

## End of Award Report

### Childhood Cancer Tissue Donations: A gift relationship?

#### 1. Background

Research use of human materials is increasingly controversial, with debates centered around several themes including ownership, control, property, privacy, and the commercial use of human tissues. Within sociological and anthropological writing, a focus of concern is the “commodification” of human tissue, where commodification describes the process by which human materials become invested with economic value and used to serve the interests of commerce (Waldby and Mitchell, 2006). In this context, the view that samples of human biological material for use in research should be regarded as “gifts” - as is currently the case in the UK and elsewhere - has come under scrutiny.

The UK Medical Research Council (MRC) guidance offers two reasons for describing tissue samples as being exchanged as part of a “gift relationship”. First, it underlines the altruistic motivation for research participation. It thus invokes Richard Titmuss’ (1970) analysis of blood donation, and encourages tissue samples to be freely given to promote the common good. However, Titmuss assumed not only that blood would be freely given, but also that it would be distributed within a voluntary, not-for-profit system, an assumption that may not always be true of modern biotechnology and medical research. A second reason cited by the MRC guidance for using the “gift relationship” model is the need to resolve the legal uncertainties over ownership. By drawing on a legal understanding of gifts of the voluntary transfer of property with no expectation of return, this approach assumes that any property rights in the donated sample are transferred, together with the control of the sample, to the recipient of the gift. However, the ethos of the “gift relationship” is increasingly criticised for demanding altruism and ceding of control from tissue donors, but obscuring the potential economic value of the tissues for recipients. Prominent in such critiques is a view that once tissues have “crossed the divide” into the “researcher” side, they become economically valuable.

The use of tissues from living child donors raises profound and distinctive questions about exchanges involving human tissues. These include questions about relationships between researchers and researched, the role of intermediaries between researchers and researched, confidence in the governance of research involving human materials, and how social representations of tissue-based research influence public, professional, and private discourses. Legal and ethical uncertainties in the area persist, and further questions have been raised by recent regulation in the area, including the Human Tissue Act 2004.

These issues are significant for tumour banks, which represent important resources for research, particularly as advances in molecular biology increasingly allow a better understanding of the pathogenesis of cancers. Molecular analysis of tumours is, for example, now allowing much improved diagnosis and treatment stratification and the identification of new therapeutic approaches. Access to sufficient samples is needed by researchers to progress with this work. Such samples are typically those “left over” after therapeutic interventions such as biopsies. Tumour banks - such as that established by the Childhood Cancer and Leukaemia

Group (CCLG) - maintain registers of these samples and permit (following scientific and ethical scrutiny) researchers to use the tissue in approved studies. However, little research exists on people's experiences of making or requesting from living individuals (particularly children) to tissue banks, and little that might guide an understanding of reasons for consenting or of the process as experienced by the participants. The need to reach such understanding at this key interface between science and society is pressing. Without better evidence about the motivations and experiences of donors, forms of regulation and governance might be introduced that fail to support what donors themselves value. But despite a large theoretical literature, there is only a small body of research that has looked at the views of donors themselves, and this work has been mainly limited to samples for large-scale "genetic" databases. Use of samples "left over" after from interventions carried out as a necessary part of diagnosis and treatment may raise quite distinctive issues.

## **2. Objectives**

The objectives of the project were to:

- Review issues of law, ethics and governance relating to the use of children's tissue from living donors for research;
- Examine longitudinally media representations of research involving tissue from children;
- Explore qualitatively the views, beliefs, preferences, and experiences of families of children with cancer about tissue donations;
- Explore qualitatively the views, beliefs, experiences and preferences of clinical staff involved in the treatment of childhood cancer about seeking consent for tissue donations;
- Quantify, using survey methods, the views and preferences of families and clinical staff;
- Use our empirical and theoretical review to develop a framework for understanding childhood tissue donations and informing policy and practice in this area.

We believe that each of these objectives has been successfully achieved, as detailed in our results section. We note, however, that we are still awaiting the return of some data from our survey of families.

## **3. Methods**

### ***Media analysis***

The search terms 'tissue', 'donation', 'child' and 'research' (and variants such as 'tissues' or 'children') were used to search Lexis-Nexis, an online database of all UK newspapers for relevant articles published 1984-2004. The Boolean operator 'AND' was used to ensure that each article retrieved contained all four search terms. The 463 articles thus retrieved were inspected to select those which were wholly or predominantly about the removal of body parts from children for medical research or medical therapeutic purposes. This generated a selection of 122 articles. We developed a coding scheme to mark up themes within the articles, which was applied to all articles after 20% of the articles were independently coded by another researcher and any differences of interpretation resolved through discussion involving a third researcher. Additionally, concordance software was used to identify sections of text where particular kinds of words were used (for example, names of body parts).

### ***Legal and ethical review***

Our analysis of the legal and ethical issues in tumour banking in childhood cancer used techniques including examination of statutory instruments, published guidance, policy documents, and relevant legal cases; critical interrogation of the legal and ethical literatures, particularly in the area of use of human tissue for research and research involving children; and synthesis of text and materials to fashion a legal perspective on a complex and challenging area.

### ***Qualitative study of families' and professionals' views***

Families and professionals were recruited using purposive sampling techniques from hospitals involved in the treatment of childhood cancer in the UK. These hospitals were in different geographical locations and had varying rates of registration of tissues in the Childhood Cancer and Leukaemia Group (CCLG) tumour bank. This tumour bank, funded through charitable donations, provides a national network of stored tissue samples for use in research. Its procedures require consent before samples can be registered, and each project intending to use samples must obtain both scientific approval from the tumour bank and separate ethical approval.

We aimed to select families who had had a child diagnosed with cancer no less than six months previously; were not in a current state of health or emotional crisis; and represented a mix of social and ethnic background, different tumour types, and age of child. Sampling of professionals from the seven centres aimed to recruit a mix of staff involved in caring for children with cancer.

Family members were mostly interviewed at home. Professionals were interviewed at their place of work. Interview prompt guides, based on a review of the literature, pilot interviews, and discussions within the project team and with staff and parent representatives, were used to structure the interviews. All participants gave written consent.

All interviews were tape-recorded and transcribed verbatim. Data analysis was based on the constant comparative method (Glaser and Strauss, 1967). For both sets of interviews, "open" codes to describe each unit of meaning were initially generated. Through comparison across transcripts, the open codes were developed into higher order thematic categories and sub-categories to provide two frameworks for coding (one for professionals and one for families), assisted by QSR N5 software. CJJ and DC continually checked and modified the framework categories to ensure an adequate "fit" with the data and MDW independently validated the assignment of the data to the categories.

### ***Survey of families' and professionals' views***

Two questionnaires were developed for use in the survey: one for parents (children were not included in the survey for ethical reasons), and one for professionals. Items for the questionnaires were initially generated using results of the qualitative study and the legal and ethical review. We consulted very widely on the questionnaires and they were extensively piloted. Both questionnaires were approved by an NHS Research Ethics Committee. The professionals' questionnaire was mailed to members of the Childhood Cancer and Leukaemia Group throughout the UK. Members include paediatric oncologists, surgeons, pathologists, and other clinical professionals involved in the treatment of childhood cancer. The questionnaire was also mailed to members of the Childhood Cancer Research Nurses Group.

Families to whom the questionnaire would be sent had to be identified and recruited by the seven CCLG treatment centres used in our earlier study. This meant that we had to gain further NHS R&D approvals from each of these centres to administer the questionnaires, and this introduced delays beyond our control.

## **4. Results**

### ***Media analysis***

We aimed to analyse print news media representations relating to removal of human material from children for research purposes. We explored the role of the UK press in reporting and generating controversies in this area and the association of these with rates of registrations of tissue in the United Kingdom Children's Cancer Study Group (UKCCSG - now known as the CCLG) tumour bank.

We found (Seale et al, 2005) that the UK organ retention controversies were associated with dramatically raised levels of newspaper coverage of issues related to removal of human materials from children for research purposes. The raised intensity of media interest in this area from 1999 onwards was associated with a fall in registrations of tissue in the UKCCSG tumour bank, showing how the controversies affected adjacent but technically unrelated areas of use of human materials. News stories in our sample offered implicit instructions on how to view the situation, suggesting a fundamental polarisation of the interests, moral standards and behaviour of the medical/scientific community and the lay community. Media reports blurred the boundaries between the use of materials from living children and those who have died; different types of materials (e.g. whole body parts and tumour tissue); and different uses of material.

In a second analysis, we explored the role of the mass media in commodification of body parts (Seale et al, 2006). Previous work has suggested that institutions such as biomedicine and bioscience objectify human materials and may also participate in their commodification. Our analysis suggests that it is misleading to imagine that these are the only institutions involved in processes of commodification. We found that media reporting of child organ retention controversies in the UK made an independent contribution to the commodification of body parts, recruiting them for use in the manufacture of a media scandal.

We revealed that press reports used a variety of rhetorical devices that contributed to the commodification of children's human materials, exploiting the potential of these to produce strong emotions in readers as part of an audience-building strategy. The use of horror language by media reports served to emphasise the overlap between journalistic and fictional genres. The readiness to fetishise the value of certain body parts, so that their mistreatment could be portrayed as violating norms of decency and respect, provided further emotional intensity. The words used to emphasise the magnitude of organ 'collections', their variety, proliferation and wide dispersal all served to conjure up images of dehumanising bodily fragmentation on a massive scale. The sensationalising tactics used suggest that the media "scandal" was not solely motivated by public interest: scandals sell newspapers. The commodification of body parts by the media helped to fuel that scandal. Our analysis shows that these commercial interests of the media have been insufficiently recognised by theorists of body commodification.

Our finding about the importance of mass media in the commodification of human materials is significant not simply as a matter of getting the analysis right for academic purposes. Scandals about bioscience have serious consequences for public views of medicine and science and

subsequent legislation, just as political scandals undermine institutions and have regulatory and political implications. The organ retention scandal was exceptionally powerful in its designation of villains, victims, heroes, and its organisation of the 'proper' responses to events and actions, in particular by polarising the interests of the medical/scientific community and the lay community. The irony of the media coverage we have analysed is that the scandal itself draws on the academic critique of objectification and commodification, invoking many of the ideas about the fragmentation of bodily integrity, the investment of commercial value in human materials, and threats to personhood. This points to the potential for the 'commodification' thesis itself to function as a template, in which all issues involving use of human tissues come to be seen involving illegitimate practices and ethical violations. There is clearly a need to distinguish more precisely where applications of 'objectification' and 'commodification' to issues involving human tissues should appropriately be made.

### ***Legal and ethical review***

Our analysis of the legal and ethical issues (McHale et al, 2007) found that law in the area of removal and use of human tissue for research purposes has developed over time, in a piecemeal fashion. There is no single piece of legislation that regulates research on human subjects. Storage and use of tissues for research is predominantly but not exclusively regulated by the Human Tissue Act 2004 (HTA), which came into force in the UK in September 2006. While it provides a more detailed statutory framework, by itself the HTA does not finally determine all the relevant issues in this area. These issues include ownership of human material, precisely what information should be disclosed to those consenting to research use of material, and how far consent should be specific or generic. Many relevant legal principles in this area derive from common law and statutory principles drawn from a range of areas including tort, family law, and property law.

Today, under English law, consent is required *both* for the surgical procedure to obtain a sample that might subsequently be used in research and, separately and additionally, for storage and use of tissue samples for research. The involvement of children in research is complicated by the diversity of approach taken by international research ethics statements, professional practice guidelines and the views of differing bioethical commentators. While some are concerned to safeguard children because of their perceived vulnerability and consequently discourage children's participation in research, others regard children as moral agents with rights and responsibilities in relation to research. Recent years have seen a shift towards ensuring access by children to research participation, but, as we have reported, positions continue to vary and debates about what might constitute children's "best interests" in research persist (Dixon-Woods et al, 2006). What is clear is that separate and additional consent, over and above that for surgery, is now required for the storage and use of the tissue for research.

The Human Tissue Act 2004 (HTA) is rooted in the concept of "appropriate consent". While the basic framework for what constitutes "appropriate consent" is set out in the legislation many issues are left to be resolved outside the legislation (McHale, 2006). Further guidance is provided in the Codes of Practice issued by the Human Tissue Authority, the new regulatory body established under the Act. However, the Codes of Practice, while providing useful guidance, are not by themselves legally binding, and in relation to certain issues provide considerable discretion. Some of the ethical issues, concerning for example the detail of information provision, will be left for scrutiny by research ethics committees.

A notable feature of the HTA is that for the first time in English law, explicit statutory provision is made for children "with capacity" to consent to the use of their material for therapeutic or research purposes during their lifetime or after their death. If a child lacks capacity or chooses

not to make a decision, the decision regarding sanctioning the use of human material is that of the person with parental responsibility.

How far the provisions of the HTA and Code of Practice can be effectively implemented in practice in the area of childhood cancer is an important question. Little is known about how information and decision-making about tumour banking can be best managed in the context of the other difficulties of communication in childhood cancer, where complex issues of family and professional dynamics and sensitivities pose many challenges (Young et al, 2003). Families of a child with a provisional or new diagnosis of cancer may be too distressed or shocked to absorb information or participate in discussions, yet be deeply committed to use of tissue for research. Explaining the relationships not only between care and research, but also between care, research, and bio-industry, as well as managing the practicalities and emotional strains of the consent process, may be a particular challenge for health professionals.

Many other important legal and ethical uncertainties remain, including how “generic” or “specific” should consent be, the interface with related issues such as the regulation of genetic information, whether there is property in human material and if so how ownership should be determined, and rights to feedback of results of research.

### ***Qualitative study of families’ and professionals’ views***

Our interviews focused particularly on situations where the tissue is collected from living children as part of their routine care, and the samples are “surplus” to diagnostic and therapeutic requirements. Interviews were conducted with 79 members of 42 families of a child with cancer, including 41 mothers and 18 fathers. In 20 families, a child or young person with cancer aged 8-19 years (11 female, 9 male) was interviewed in his or her own right. The families were from socially mixed backgrounds; nine participants were of minority ethnicity. Interviews were also conducted with 54 staff members at the seven participating centres, including 15 consultants in paediatric oncology/haematology, 7 surgeons, 9 pathologists, 8 research nurses, three specialist nurses and 12 other health professionals. This was thus an unusually large and robust qualitative study.

All families and staff interviewed were in favour of use of tissue samples for research. Professionals and families appeared able to give a moral account of tumour banking, and families in particular seemed to derive important comfort from their involvement in banking of tissue. In describing why they would consent to tumour banking, families emphasised their membership of what they saw as a well-defined paediatric oncology community. Participants frequently referred to the history of rapid progress in the treatment of childhood cancer in the last 30 years. They were committed to a narrative of hope and scientific progress, and saw tissue samples as critical to achieving further discoveries that would improve survival and outcomes. Family members emphasised their reciprocal relationships with other members of the community, and in particular their feeling of indebtedness to previous generations of families who had taken part in research, as well as for the care their child had received.

*You realise that, you know that there’s children who are alive who’ve got through this, whatever form of cancer, and there are children who have died, but equally the way we see it they’ve paved the way if you like. Without them we might not be here now (parent 6)*

While professionals were concerned to manage the consent process in ways that were respectful and sensitive to families at times that were often fraught and difficult, families were

generally satisfied with the approaches about tumour banking they had experienced, and "atrocious stories", which are often prominent in patients' narratives, were mostly absent. Participants' accounts suggest that a key element of trust was that families and professionals were all perceived as members of the same community, sharing the same set of commitments, values, and aspirations. The argument in the socio-anthropological literature that people who take part in research involving human tissues feel disenfranchised and lack trust did not seem to be an accurate way of describing this community.

Families members' willingness to consent to tumour banking was not, however, unconditional: it was not an obligation that they felt in any way forced into honouring. Three features of participants' accounts are of particular note in understanding their orientations towards consent: first, the ontological status of the tissues as "waste"; second, their need for assurance of absence of risk; and third, the comforts deriving from trust and confidence.

For families, the tumour sample was reported to have an alien status; 25 participants explicitly described the tumour as foreign to the child. This was an account of the tissue that professionals helped to co-produce, and it functioned to create the tissues as an alienable object that could be seen as not "of" the child. This allowed an understanding of its status as "waste" on removal from the child. Importantly, this designation of the tumour samples was not transitive to all other parts of the body, and many accounts emphasised the distinction between such tissue and bodily materials and parts that were thought to be inextricably linked with personhood.

*they're not part of me any more I don't exactly want them back so. What would I want them back for? (Child 69)*

*It's not like they're taking organs. This is just purely tumour. I think that once the tumour's out it's out. And I think that as to what happens to it then I don't think it particularly bothers does it, because it's out of your body and it is just tumour. (Research Nurse 3)*

At the same time as the tissue samples were constructed as "waste" from the families' perspective, the accounts of both families and professionals explicitly recognised the value of the material to researchers. As Simmel (1900) noted, value is not an inherent property of objects, but the outcome of a judgement made about them. Our analysis suggests that the consent process allows the tissue sample to discard its previous status as an object of negative value in the eyes of families and transform it into something valuable, and indeed this notion of retrieving something good from a bad situation was frequently cited as a comfort for family members.

Families clearly emphasised that they would not consent to tumour banking if it involved risk to their child's health, but many also emphasised that if no risks were involved then there was a community responsibility to consent.

*If it doesn't harm anybody, if it's not harming the child, really what's the problem, as long as it's going to help somebody else? (Parent 6)*

Families had a set of "reasonable expectations" about what would happen to the tissues, and generally did not feel any need to have further control over the samples. Most, for example, did not expect to be approached to consent to individual studies. They had high levels of trust in the people who approached them about tumour banking, and confidence that there were systems of governance in place for research using the samples. Families were mostly concerned that

the samples would be put to "good use".

*even though it came from my daughter I don't think of it as part of her you know, parts of her floating out there somewhere. It was just something that never should have been. So you know I feel quite strongly that it just went and I hope it will be used in a good way really. I say it would be a shame, given how we were told it's so rare, if her samples were wasted because I think a lot could be learned. (parent 25)*

There was considerable evidence that, though acceptable to some, describing tissues as "gifts" was troubling to many participants. The "gift" metaphor provoked considerable discomfort among both families and professionals and some (including children and young people themselves) were actively offended by it. Rather than securing the cooperation of potential donors, the "gift" metaphor had the potential to undermine it.

*It is not a gift. If they had called it that it would have held me back. A brain tumour is not a gift, it is an aid to research (child 42)*

*When it's something that is causing you so much anguish and so much heartache then you don't see it as a gift in any shape or form to anybody really (parent 55)*

Our work suggests that the "gift" model may be ill-suited to describing tissue donation for childhood cancer research in several ways. First, it was seen by participants in our study to involve a metaphorical incongruity that did not express their own views of the process. Second, our findings suggest that rather than conforming to Titmuss' model, with its emphasis on a quite demanding form of altruism, consenting to tumour banking is better understood as being governed by the norm of reciprocity as outlined by Gouldner (1960).

Rather than understanding consent to tissue donation as altruism in the sense Titmuss intended - which involves some inconvenience or discomfort - it might instead be seen as a form of what Putnam (2000) terms *generalised reciprocity*. Generalised reciprocity refers to the confident expectation that if one does something for someone, at some later point the favour will be returned, even if not by the same person or in the same form. Thus participants in our study saw themselves engaged in the kinds of reciprocitarian relations that Kolm (2006) sees as largely characteristic of community, arguing that their importance is related to the intensity of the sense of community of the members. Such a perspective captures the sense in which family members felt they were making a reply to "gifts" already received rather than initiating a gift cycle through consenting, but also underlines the absence of feelings of coercion: family members in our study were explicit that while they were motivated by a community ethic, this did not extend to doing things that they felt uncomfortable about. This kind of reciprocity is of course dependent on the trust invested by community members in each other.

The accounts of participants in our study point to the terms of the "social licence" for use of tissue samples for research. The concept of "social licence", as defined in the work of Gunningham and colleagues (2004) has developed in the context of work on corporate social responsibility and the environment. For our purposes, it refers expectations and demands of society, or influential elements within society, that relate to the conduct of those conducting research. Compliance with formal regulatory rules is necessary, but not necessarily sufficient, for researchers to deliver on the commitments of the social licence. Researchers must also avoid "scandals". Scandal, as Lull and Hinerman (Lull & Hinerman 1997) define it, occurs acts "that disgrace or offend the idealized, dominant morality of a social community are made public and narrativized by the media, producing a range of effects from ideological and cultural

retrenchment to disruption and change". We argue that scandals are profoundly important for regulators, because as, Giddens (1990) notes, people place their trust in expert systems based on the experience that such systems generally work as they are supposed to. Scandals appear to demonstrate the violation of background, and often implicit, norms and assumptions. They thus function like the "breaching" experiments of ethnomethodologists (Garfinkel 1984) by appearing to reveal through the infraction of norms the underlying social order. Scandals work in part by suggesting that background assumptions that all was well - or was well-controlled - were false. Discovering the content of these background assumptions, which form part of the terms of the social licence, is thus a key task.

Our findings are of critical importance in designing models of regulation and governance. Currently dominant socio-anthropological accounts tend to stress sinister and exploitative features of biobanks, including commodification of tissue. Claims of widespread disenfranchisement, disempowerment, and lack of trust in scientific research, have led to proposals for "solutions" such as individual property rights for tissue donors as a means of restoring control and sharing in profits (Laurie, 2002). Our work suggests that, for the childhood cancer community, an approach that recognises the values in the community, including solidarity, is needed. Models of governance that focus on organisational arrangements rather than individual rights are promising, and the possibilities of a charitable trust model for tissue banks (Winickoff and Winickoff, 2003) should be considered. Though such approaches will involve their own problems, they may offer a more appropriate means of securing the social license for tissue banking.

### ***Survey of families' and professionals' views***

The questionnaire was mailed to 521 members of the CCLG and 32 members of the Childhood Cancer Research Nurses Group. We received 330 responses, representing a response rate of 60%. Given the known difficulties of conducting survey research in this area we were very satisfied with this response. Respondents were approximately 50% female, 50% male. Around 8% of respondents were pathologists, 8% were nurses, 11% were surgeons, and 48% worked as clinicians in paediatric oncology or haematology. The remainder worked in a variety of areas concerned with childhood cancer.

All respondents reported that they were either strongly in favour (89%) or in favour (11%) of using tissue samples for research. Professionals were either very confident (41.5%) or reasonably confident (51%) that there were good ethical arrangements for use of tissues in childhood cancer research. They reported that they felt that families were either very happy (36%) or reasonably happy (58%) to consent to tumour banking, with only 4 respondents suggesting that families are likely to be unhappy. The vast majority (89%) reported that both parents and the child (if able) should be asked for consent, with only 9% suggesting that the parents only should be asked. About 41% reported that it would be easy to assess capacity to consent in children, but 55% reported that it would be difficult or very difficult. There was a range of views on which professional would be most appropriate to obtain consent, though most (87%) did not feel that the surgeon who removed the tissue would be suitable for this role, and over 90% of respondents indicated that junior doctors and independent researchers were also not the most appropriate individuals for seeking consent. The majority of respondents (92%) favoured "generic" over "specific" consent, indicating that families would consent once only to tissue banking rather than to each individual project. Various difficulties in approaching and managing the consent process were identified, including the problems of identifying a suitable time to approach families, having suitable trained staff in place, and maintaining a paper trail.

As our qualitative study had also suggested, obtaining consent for tumour banking can itself be understood as an altruistic endeavour on the part of professionals, as those who obtain consent for the most part have no personal gain. Though there is some previous research that has acknowledged the special role of staff who gain consent for organ transplants, to our knowledge this is the first time that the role of those involved in gaining consent for tissue banking has been explicitly acknowledged.

At time of writing this report we are still awaiting the return of questionnaires from the families from some of the centres (one centre in particular has experienced significant delays in sending out the survey), and we are therefore currently unable to offer results from this element of the project. All data from returned questionnaires to date have been entered into a statistical package for processing and we hope to begin our analysis shortly.

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## **5. Activities**

### **Conferences**

A full list of conference presentations is available on ESRC Society Today and on our project website (<http://tinyurl.com/2wurp8>). We have presented our findings at a number of major international conferences, perhaps most notably at SIOP 2006, where Mary Dixon-Woods was keynote speaker at the major international childhood cancer conference of the year and addressed nurses, doctors, researchers, and families.

### **Workshop**

The Principal Investigator ran a highly successful Science in Society workshop on the theme of "Governing medical research and medical practice: what's the difference" at Goodenough College, London, in January 2007. This workshop, which was very over-subscribed, attracted an international audience and included two very prominent speakers from the US - Professors Charles Bosk and Raymond de Vries - as well as top UK speakers. The Workshop sought an exploration how what is "science" and "non-science" influence regulation and governance, including how models and practices of consent rely on distinctions between science and non-science that are often unstable. A report of our workshop is available here:

<http://tinyurl.com/2yzgnx>

## **6. Outputs**

We currently have a large number of papers either submitted or in preparation for submission to major journals. Some of our published outputs have been in very high impact journals - *The Lancet Oncology* has an impact factor of 9.6 and the *BMJ* an impact factor of 9.052, for example.

McHale J, Habiba M, Dixon-Woods M, Cavers D, Heney D, Pritchard-Jones K. (2007) Consent and childhood cancer tissue banking: the impact of the Human Tissue Act 2004. *The Lancet Oncology* 8: 266-272

Dixon-Woods M, Young B, Ross E. (2006) Researching chronic childhood illness: the example of childhood cancer. *Chronic Illness* 2: 165-177

Seale C, Dixon-Woods M, Kirk D. (2006) Commodification of body parts: by medicine or by media? *Body and Society* 12: 25-42

Seale C, Kirk D, Tobin M, Burton P, Grundy R, Pritchard-Jones J, Dixon-Woods M. (2005) Effect of media portrayals of removal of children's tissue on a UK tumour bank. *BMJ* 331: 401-403

In addition, the following paper used theorisations developed during the project:  
Dixon-Woods M, Ashcroft RE, Jackson CJ, Tobin MD, Kivits J, Burton PR, Samani NJ. Beyond "misunderstanding": written information and decisions about taking part in a genetic epidemiology study. *Social Science and Medicine* (accepted March 2007)

## **7. Impacts**

There has been considerable interest in our study from the childhood cancer community. The results of our project have informed the redesign of the CCLG Tumour and Leukaemia Bank procedures to comply with the Human Tissue Act. Our study findings are also being used to help in the redesign of the Patient Information Leaflets and training for taking consent.

There was international media coverage of our findings reported in our 2005 BMJ paper, including interest from North America.

Our work on the project has been directly relevant to gaining funding for further important projects in the area of regulation and governance of health research, including the following:

- Trust, confidence and the regulation of risk: examining the Research Governance Framework for Health and Social Care. Economic and Social Research Council 2007-2008 Dixon-Woods M, Bryman A, Ashcroft R.
- Review of regulation of medical research. Medical Research Council/Wellcome Trust. 2006-2007 Dixon-Woods M, Ashcroft R, Brownsword A, Bryman A, Yeung K.
- Analysis of Research Ethics Committees' letters about cancer trials and human tissue. 2007-2008 Dixon-Woods M, Ashcroft R, Bryman A, Angell E. Central Office for Research Ethics Committees.
- Qualitative analysis of Research Ethics Committees' letters and accreditation reports. Central Office for Research Ethics 2006 Dixon-Woods M, Ashcroft R, Angell E. Committees.

## **8. Future Research Priorities**

This is clearly an exciting and productive area for future research, and sound social science research will be needed as regulators and policy makers engage with the contested issues in this field. Ethnographic work investigating how rules (both formal and informal) and decisions about tumour banking are made and implemented in clinical settings where consent must be sought would be very valuable. Ethnographic work in settings such as Research Ethics Committees and scientific committees would be an important complement to this. Further investigation of the organisational issues in tumour banking would be very useful, for example to theorise why rates of tissue registration vary so widely between different centres. We would also like to see work from a political economy perspective that offers a more critical interrogation of the "commodification" thesis as it might apply to communities such as childhood cancer, as well as legal and ethical work that draws on international developments such as those relating to the harmonisation of biobanks.