate. We thought that anything that helps, you know helps with cancer or anything like that. And there was no harm to me or the baby so we thought, well, "yes, it's a good idea"' (M013).

The sense that not a lot was involved was expressed in a number of other ways also. Interviews included remarks such as 'it didn't harm either the baby or

myself'; 'I wasn't going to do anything with it'; 'it was no use to me'; 'otherwise it would have just been thrown away'; 'nobody is going to miss two inches of cord'; 'it was easy'; 'it's no big deal'; 'no cost to myself';² Interestingly, many women indicated that 'it would probably have been a harder decision' had the request not involved waste material (M036). For example:

'No, I mean it wasn't as if they were wanting to stick pins in my daughter, you know, I wouldn't have liked that very much' (M006).

'I probably would have consented to a blood sample, but I probably would have had a bigger chat with somebody to know more' (M013).

Only one woman mentioned feeling that one ought to help whatever the cost: 'Even if you're called on to help out somebody and it does cause you problems, you still go ahead and do it' (M034).

In addition, only one woman that we spoke to expressed regret at donating:

' "Do you want to donate your umbilical cord?" I think someone said it was for asthma. Was it for asthma, I'm sure that what's somebody said it was for, something to do with asthma. And I don't know, at the time I said "yes". I wished I hadn't have done, I must admit. I really wished that I had more information and that I was better informed and I wish I wasn't put on the spot to make that decision because I don't think that I was in the right frame of mind to make the right decision' (M040).

Thus, we suggest that as well as there being degrees of participation there are also styles of participation. Findings reflect the 'active' participant, who is keen to make a contribution; the 'cost/benefit' participant who balances the cost to themselves and their baby (seen as almost negligible) against the benefit that their contribution might make to others (seen as being high, particularly in light of the potential eradication of disease); the 'passive' participant who shrugs their shoulders and cannot really see any reason not to donate, and the 'reluctant' participant, of whom there was only one case, that mentioned above. Most women appear to belong to the second category.

2.4. Reasons for refusal

Reasons for refusal fell into two broad categories: local factors regarding the funding of the NCCGP and wider concerns over future use and control of the samples. Prior to the establishment of the NCCGP, the proposal to create a biobank generated a significant amount of discussion in the local press. Most of the press coverage centred on the role of British Nuclear Fuels Limited (BNFL) who were heavily involved in the initial funding of the biobank. BNFL operate a nuclear re-processing plant in Cumbria at Sellafield which has been associated with allegations about the effects of excessive radiation causing a higher than average incidence of childhood leukaemia (Dickinson and Parker 2002).

² Sources for these quotes are: M033; M043; M029; M002; M037; M013; M027; M003.

Interviews with those who refused to donate indicate that concerns regarding BNFL were a factor. One woman, whose daughter had died of leukaemia, said:

'It's like when this woman said to us it's privately funded and I said who by, and she said it's done by Newcastle University, there is a professor over there or something, and I said yes but who is it funded by? I said anything to do with Sellafield? ... Why, have you got a problem, she says, with research into cancer? I said I think you are asking the wrong person that, my daughter died twelve years ago with leukaemia. I said any research is good research but when it is being funded by [BNFL], we are being used as guinea pigs' (M039).

Another non-participant replied that when she discovered that the project was financed by BNFL, 'everything became more clear' (M041). Interviews with the NCCGP's Ethics Advisory Group and with community groups opposed to the database raise similar concerns that if BNFL funded the database, 'they would in some way manipulate [the research] to their own ends' (C002).

Apart from funding issues, some 'refusers' were worried about the use and control of their samples. For instance one woman (M060) established the fact that she had donated stem cells to another project but was not happy to donate to the NCCGP because she thought the purpose of their research was vague and she also did not want to provide access to her medical records as she could not understand why this was needed. Another woman stressed how guilty she felt about not donating:

'[They're] storming forward with advances and I thought, "I just don't know enough about this". I didn't want to be hurried into a decision and I think at the time they were saying...it was going to be used to find out, for research on asthma and I felt terribly guilty saying "no" because I had four healthy children and I appreciate how lucky I am.' (M056).

She said she wanted to protect her baby but could not do so if she donated to NCCGP as she had no control over what was done to the samples. Lack of control was cited in several accounts as a reason for not donating, rather than not wanting to help. One said, 'I feel like I've got some paranoid conspiracy thing going on but there you go. It's with not knowing anything about it, I suppose. I find that really spooky' (M035).

Another said, 'Before I had a child of my own, it was just a general concern about the database and what they might abuse in the future – that you might have very little control over that despite the best safeguards and the best intentions in the world. But when actually the child is there, it's their consent as well that you're giving...maybe it's being used for something you're not aware of and you don't know that you ought to withdraw your consent on such and such a day' (M071).

Thus, our study suggests that non-participants are also eager to help medical research and feel a generalised cultural pressure or imperative to donate, which is perhaps particularly acute during pregnancy when they are recipients of much medical support. However, despite their willingness to help, our work shows that 'refusers' felt they could not supply samples in this case partly due to the

particular circumstances of the NCCGP and partly due to more generalised concerns for their baby's welfare³.

2.5. Risk, communication and understanding

Normative literature on the ethics of biobanking refers to 'risk' in such terms as the use and potential abuse of samples, and concerns over third party access (House of Lords 2001, Kaye and Martin 2000). The NCCGP's own literature emphasised that all information would remain confidential and only be used for medical research (NCCGP consent forms, further information leaflets, mother's questionnaire, 2001). Our study was concerned with how risks were communicated by the NCCGP team during the consenting process⁴. Our findings reveal that donors were told little about the database and had a relatively limited understanding of the aims of the gene bank and use of their samples.

Our interviews found that the written forms provided the only detailed source of information for donors about the NCCGP. Little was said about the biobank and any risks associated with it during the consenting process. Community mid-wives usually spent 'about thirty seconds' on the consenting process since so much other information must be passed on to the mothers-to-be (CMW02). As one mid-wife in a group interview put it,

'[Requesting samples for the NCCGP is] only a very very small portion of our care and after this we've got so many other things to talk about because they are having diagnostic tests on their own baby and we've got a lot to cover so, I've got to be honest, after the first interview I don't really bring it up again unless they come back to me with any questions.' (CMW01)

Many women felt that compared to other tests and procedures undergone during pregnancy, donating the afterbirth was a minimal risk. One interviewee compared the donation to an amniocentesis. 'Because of my age being over 40 I had an amniocentesis. [The] amnio could have damaged her but nothing in the database could damage her' (M037).

In addition, women also seemed to have a limited understanding of the NCCGP's aims and the use of their samples. For example, many were surprised to learn that samples would be kept for as long as sixteen years, at which point

³ We thank an anonymous reviewer for pointing out a third possible reason, i.e. parents' unwillingness to give consent for their child. Whilst this is a crucial point in medical ethics more generally, interviewees in this study attached variable importance to it. For instance, many women expressed doubt that they would even remember to tell their child about their donation to the NCCGP. For more on the issue of children's involvement in database research, see Williamson, E., Goodenough, T., Kent, J., Ashcroft, R., in press. Children's Participation in Genetic Epidemiology: Consent and Control. In Tutton, R., and Corrigan, O., eds. *Donating and Exploiting DNA: Social and Ethical Aspects of Public Participation in Genetic Databases*, London: Routledge.

⁴ The notion of 'risk', as we use it, is a social science term and NCCGP forms make no mention of the word. The term 'communication' is our own, as the NCCGP would characterise their forms as 'information giving' and 'requests for consent'.

their child would have the right to withdraw their sample⁵. Many had little idea who would benefit from the research and what type of research would be conducted. For example, responses include:

MWB: *'I'm starting to feel like I'm quizzing you'*

Participant: *'I don't know a lot about it, I'm not really read up in the genetics or anything at all. I can't remember [what it was for]'* (M007).

'I don't think an awful lot was said about it' (M028).

'Maybe I read it wrong but I thought they were doing it individually, your placenta individually, to see how they've worked during the pregnancy. Is that what they are doing? To tell you the truth, I just thought I would do it and whatever, see what happened when' (M042).

'They didn't really say anything at all, just like, when you say Genetics Projects, I just thought it would help to look for, I don't know, a cure or something. I don't know' (M046).

The point here is that pregnant women are alert to issues about the health of their child and are likely to be eager to donate to medical research that they perceive might benefit themselves or their children and families. Clearly, the high participation rates of the NCCGP were due, in part, because of the timing and context of the request. In other words, the relative ease of the donation and the setting in which it took place, may have masked the possible risks involved and influenced donors' levels of interest regarding exactly what it was they were donating to and for. It seems, then, that the reason for the high participation rate in the NCCGP (the ease of taking afterbirth as a source of DNA) is also the reason for concern about the validity of its consenting procedures. Whilst afterbirth may be 'waste material' in the antenatal context, and described as such by the NCCGP, such material carries significant and lasting value in the context of biobanking.

3. Discussion: contributions and implications

All the above points have clear implications for the design and conduct of the UK Biobank and similar database projects, particularly in the recruitment of donors and for understanding how and why potential donors might participate. Beyond the nature of participation, however, our project allows us to explore and comment on a number of related themes in population-based genetics research.

3.1. Altruism, reciprocity and benefits-sharing

Earlier we showed that the language of helping (see also Gustafsson Stolt et al 2002) is present in the accounts of both participants and non-participants in the NCCGP. Our study suggests that NCCGP participants are not as straightforwardly

⁵ The child's right to withdraw is clearly stated in both NCCGP consent forms and further information leaflets.

altruistic as is usually assumed and that those who do not participate are as equally altruistic as their participating counterparts. At least some donors are motivated by the expectation that someone (perhaps even themselves or their family) will one day benefit from advances in medical research. Donation for these women therefore involved an assumption about reciprocity and benefit-sharing (even if not articulated in those terms) and was not simply an instance of one way gift-giving.

These data, therefore, run counter to notions of altruism and gift-giving that underlie many discussions about genetic research. The U.K. Medical Research Council, for instance, characterizes genetic donation as a “‘gift relationship’ between participants and researchers”, since this ‘underlines the altruistic motivation for participation in research’ (MRC, 2001:8). Public consultations for the UK Biobank also cite altruism as a reason for donation. One report claims that altruism is ‘the one primary motivating force that stimulates people to volunteer’ (People, Science & Policy 2002:11). NCCGP team members also mentioned altruism as a motivating factor. One referred to the ‘huge body of altruism in the general public’ as an explanation for such a high response rate, which was not seen as a surprise (T587). Another suggested that ‘people on average do have an altruistic streak and mostly people are happy to be involved in medical research that they can see might be of greater good’ (T081). It has been claimed that ‘donations based on economic self interest rather than altruism tend to be devalued’ (Nelkin 1998:36). Our argument, however, is that we need to recognise the element of expected benefits that appears to be present in some peoples’ motivations for donating.⁶

This finding echoes Marcel Mauss’ original work, which emphasises that the idea of gift giving is based on *reciprocity*. A ‘gift relationship’ stresses that exchanges are in fact based on *interlocking obligations*. Refusal to give ‘is to reject the bonds of alliance and commonality’ (Mauss 1997:13). Somewhat provocatively, we may say that altruism is rarely, if ever, uncalculated. In the words of Mary Douglas, ‘there are no free gifts ... A gift that does nothing to enhance solidarity is a contradiction’ (Douglas 1997:vii–xviii). People are willing to give, it seems, not as unilateral acts of kindness, but as part of an interdependent system of giving and receiving – of *sharing*.

3.2. Informed consent

Our work provides empirical insight into discussions of informed consent. Data show that: a) the decision to donate to the NCCGP was a relatively easy one for women to make since they felt the afterbirth was of no use to them, or their

⁶ We recognise that altruism is a concept not easily captured. Differing views about the ‘true’ motivation behind altruistic acts formed part of the early debates in sociobiology and continue to rage in philosophy, evolutionary psychology and the social sciences. See, for example, Sober and Wilson, 1999. Our claim is that our data gives voice to the view that donating is often motivated by a degree of rational evaluation of potential benefits. For more on altruism in the context of genetics, see Tutton, R., 2002. Gift relationships in genetics research, *Science as Culture*, 11, 523–542.

baby, post delivery; b) that donors were informed of the NCCGP's aims and details in the briefest of terms and that they asked few questions about the database; c) that women felt they would have asked more questions if the sample had been of a different type, such as blood or a cheek swab⁷, and d) that donors' understandings of the NCCGP were usually limited. Thus, the social context of pregnancy raises the ethical question of informed consent: if women are uncertain about what they donated, how clear can they be about the rationale of the research to which they contributed, or about the nature of the uses to which their information and samples would be put? Whilst a high response rate is important in population genetics, we argue that, in future studies, researchers and policy-makers should attend to the social processes that result in achieving a particular response rate, not just the actual rate itself⁸.

3.3. *The importance of context*

Our project has highlighted the importance of context in understanding the issues at stake in biobanking and in opening up new lines of inquiry. Our data reflect the difficulty of distinguishing between making a genetic donation and requests that form part of routine antenatal care. It also draws attention to how local issues (in this case the role of BNFL in first funding the biobank) can influence potential donors' perceptions and views of the database. We found that the request to donate took place in an environment and locality where notions of risk were coloured by the very community in which people lived. In regards to Cumbria, it seems impossible to separate a discourse of biobank risk from a discourse of nuclear risk and researchers cannot presume to know if, how, and to what extent perceptions of one type of risk affect perceptions of the other. Therefore, it is clear from our study that attention needs to be paid to the social context of the targeted population in case particular (hitherto unidentified) characteristics of that population affect levels and styles of consent, altruism, participation and refusal.

3.4. *Notions of 'community'*

Much work has shown that communities are shaped in particular historical contexts. The term 'community' itself can have multiple meanings (for example, in terms of cultural, epidemiological, or political significance) and attempts to divide people into communities and populations are neither natural nor neutral (Brunger 2003). Whilst it is acknowledged that biobanks raise questions for entire communities, and not just for individuals, our project suggests that the

⁷ Of course, if a more invasive sample had been requested, this does not necessarily mean that women's understandings of the gene bank would have been greater.

⁸ For more on consent and database research, see: Chadwick, R., and Berg, K. 2001. Solidarity and equity: New ethical frameworks for genetic databases. *Nature Review Genetics* 2, 318–321 and O'Neill, O. 2002 *Autonomy and Trust in Bioethics*. Cambridge: CUP.

concept of community, when used in relation to population genetics, must be empirically investigated and properly theorised. Terms such as ‘community consultation/consent/participation’ must be fully deconstructed so that their usefulness and limitations are recognised and false claims regarding levels of community approval are avoided.

3.5. Value of empirical and interdisciplinary research

Finally, our project provides a case-study of the benefits that can be achieved when using sociological theory and empirical methods to address normative bioethical debates (Haines 2002, Flyvbjerg 2001). An overall achievement of our work is that we are in a position to ask the sorts of questions raised above regarding the nature and use of concepts such as ‘donation’, ‘altruism’, and ‘consent’. Our work has also added to sociological debates (e.g. Bauman, Giddens, Foucault, Osborne) on the nature of modernity and ethical reasoning and behaviour (Haines and Whong-Barr 2003).

From our project, we can see that it is necessary to problematise notions of participation and donation and investigate the particular circumstances in which ethical issues arise. It is also necessary to attend to the details of genetics research – ‘on the ground’, so to speak. Who is doing the recruiting and in what medical and social context? How will they seek consent? In other words, we must pay attention to the processes behind donation rates and not just the rates themselves. Whilst much ethical focus is on the governance and on the managers of biobanks, our work shows the importance of also considering the role of those who are actually taking samples and interacting with potential donors. After all, ‘the social’ is the filter through which the ethical and legal issues emerge, take shape, and are given prominence. Thus, only through empirical research can we provide much needed evidence to inform normative discussions and policy-making in the area of population genetics.

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Address:

PEALS
BioScience Centre
Times Square
Newcastle upon Tyne
NE1 4EP, UK

Tel: +44 (0)191 241 8605

E-mail: m.t.whong-barr@ncl.ac.uk

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